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VOL. 31, NO. 2 **FALL 2016**

Novi Libri

Preface

This edition features an essay by professor Murray Joseph Casey, M.D., Ph.D. This essay traces the Affordable Care Act (ACA) from initiation through the regulations implementing the ACA requirements for preventive health services for women. It presents ethical objections to the mandated provision of contraception and abortion services in compliance with ACA regulations by the Little Sisters of the Poor, an international order of consecrated nuns dedicated to care of the elderly poor. The author's purpose is to explain the fundamental issues raised by the legal challenge to the ACA by the Little Sisters of the Poor.

The second article in this edition, by Patrick James Baggot, M.D. and Rocel Medina Baggot, M.D., is a pilot study of children with Down syndrome illustrating how the rate of neurological growth may be doubled. One diagnosis (Down syndrome), a larger study (218), and a single outcome measure were used before and after the Institutes for the Achievement of Human Potential (IAHP) developmental profile. Each child was compared to himself, before and after treatment. Study patients were encouraged to crawl early and engage in movement and balance exercises. The children were taught to read and count from a very young age. Nutrition and physiology were also addressed. Before IAHP treatment, children had neurologic age/chronologic age=0.55. This is consistent with standard median Down syndrome IQs of about 40. After treatment, from initial exam to first followup, children had delta NA/CA = 1.43. The rate of neurologic progress more than doubled. While surprising, these results are consistent with the scientific literature.

Priscilla K. Coleman, Ph.D., and Debbie Garratt, R.N., M.Ed., in the third article, note that women who place a child for adoption have historically been far less actively researched than the other individuals in the adoption triad (adoptees and adoptive parents). They often have unmet psychological needs related to the decision to place for adoption, the placement experience, and as they endeavor to move forward postadoption. In this article an effort is made to provide a description and analysis of the professional literature on women's placement experiences, with attention to methodological challenges inherent in deriving valid results. Next an overview of the results of a mixed method pilot study on birth mothers' decisionmaking and adjustment is shared. Finally, the most pressing future research needs on the topic of adoption placement from the birth mother's perspective are outlined. Employing the following search terms: adoption, openadoption, closed adoption, birthmother, biological mother, relinquishment, and adoption placement, an exhaustive search for empirical journal articles, reviews, and edited book chapters was conducted yielding over 80 publications. Sources spanning a 50 year period (1974-2014) were identified via MEDLINE, PUBMED, and PsycINFO. Based on an indepth analysis of the best available evidence on the psychological lives of women who choose adoption, an argument is made for more focused research attention and enhanced sensitivity to the unmet needs of birth mothers in our communities. As the experiences of birth mothers are more fully understood, more substantive and compassionate counseling before, during, and after adoption will become more feasible.

The *Verbatim* section includes papers from the Matthew Bulfin Educational Conference in Washington, D.C., February 20-21, 2016, sponsored by the American Association of Pro-Life Obstetricians & Gynecologists and the American College of Pediatricians. These short essays, summaries, and outlines of the presentations include the following topics: (1) the myth of moral neutrality in medicine; (2) a defense of freedom of speech in a diverse culture; (3) transformation of viewpoint in medical practice; (4) safe sex belief and sexual risk behaviors among adolescents; (5) healthy management of very early adolescent pregnancy; (6) behavioral methods of family planning; (7) the importance of fathers in family structure and child wellbeing; (8) maximizing human potential by endogenous tissue generation and restoration; (9) insertional mutagenesis and autoimmunity induced disease caused by human fetal and retroviral residual toxins in vaccines; and (10) transgender medicine.

The Novi Libri section includes a new book by Helen Watt, entitled "The Ethics of Pregnancy, Abortion and Childbirth: Exploring Moral Choices in Childbearing."

This fall edition concludes volume 31 of *Issues in Law & Medicine*.

Barry A. Bostrom, J.D.
EDITOR-IN-CHIEF

Articles

Dignum et justum est: *Obamacare and Travail of the Little Sisters*

Murray Joseph Casey, M.D., M.S., M.B.A., Ph.D.*

ABSTRACT: This essay traces the Affordable Care Act from initiation through the bureaucratic unfolding of required preventive health services for women and presents the ethically reasoned objections to provision of certain services and compliance with regulations for implementation by the Little Sisters of the Poor, an international order of consecrated nuns dedicated to care of the elderly poor. The author's intent is to understand and intelligently convey the fundamental issues raised by their challenge.

The Affordable Care Act, signed into law by President Obama on March 28, 2012, followed a week later by amendments to the Health Care and Education Reconciliation Act of 2010, constitute what has become known as the "Affordable Care Act" (ACA),[1] popularly termed "Obamacare." Section 1001 of the ACA amends the Public Health Service Act of 2012 to add minimum coverage provisions for group and individual health insurance plans, including, "with respect to women, such additional preventive care and screenings not described…in comprehensive guidelines supported by the Health Resources and Services Administration [HRSA]…," an agency of the Department of Health and Human Services (HHS).[2]

Thereby, the majority of Congress and our President essentially delegated to HRSA, an unelected administrative bureau, the authority for determining "with respect to women" the "additional preventive care and screenings" that must be covered by health plans according to ACA mandate. On August 1, 2011, HRSA adopted and released guidelines for ACA required coverage by group health plans and health insurance issuers beginning on or after August 1, 2012, for "women's preventive health *services*" (italics added).[3] Note well the change in diction from "preventive care and screenings," designated by law, to

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[1] Morse EA. Lifting the Fog: Navigating the Penalties in the Affordable Care Act. *Creighton L. Rev.* 2013;46:207-257. p. 208.

[2] *Ibid.*, pp. 232-234.

[3] Federal Register, Vol. 78, No. 127, July 2, 2013/Rules and Regulations. p. 39870.

"preventive *services*," as defined by the HRSA. According with "HRSA Guidelines," ACA required preventive health *services* for "women with reproductive capacity" without cost sharing include "contraceptive methods" and "sterilization."[4]

Simultaneous with this release, on August 1, 2011, the U.S. Departments of Health and Human Services, Labor and Treasury, which are jointly responsible for administrating and enforcing the ACA, provided authority to exempt from the requirement to cover contraceptive services the group health plans of nonprofit "religious employers," such as "churches, their integrated auxiliaries, and conventions or associations of churches," as well as "the exclusively religious activities of any religious order," whose primary "purpose is inculcation of religious values" and primarily employs and serves persons "sharing its religious tenets."[5] When final regulations were issued on February 10, 2012, a "temporary safe harbor from enforcement of the contraceptive coverage requirement" until August 1, 2013, was allowed for the group health plans of "certain nonprofit organizations with religious objections to contraceptive coverage."[6] Having published the proposed rules on February 15, 2012, the Departments invited public comment.

This communication reviews the response of the Little Sisters of the Poor ("Little Sisters"), an international order of consecrated nuns whose mission is to serve the elderly poor, later joined by other respondents, then tracks the evolution of ACA mandated rules and regulations, the implications of enforcement and the ethical challenge. Specifically this is not a law review. The query is, "What's all the hub-bub?" not how matters will be solved. Morally, for the analytic reader, this will be within an ethical framework. At law, this will follow Court decision.

The Little Sisters Protest

In compliance with Catholic doctrine which holds that there is objective moral order knowable by the intellect and that certain intrinsically evil actions, such as direct sterilization, contraception and induced abortion, are never morally justifiable regardless of the circumstances,[7] the Little Sisters on March 1, 2012, issued a statement that with good conscience they can not "directly provide or collaborate with the provisions of services that conflict with Catholic teaching,…" when providing health insurance benefits for employees of their homes for the aged.[8] Along with the Departments of Labor and Treasury, HHS next published an advance notice nearly a year later on February 6, 2013, proposing rules that might achieve their goals of "broad access" to contraceptive services without cost sharing for employees and students of nonprofit religious "eligible organizations" with religious objections to providing coverage for these services in their health care plans.[9] In such cases, the health insurance issuers would be required to

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[4] *Ibid.*, pp. 39870-39872.

[5] *Ibid.*, p. 39871.

[6] *Ibid.*

[7] Smith R. Formal and material cooperation. *Ethics & Medics*, 1995;20(6):1-2.

[8] Little Sisters of the Poor. Statement of the Little Sisters of the Poor on the HHS Mandate, March 1, 2012 (http://www.littlesistersofthe poor.org/44-news-a-events/259-lsp-statement-on-hhs-preventive-services-mandate) (accessed January 1, 2016.).

[9] Federal Register, Vol. 78, No. 127, July 2, 2013/Rules and Regulations. p. 39871.

"assume sole responsibility, independent of the eligible organization and its plan, for providing contraceptive coverage to participants and beneficiaries without cost sharing."[10] For self-insured eligible organizations with religious objections to contraceptive services, third party administrators of group health plans would be required to pay for this coverage or arrange for health insurance issuers to provide contraceptive coverage to participants and beneficiaries without cost sharing.[11] Insurance issuers would be able to offset the costs incurred by the third party administrator and the issuer by claiming an adjustment in the Federally-facilitated Exchange user fee.[12] That is a reduction in the fees required from insurers to participate in the insurance exchanges created by the ACA.

In April, 2013, the Little Sisters submitted formal comments to HHS pointing out that Christian Brothers Services, the third party administrator of their sponsored health care plan, also shares the sisters' commitment to Catholic teaching and indicating that the possibility of financial penalties levied for noncompliance with the proposed arrangements could threaten the operation of their homes for the aged.[13]

HHS Defines Required Contraceptive Methods For "Preventive Care" and Offers "Accommodation"

After receiving over 400,000 comments, the Departments promulgated the final Rules and Regulations on July 2, 2013, for ACA mandated "women's preventive health services" coverage, which includes "all Food and Drug Administration (FDA)-approved contraceptive methods, sterilization procedures, and patient education and counseling for women with reproductive capacity…without cost sharing," and defined the requirements necessary for certain eligible organizations with religious objections to contraceptive coverage to be exempted from providing contraceptive services in their health care plans.[14] Morally and in conscience troubling for Catholic institutions and for several or more other health plan sponsors are the mandated provisions of sterilization *per se* and certain (or all) contraceptive methods. Particularly morally repugnant to some health care plan sponsors are listed "preventive care benefits" for "Emergency contraception, like Plan B® and ella® ";[15] because the endometrial effects of Plan B® (levogesteron) and ella® (ulipristal acetate) may be hostile to implantation of the developing conceptus and in the case of ulipristal acetate, possibly embryotoxic.[16] For an eligible organization to

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[10] *Ibid.*

[11] *Ibid.*, p. 39871.

[12] *Ibid.*

[13] Little Sisters of the Poor. Notice of Proposed Rulemaking on Preventive Services. File Code No. CMS-9968-P (http://www.littlesistersofthepoor.org/images/stories/downloads/LSP%20NPRM%20Comments%20for%20Filing%2020130408.pdf) (accessed January 21, 2016).

[14] Federal Register, Vol. 78, No. 127, July 2, 2013/Rules and Regulations, p. 39871.

[15] HealthCare.gov. Preventive care benefits for women (http://www.healthcare.gov/preventive-care-women/) (accessed November 16, 2015); HealthCare.gov. Health benefits & coverage. Birth control benefits (http://www.healthcare.gov/coverage/birth-control-benefits/) (accessed November 16, 2015).

[16] HealthCare.gov. Preventive care benefits for women (http://www.healthcare.gov/preventive-care-women/) (accessed November 16, 2015); HealthCare.gov. Health benefits & coverage. Birth control benefits (http://www.healthcare.gov/coverage/birth-control-benefits/) (accessed November 16, 2015).

avoid contracting, arranging, paying, or referring for contraceptive coverage, it must execute self-certification that it opposes providing coverage for some or all of the required contraceptive services, that it is a nonprofit entity and that it is a religious organization; and a copy of the self-certification must be provided to the health plan issuer or third party administrator prior to the beginning of the first plan year or to any new plan issuer or third party administrator with change of plans.[17] Once executed, self-certification need not be submitted to any of the government Departments, though the document must be retained in the eligible organization's records and available for examination upon request by the Departments.[18] The process of exemption from providing contraceptive services by self-insured eligible organizations that do not use third party administrators is much more onerous, but when finally submitted, "the Departments will provide a safe harbor from enforcement of the contraceptive coverage requirement while additional accommodation is considered."[19]

These Rules and Regulations were applied to the plans of eligible organizations beginning on or after August 1, 2013, but at the same time the temporary safe harbor for enforcement of the requirement for contraceptive coverage was extended to January 1, 2014.[20] When granting an injunction temporarily relieving Wheaton College from complying with the regulation to complete and transmit government prescribed Employee Benefits Security Administration (EBSA) Form 700 to self-certify religious objection against providing contraceptive coverage,[21] the U.S. Supreme Court noted that because the college had already notified the Government without using the form it meets the requirements on religious grounds for exemption from providing contraception.[22] So nothing "precludes the Government from relying on this notice…to facilitate provision of full contraceptive coverage under the Act."[23] In light of this ruling, the Departments of HHS, Labor and Treasury augmented the accommodation to eligible employers with an option to opt out of covering contraception by notifying HHS instead of sending the self-certification form to its insurer or third party administrator.[24] Rules and Regulations require health insurance issuers to expressly exclude contraceptive coverage from an eligible organization's group health plan when exempted, separate any enrollment

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[17] Federal Register, Vol. 78, No. 127, July 2, 2013/Rules and Regulations. pp. 39874-39875.

[18] *Ibid.*, p. 39875.

[19] *Ibid.*, pp. 37880-37881.

[20] *Ibid.*, p. 39872.

[21] EBSA Form 700—Certification (revised 2014) (www.dol.gov/.../preventiveserviceseligibleorganizationcertificationform.doc) (accessed January 13, 2016).

[22] Supreme Court of the United States. No. 13A1284. Wheaton College v. Sylvia Burwell, Secretary of Health and Human Services, et al., 573 U.S.___ (2014), July 3, 2014.

[23] *Ibid.*

[24] Brief for the Respondents. No. 15-105. Little Sisters of the Poor Home for the Aged, Denver Colorado et al. v. Sylvia Burwell, Secretary of Health and Human Services, et al. and No. 15-119 Southern Nazarene University et al. Sylvia Burwell, Secretary of Health and Human Services, et al. On Petitions for Writs of Certiorari to the United States Court of Appeals for the Tenth District. pp. 8-9; Supreme Court of the United States. No. 13A1284. Wheaton College v. Sylvia Burwell, Secretary of Health and Human Services, et al., 573 U.S.___ (2014), July 3, 2014.

materials regarding contraceptive coverage, notify participants and beneficiaries that the issuer provides separate payment for these services with no additional cost, and segregate all premium revenue collected from the eligible organization while accounting this segregation of funds.[25]

Failure of the HHS "Accommodation" to Satisfy Religious Objection

In any of these situations, by executing and providing self-certification of religious objection to contraceptive coverage in accord with federal Rules and Regulations, an eligible organization becomes a *necessary proximate cause* for the provision of sterilization and contraception, including methods with potential for inducing abortion of concepti.[26] Because this act initiates and implements the ACA requirement that an insurance issuer or third party then *must* independently provide coverage for sterilization procedures and all FDA-approved contraceptive methods without cost sharing.[27] A proximate cause "is not necessarily the closest cause in time or space nor the first event that sets in motion a sequence of events leading to an injury. A proximate cause produces particular, foreseeable consequences without the intervention of an unforeseeable cause."[28] For instance, if I know that a madman will kill you if he had a gun, I give him a gun and he kills you, that *is* a necessary proximate cause!

Even though ACA regulations may be intended by their authors to shield objecting eligible organizations from directly providing coverage for sterilization and contraceptive services, morally and in conscience, an eligible organization by complying with the requirements to self-certify would essentially, materially and immediately cooperate with the insurance issuer or third party's provision of these services.[29] The Little Sisters' case is even more complicated, because health care coverage for employees of their charitable homes for the poor is through the Christian Brothers Employee Trust, a self-funded plan that provides health and welfare benefits, consistent with Catholic doctrine, to the employees of Catholic employers nationwide.[30]

Facing $100 per day fines for each individual not covered for contraceptive services at the beginning of the next January 1 renewal of their sponsored health care plan, on September 24, 2013, the Little Sisters joined by Christian Brothers Services, third-party administrator of the Christian Brothers Employee Trust, and the Trust filed a class action suite for relief in federal court versus Kathleen Sebelius, Secretary of HHS, and

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[25] Federal Register, Vol. 78, No. 127, July 2, 2013/Rules and Regulations. pp. 39877-39878.

[26] The National Catholic Bioethics Center. Module 6. Reading. What is the principle of cooperation in evil? (http://ncbcenter.org/document.doc?id=139) (accessed January 13, 2016.); Catholic Encyclopedia: Occasions of Sin (http://www.newadvent.org/cathen/11196a.htm.) (accessed January 14, 2016).

[27] Federal Register, Vol. 78, No. 127, July 2, 2013/Rules and Regulations. pp. 39871, 39875).

[28] The Free Dictionary (http://legal-dictionary.the freedictionary.com/Proximate+Cause) (accessed January 13, 2016).

[29] The National Catholic Bioethics Center. Module 6. Reading. What is the principle of cooperation in evil? (http://ncbcenter.org/document.doc?id=139) (accessed January 14, 2016).

[30] Christian Brothers Services Statement on Mandate Regarding Contraception (https://www.cbservices.org/newsroom/Statement-on-HHS-Mandate-Regarding-Contraception-CBS-2012.pdf.)(accessed January 15, 2016).

the Secretaries of the Departments of Labor and Treasury.[31] After initial denial by the U.S. 10th Circuit Court of Appeals in Colorado, U. S. Supreme Court Associate Justice Sonia Sotomayor granted temporary protection on December 31, 2013, the day before mandated fines were scheduled to take effect.[32] On January 24, 2014, the full U.S. Supreme Court granted relief to the plaintiffs while the case proceeded in the lower court.[33]

HHS Mandate Held to Violate Free Exercise of Religion

Later that year, in a celebrated case, *Burwell v. Hobby Lobby Stores*, et al., June 30, 2014, the U. S. Supreme Court held that HHS regulations mandating insurance coverage for contraceptive services under the ACA, while imposing multimillion dollar penalties for noncompliance on the *closely-held* for-profit corporate plaintiffs with religious objections to providing all FDA-approved contraceptive methods, violate the plaintiffs' "exercise of religion," according to the Religious Freedom Restoration Act (RFRA) of 1993.[34] The RFRA prohibits government from imposing "substantial burden" on religious exercise unless so doing is the least restrictive means of furthering a compelling government interest. In this case, owners of the closely-held plaintiff for-profit corporations expressed sincere Christian beliefs that "life begins with conception" and it would violate their religion to facilitate access to contraceptive methods that may be abortive.[35] The Supreme Court's majority opinion held that Congress designed the RFRA to provide merchants with very broad protection for religious liberty, that extending the free-exercise rights to closely-held corporations within the RFRA definition of "persons" is meant to protect the religious liberty of humans who own or control them, and that the government had "failed to show that the HHS contraceptive mandate is the least restrictive means of satisfying that interest," noting that "Religious employers, such as churches, are exempt from the mandate."[36]

As the Little Sisters' case continued on July 14, 2015, a three judge panel of the U.S. 10th Circuit Court of Appeals ruled against the Little Sisters and Christian Brothers, who had been joined in their suite by four Oklahoma Christian colleges and Reaching Souls

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[31] Little Sisters of the Poor Home for the Aged, Denver Colorado, et al. v. Kathleen Sebelius, et al. Case 1:13-cv-02611 Document 1 Filed 09/24/13 USDC Colorado (http://www.becketfund.org/wp-content/uploads/2013/09/Little-Sisters-of-the-Poor-and-Christian-Brothers-v.-Sebelius.pdf) (accessed January 15, 2016).

[32] Little Sisters of the Poor v. Burwell. The Becket Fund (http://www.becketfund.org/littlesisters/) (accessed January 15, 2016).

[33] U.S. Supreme Court Protects Little Sisters of the Poor. The Becket Fund (http://www.becketfund.org/littlesisters/) (accessed January 15, 2016).

[34] Supreme Court of the United States. Syllabus: No. 13-354. Burwell, Secretary of Health and Human Services, et al v. Hobby Lobby Stores, Inc., et al., together with No. 13-356. Conestoga Wood Specialties Corp. et al. v. Burwell, Secretary of Health and Human Services, et al. Decided June 30, 2014.

[35] *Ibid.*

[36] *Ibid.*

International, an overseas Christian missionary organization.[37] The majority decision basically rested on their interpretation that the "petitioners had failed to establish" that the government's accommodation mandating third party payment for contraception services actually imposes "any burdens" on the petitioners themselves.[38] While Judge Baldock, one of the appellate court's three judge panel, agreed with the others that "the accommodation does not impose a substantial burden on employers with insured plans,…" in the Little Sisters' case it is because of the special circumstance that the Little Sisters self-insured plan was administered by Christian Brothers Services, which had promised not to provide contraception coverage even if the Little Sisters opt out, that "the Little Sisters had not established a substantial burden..."[39] Although a majority of the full 10th Circuit Court's judges voted against rehearing the case *en blanc*, five of the judges dissented: "When a law demands that a person do something the person considers sinful and the penalty for refusal is a large financial penalty, then the law imposes a substantial burden on that person's free exercise of religion."[40]

Little Sisters Appeal to the Supreme Court

Attorneys for the Little Sisters et al. promptly petitioned the U.S. Supreme Court for *writs of certiorari* (July 23, 2015), seeking judicial review at the highest level.[41] The Little Sisters soon were joined in their petition by more than a dozen Jewish, Christian, secular and professional organizations, and the attorneys general of twenty states.[42]

The U.S. Department of Justice responded (September 30, 2015) acknowledging that the Supreme Court should resolve the question but argued that the Court ought first consider and resolve *Roman Catholic Archbishop of Washington v. Burwell* appealed

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[37] Fox News.Com. Denver court rules against Little Sisters of the Poor in contraception coverage case (http://www.foxnews.com/politics/2015/07/15/denver-court-rules-against-little-sisters-poor-contraception-coverage-case/) (accessed November 16, 2016); Jeffrey TP. 5 Judges: Forcing Contraception Reg on Nuns Like Providing 'Only Non-Kosher Food' to Jewish Prisoner. CNS News.com, September 24, 2015 (http://www.cnsnews.com/news/article/terence-p-feffrey/5-judges-forcing-contraception-reg-nuns-providing-jewish-prisoner) (accessed November 16, 2015).

[38] Brief for the Respondents. No. 15-105. Little Sisters of the Poor Home for the Aged, Denver Colorado et al. v. Sylvia Burwell, Secretary of Health and Human Services, et al. and No. 15-119. Southern Nazarene University et al. v. Sylvia Burwell, Secretary of Health and Human Services, et al.. On Petitions for Writs of Certiorari to the United States Court of Appeals for the Tenth District. p. 12, pp. 13-14.

[39] *Ibid*., p. 13.

[40] Judges Hartz, Kelly, Tymkovich, Gorsuch and Holmes, Dissenting. No. 13-1540. Little Sisters of the Poor Home for the Aged, Denver, Colorado, et al. v. Sylvia Methews Burwell, et al., No. 14-6026. Southern Nazarene University, et al., v. Sylvia Mathews Burwell (https://www.ca10.uscourts.gov/opinions/13/13-1540.pdf) (accessed January 25, 2016); Jeffrey TP. 5 Judges: Forcing Contraception Reg on Nuns Like Providing 'Only Non-Kosher Food' to Jewish Prisoner. CNS News.com, September 24, 2015 (http://www.cnsnews.com/news/article/terence-p-feffrey/5-judges-forcing-contraception-reg-nuns-providing-jewish-prisoner) (accessed November 16, 2015).

[41] Supreme Court of the United States. Docket, No. 15-105, etc. (http://www. supremecourt.gov/Search.aspx?FileName=/cocketfiles/15-105.htm) (accessed January 20, 2016).

[42] SCOTUSblog. Little Sisters of the Poor Home for the Aged v. Burwell (http://www.scotusblog.com/case-files/cases/little-sisters-of-the-poor-home-for-the-aged-v-burwell/) (accessed January 19, 2016).

from the U.S. Court of Appeals for the District of Columbia. Contemporaneous with the government's response, the 8th Circuit Court of Appeals in St. Louis, when granting a preliminary injunction in *Sharpe Holdings v. HHS*, came to an opposite and conflicting conclusion from the Little Sisters case heard by the 10th Circuit Court. In deciding the Sharpe Holdings case, the 8th Circuit Court wrote that the HHS "accommodation does not qualify as the least restrictive means of furthering a compelling government interest…the government could provide contraceptive coverage to the affected women by other means."[43] The government respondents contend that the Little Sister's case "would be an especially unsuitable vehicle" to revolve these issues "because of the unusual and uncertain circumstances" raised in 10th Circuit Court Judge Baldock's reasoning that although the Little Sisters' plan is self-insured, "their employees would not receive contraceptive coverage even if they opted out," because of the Christian Brothers Services' promise.[44] The Respondent's Brief acknowledges a footnote, not included in the petitioner's preliminary injunction record, that in addition to Christian Brothers Services, the Little Sisters' self-insured plan also relies on another party, Express Scripts, to administer prescription drug claims.[45] If Express Scripts would provide contraceptive coverage under the accommodation, 10th Circuit Court Judge Baldock's conclusion would not be pertinent;[46] whereas, the Little Sisters' conscientious objection against facilitating contraceptive coverage would remain cogent.

The Little Sisters' attorneys replied (October 13, 2015) that the government's response directing attention to the *Roman Catholic Archbishop of Washington v. Burwell* case was an attempt to "hand-pick its preferred case and to constrain the scope" of the Supreme Court's review.[47] After "trying to pick and choose which religious groups to exempt from the contraceptive mandate, HHS should not now be allowed to pick and choose its opponent or which questions it must confront in defending its actions."[48] The Little Sisters' attorneys countered the government's insistence that their case is "especially unsuitable" for Supreme Court review because of the "the unusual and uncertain circumstances" raised by Christian Brothers' promise. The reply reiterated the Sisters' complaint that HHS regulations would compel them to assist in the government's effort to obligate or incentivize third parties to provide contraceptive coverage for their employ-

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[43] Sharpe Holdings, Inc. v. HHS, No. 14-1507, 2015. (September 17, 2015); Brief for the Respondents. No. 15-105. Little Sisters of the Poor Home for the Aged, Denver Colorado et al. v. Sylvia Burwell, Secretary of Health and Human Services, et al. and No. 15-119. Southern Nazarene University et al. v. Sylvia Burwell, Secretary of Health and Human Services, et al. On Petitions for Writs of Certiorari to the United States Court of Appeals for the Tenth District. pp. 14-20.

[44] Brief for the Respondents. No. 15-105. Little Sisters of the Poor Home for the Aged, Denver Colorado et al. v. Sylvia Burwell, Secretary of Health and Human Services, et al. and No. 15-119. Southern Nazarene University et al. v. Sylvia Burwell, Secretary of Health and Human Services, et al. On Petitions for Writs of Certiorari to the United States Court of Appeals for the Tenth District. pp. 13, 20.

[45] *Ibid.*, pp. 20-21.

[46] *Ibid.*, pp. 13, 20-21.

[47] Reply Brief of Petitioners. No. 15-105. Little Sisters of the Poor Home for the Aged, Denver Colorado et al. v. Sylvia Mathews Burwell, Secretary of Health & Human Services, et al. p.1.

[48] *Ibid.*

ees, maintaining that "those circumstances are common to more than 400 non-exempt religious employers."[49] Moreover, the third party administrator for the health care plan of Reaching Souls International, a co-petitioner with the Little Sisters, confirmed that it *will* provide contraceptive coverage to employees if eligible organizations were to comply with self-certification.[50] The Little Sisters' petition, therefore, combines a case in which the ultimate provision of coverage for contraception is uncertain and one in which it is certain because the third party administrator is willing to provide the coverage, making this a "particularly good vehicle" to resolve the question.[51] What matters, quips the reply, is "which vehicle is best for this Court, not for HHS."[52] Finally, the Little Sisters' reply challenges HHS on Constitutional grounds, complaining that the government's Rules and Regulations which exempt "churches, their auxiliaries" and "associations of churches," shelter churches and other nonprofit religious organizations from the requirement to cover contraceptive services in their group health plans but not the Little Sisters, violate the free exercise protections of the First Amendment.[53]

The Supreme Court of the United States on November 6, 2015, granted *certiorari*, agreeing to consolidate, hear and consider the cases of *Little Sisters Home for the Aged et al. v. Burwell; Priests for Life et al. v. Department of Health & Human Services; and Roman Catholic Archbishop of Washington et al. v. Burwell* along with *David A Zubik et al. v. Burwell*.[54] It is the expressed intent of these petitioners to offer health plan coverage to their employees and students in manners consistent with the eligible organizations' religious beliefs. In summary, questions at issue are: 1) whether HHS regulatory methods for nonprofit religious employers to comply with the contraceptive mandate eliminates the substantial burden on the petitioners' religious exercise or violates the Religious Freedom Restoration Act (RFRA) of 1993, 2) whether HHS satisfies the RFRA test for overriding sincerely held religious objections even if overriding the religious objections will not fulfill the HHS intent to provide contraceptives at no cost to religious objectors' employees and students, 3) whether the ACA mandate to provide contraceptive services violates the religious freedom of non-exempt nonprofit religious organizations (*i.e.*, eligible organizations), and 4) whether the government can force objecting nonprofit religious organizations in violation of their religious beliefs to facilitate the provision of

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[49] *Ibid.*, pp. 3-4.

[50] *Ibid.*, p. 5

[51] *Ibid.*, p. 6.

[52] *Ibid.*, p. 5.

[53] *Ibid.*, pp. 9-12.

[54] Supreme Court of the United States. Docket, No. 15-105, etc. (http://www. supremecourt.gov/Search.aspx?FileName=/docketfiles/15-105.htm) (accessed January 20, 2016).

sterilization, abortifacients and contraception in employer sponsored health care plans for their employees and students.[55]

Though ethically opposed to the government's goal of providing coverage for contraceptive services, according to their brief, the petitioners do *not* challenge the legality of the effort: they ask not to participate in that objective. While being subjected to the burden of massive government fines for refusal, the petitioners believe that cooperation with provision of coverage for those objectionable services or the submission of documentation that initiates the coverage is a violation of their religious freedom. Furthermore, the petitioners contend that the government can arrange methods for providing contraceptive services without cost sharing to employees and students unable to obtain those services through health care plans of objecting eligible organizations by means that do not violate the employers' religious beliefs and moral objections.[56]

Following the death of Associate Justice Antonin Scalia on February 13, 2016, the eight judges of the U. S. Supreme Court heard oral arguments on March 23, 2016, from attorneys representing the Little Sisters and six other religious non-profit petitioners joined in their common cause against HHS rules and regulations for the provision of contraceptive services. A key argument by the petitioners was that compliance with the mandated regulations would impose a substantial burden to their exercise of religion in violation of the RFRA of 1993.[57] On the other hand, government attorneys told the Court that it could not provide contraceptive coverage to the plaintiff's employees without returning to Congress for an amendment to the ACA mandate.[58] With an eye toward resolution, the Supreme Court on March 29, 2016, ordered attorneys consolidated for the plaintiffs' cases and the government's attorneys each to submit by April 20, 2016, one new brief on each side of the controversy and then single replies, expecting that with further "clarification and refinement," the parties should be able to "arrive at an approach…that accommodates the challengers' religious exercise while at the same time ensuring that women covered by the challengers' health plans receive full and equal health coverage, including contraceptive coverage."[59]

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[55] Brief for Petitioners in Nos. 15-35, 15-105, 15-119, & 15-191. East Texas Baptist University, et al. v. Sylvia Burwell, et al., Little Sisters of the Poor Home for the Aged, Denver, Colorado, et al. v. Sylvia Burwell, et al., Southern Nazarene University, et al. v. Sylvia Burwell, et al., Geneva College, et al. v. Sylvia Burwell. On Writs of Certiorari to the United States Courts of Appeals for the Third, Fifth, Tenth, and D.C. Circuits. (January 4, 2016); Brief for Petitioners in Nos. 15-1418, 14, 1453 & 14-1505. David A Zubik, et al. vs. Sylvia Burwell, et al., Priests for Life, et al. v. Department of Health & Human Services, et al., Roman Catholic Archbishop of Washington, et al. v. Sylvia Burwell, et al. On Writ of Certiorari to the United States Courts of Appeals for the Third & D.C. Circuits (January 4, 2016).

[56] *Ibid.*

[57] Denniston L. Court seeks new way to decide birth-control cases. SCOTUSblog. March 29, 2016 (http://www.scotusblog.com/2016/03/court-seeks-new-way-to-decide-birth-control-cases/)(accessed March 30, 2016).

[58] *Ibid.*

[59] *Ibid.*; Little Sisters of the Poor Home for the Aged v. Burwell. SCOTUSblog. March 23, 2016 (http://www.scotusblog.com/case-files/little-sisters-of-the-poor-home-for-the-aged-v-burwell/)(accessed July 20, 2016).

In forthcoming briefs, the petitioners clarified that their religious exercise would not be infringed were they "to do nothing more than contract for a plan that does not include coverage for some or all forms of contraception;" and the government confirmed that "…insured plans could be modified" to provide contraceptive coverage to employees through the petitioners' insurance companies "without any such notification from petitioners."[60] Then, on May 16, 2016, quoting their instructions of March 29, 2016, to provide supplemental briefs addressing "whether contraceptive coverage could be provided to petitioners' employees, through petitioners' insurance companies, without…notice from the petitioners" and encouraged by refinement in the positions of the parties, the eight judge Supreme Court ruled unanimously to vacate conflicting judgments by the several Courts of Appeal. Cases each were remanded to its respective Appeals Court to arrive at an approach that "accommodates the petitioners' religious exercise while at the same time ensuring that women covered by petitioners' health plans receive full and equal health coverage, including contraceptive coverage."[61] With this, citing the public notice of *Wheaton College v. Burwell* (*vide supra*), the Court noted that nothing in the opinion "precludes the Government from relying on this notice… to facilitate the provision of full contraceptive coverage."[62] Accordingly, "Because the Government may rely on this notice, the Government may not impose taxes or penalties on petitioners for failure to provide the relevant notice."[63] The opinion was careful to note that the Supreme Court expresses no view on the merits of the cases and has not decided "whether the petitioners' religious exercise was substantially burdened, whether the Government has a compelling interest or whether the current regulations are the least restrictive means of serving that interest."[64] Thus, aside from relief from the burden of massive government fines levied upon the Little Sisters and co-plaintiffs, matters have not been settled.

The Crux of the Matters

This is a complex history, but no less so than many questions that reach our U.S. Supreme Court. The forgoing attempt to succinctly as possible chronologically present the major issues raised by the Little Sisters of the Poor, those who have joined and friends in their case poses other matters, both practical and ethical, that deserve thoughtful

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[60] United States Supreme Court. Nos. 14-1418 David A. Zubik, et al. Petitioners v. Sylvia Burwell, Secretary of Health and Human Services, et al.; 14-1453 Priests for Life, et al., Petitioners v. Department of Health and Human Services, et al.; 14-1505 Roman Catholic Archbishop of Washington, et al., Petitioners v. Sylvia Burwell, Secretary of Health and Human Services, et al.; 15-35 East Texas Baptist University, et al., Petitioners v. Sylvia Burwell, Secretary of Health and Human Services, et al.; 15-105, Little Sisters of the Poor Home for the Aged, Denver, Colorado, et al. v. Sylvia Burwell, Secretary of Health and Human Services, et al.; 15-119, Southern Nazarene University, et al. v. Sylvia Burwell, Secretary of Health and Human Services, et al.; 15-191, Geneva College Petitioner v. Sylvia Burwell, Secretary of Health and Human Services, et al. 578 U.S.___ (2016), May 16, 2016.

[61] *Ibid.*

[62] *Ibid.*

[63] *Ibid.*

[64] *Ibid.*

public attention. The plaintiffs' legal challenge against ACA mandates requiring the provision of contraceptive services through non-exempted employer sponsored health care plans provided by nonprofit eligible religious organizations unless they self-certify and provide their religious objections, thereby triggering HHS arrangements to deliver these services, soon should be settled at least for now by Court decision, optimistically through confirmation of mutually agreed resolution between the plaintiff parties and the government. Notwithstanding the anticipated legal decisions regarding exemption from ACA mandated insurance coverage for sterilization and contraceptive services and the standing of rules for accommodation to exempt eligible organizations with religious objections to contraception, it remains practically and ethically appropriate to consider whether the Little Sisters and co-plaintiffs are simply "stirring a tempest in a teapot" or are their protestations right and just?

Let us first return to the congressional amendment designating the inclusion of "preventive care and screenings" for women in the ACA, as signed into law by President Obama on March 28, 2010. Ordinarily, the United States Public Health Service National Institutes of Health defines "Preventive Health Care" as screening for disease, vaccinations, genetic testing, attention to early symptoms and signs of disease, counselling to encourage exercise, healthy diet and weight, safe sexual relationships, use of safety restraints in automobiles, and against tobacco and illicit drug use and immoderate use of alcohol, but there is nothing in this definition about contraception, abortion, or sterilization.[65] So where and how do contraceptive methods, potential abortifacients and sterilization slip into ACA mandated "preventive health services" for "women who may become pregnant"?[66]

According to the Federal Register, HRSA, an administrative bureau of HHS tasked with providing guidelines for women's preventive health services, adopted recommendations for women's preventive services from the Institute of Medicine (IOM) as the rationale upon which ACA mandated contraceptive methods rest.[67] The IOM is a division of the private, nonprofit National Academies of Sciences, Engineering and Medicine, which operating under an 1863 congressional charter intends to provide independent scientific advice to inform public policy decisions.[68] In their July 19, 2011, report *Clinical Preventive Services for Women: Closing the Gaps*, the IOM in addition to those preventive services recommended for men, laudably recommends seven more evidence-based preventive services for women, including screening for gestational diabetes, counselling and screening methods for sexually transmitted diseases, comprehensive lactation counselling and support, screening and counselling regarding interpersonal and

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[65] National Institutes of Health/U.S. National Library of Medicine. Preventive health care (https://www.nlm.nih.gov/medlineplus/ency/article/001921.htm) (accessed January 25, 2016).

[66] Preventive care benefits for women. HealthCare.gov (http://www.healthcare.gov/preventive-care-women/) (accessed November 16, 2015); Health benefits & coverage. Birth control benefits (http://www.healthcare.gov/coverage/birth-control-benefits/) (accessed November 16, 2015).

[67] Federal Register, Vol. 78, No. 127, July 2, 2013/Rules and Regulations. p. 39870.

[68] The National Academies of Science, Engineering and Medicine. Institute of Medicine. What is IOM? (http://iom.nationalacademies.org/About-IOM.aspx) (accessed January 25, 2016).

domestic violence, and at least one well-women visit annually to obtain these services.[69] This IOM report also recommends for women the "full range" of "contraceptive methods, sterilization procedures, and patient education and counseling…"[70] Committee members who contributed to the IOM report were volunteer professionals from secular and Jewish universities and academic institutions, who had special interests in matters relating to public health and policy.[71] None were from specifically Catholic universities or institutions or entities identifiable as fully sharing their ethics concerning natural law and human reproduction.

Taking liberty with the designation of "additional preventive care and screenings" for women, according to congressional definition in Section 1001 of the Public Health Service Act (*vide supra*), HRSA not only based its "guidelines for women's preventive health services" on the IOM report of recommended "evidence-based preventive services" but also included contraceptive services and sterilization.[72] Now, it must be submitted that contraception does not prevent disease; contraception is intended to prevent pregnancy. And pregnancy is not a disease.

To be sure, pregnancy may be occasionally complicated by disease. The non-pregnant times of women's reproductive years, as well, may be complicated by disease. Whatever may be their status, it is clearly the charge of preventive medicine to vaccinate, screen and counsel women in order to protect, promote and maintain their health and well-being and that of their offspring and to prevent disease and disability.[73] But pregnancy is not a disease. Pregnancy is the natural human function for propagation of our species.

Indeed, in *General Electric v. Gilbert* the Supreme Court of the United States, citing findings from evidence given in the U.S. District Court, Richmond Virginia, rejected the view that pregnancy is even similar to disease or disability, holding to the district court's conclusion that, "The great mass of expert testimony presented here on the subject merely confirms what appears obvious to any layman: pregnancy is not a disease, as that term is commonly understood…"[74] Pregnancy is not a disease to be prevented. Biologically and in law this is incontrovertible.

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[69] Institute of Medicine. Clinical Preventive Services for Women: Closing the Gaps. July 19, 2011 (https://iom.nationalacademies.org/~/media/Files/Report%20Files/2011/Clinical-Preventive-Services-for-Women-Closing-the-Gaps/preventiveservicesforwomenreportbrief_updated2.pdf.)(accessed January 25, 2016).

[70] *Ibid.*

[71] *Ibid.*

[72] Federal Register, Vol. 78, No. 127, July 2, 2013/Rules and Regulations. p. 39870.

[73] American College of Preventive Medicine. What is Preventive Medicine? (http://www.acpm.org/?page=whatispm) (accessed January 26, 2016).

[74] United States Supreme Court. No. 74. General Electric Co. v. Gilbert (December 7, 1976; United States District Court, E.D. Virginia, Richmond Division. Martha V. Gilbert v. General Electric Company 375 F. Supp. 367 (April 13, 1974); Morse EA. Lifting the Fog: Navigating the Penalties in the Affordable Care Act. *Creighton Law Review*. 2013;46:207-257. p. 234.

Some pharmaceutical formulations marketed and generally used for contraception may be properly and with good medical judgment preferably prescribed and used for the prevention and treatment of disease. When this is the *direct intent* and the therapeutic and/or prophylactic benefits of such medications outweigh possible unintended but foreseeable untoward and contraceptive effects with little or no abortive risk, according with the ethical principles of double effect and proportionate reason and in accord with magisterial and traditional Catholic teachings from natural law it could be argued that use of these formulations might be justified in some cases as a matter of preventive medicine and public policy.[75] This is not the Little Sisters and co-plaintiffs' contention in their case against HHS. Their complaint is that the government's regulatory accommodation does not exempt them from the statutory obligation to provide coverage for *contraceptive services*, but rather in fact while threatening disabling fines, the regulation would require them to directly facilitate this provision by self-notification of their religious objections. The complainants contend that the Rules and Regulations in effect, therefore, violate the RFRA of 1993, which prohibits government from imposing "substantial burden" on religious exercise unless so doing is the least restrictive means of furthering a compelling government interest. Besides, they complain that government's exemption of churches and integrated auxiliaries, conventions or associations of churches from the requirement to provide contraceptive services in their health care plans but not the plaintiffs violates the establishment clause of the U. S. Constitution.[76] Rather than being exempt from mandated health care plan coverage for provision of contraceptive services, by self-certification of their religious objections, the Little Sisters and co-plaintiffs immediately would put into effect HHS arrangements for the provision of contraceptive coverage by the insurance issuers or third party administrators of their plans, acts which the plaintiffs believe are morally wrong.

Given the questionable inclusion by HRSA of required coverage with no additional cost for sterilization and all FDA-approved contraceptives in ACA regulated health care plans, the exemption of churches, affiliates and under the order of law closely-held for-profit companies with religious objections to providing contraceptive services and the plaintiffs' uncontested ethical and religious objections against providing or materially cooperating in this coverage, the adamant insistence by HHS that the Little Sisters and their co-plaintiffs must take part in the government's plan to deliver contraceptive services is inexplicable.

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[75] Casey MJ, Salzman TA. Therapeutic, prophylactic, untoward, and contraceptive effects of combined oral contraceptives: Catholic teaching, natural law, and the principle of double effect when deciding to prescribe and use. *Am. J. Bioethics* 2014;14(7):20-34.

[76] Reply Brief of Petitioners. Little Sisters of the Poor Home for the Aged, Denver Colorado et al. v. Sylvia Mathews Burwell, Secretary of Health & Human Services, et al. pp. 9-12; Brief for Petitioners in Nos. 15-35, 15-105, 15-119, & 15-191. East Texas Baptist University, et al. v. Sylvia Burwell, et al., Little Sisters of the Poor Home for the Aged, Denver, Colorado, et al. v. Sylvia Burwell, et al., Southern Nazarene University, et al. v. Sylvia Burwell, et al., Geneva College, et al. v. Sylvia Burwell. On Writs of Certiorari to the United States Courts of Appeals for the Third, Fifth, Tenth, and D.C. Circuits (January 4, 2016).

Doubling the Rate of Neurologic Development in Down Syndrome: A Pilot Study

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ABSTRACT:
Background: **Recently, Von Tetzchner and colleagues completed the first study in three decades of the method of Institutes for the Achievement of Human Potential (IAHP.) They found no benefit. Because Von Tetzchner's study had few patients (17-18), many diagnoses, and numerous (13) different outcome measures, these flaws may have obscured a treatment benefit with excessive variance.**

This study was designed to correct those flaws. One diagnosis (Down syndrome), a larger study (218), and a single outcome measure were used before and after (the IAHP developmental profile). Each child was compared to himself, before and after treatment. The goal was to minimize variance.
Methods: **Study patients were encouraged to crawl early and engage in movement and balance exercises. Patterning was used to help children learn to crawl. The children were taught to read and count from a very young age. Nutrition and physiology was also addressed.**
Results: **Before IAHP treatment, children had neurologic age/chronologic age=0.55. This is consistent with standard median Down syndrome IQs of about 40. After treatment, from initial exam to first follow-up, children had**

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delta NA/CA = 1.43. The rate of neurologic progress more than doubled. The p value was $p < 10^{-15}$.
Discussion: **The animal literature on environmental studies provides strong foundation for IAHP methods. Human adoption literature demonstrates substantial catch-up recovery is possible in humans. While surprising, these results are consistent with scientific literature.**
Conclusion: **Conventional methods, according to von Tetzchner, have no proven benefit. The evidence presented here demonstrates a strong, clinically significant benefit, which is highly statistically significant. The IAHP method enhances development and cognitive performance, and is highly cost effective since 1) it works and 2) most of therapy is done by parents.**

This study is a verbatim reprint of Baggot PJ and Baggot RM (2016), Doubling the rate of neurologic progress in Down syndrome: a pilot study, *Journal of American Physicians and Surgeons*, 21 (2): 41-46. It is reprinted here to make it available to a wider audience of physicians and scientists, as the *Journal of American Physicians and Surgeons* is not indexed on Pubmed. For metanalyses, it should be counted once, not twice.

After World War II, in which physical therapist Glenn Doman fought Nazi Germany as a decorated American Army commander, he and hiscolleagues developed methods and exercises for the neurodevelopmental rehabilitation of children. These techniques were used for children with cerebral palsy, autism, developmental delay, Down syndrome, and a wide variety of other neurodevelopmental disorders. Doman and colleagues opened the Institutes for The Achievement of Human Potential (IAHP) in 1955, and published their work in 1960 in the *Journal of the American Medical Association.*[1]

The use of educational and behavioral interventions to improve long-term neurologic outcomes is a very controversial area in developmental pediatrics. While some studies support their efficacy,[2-3] other studies failed to demonstrate benefit.[4-5] Overall, there is a paucity of data from which to draw definite conclusions. Many of the studies were performed in the remote past, and surprisingly few new data have been published since.

Recently, von Tetzchner et al.[6] published a study on the IAHP method, the first in more than three decades, in the *Journal of Developmental Neurorehabilitation*. Von Tetzchner's article contained some flaws that may have obscured a real benefit of treatment. The groups were very small (17 and 18). In each group there were many different diagnoses, including genetic syndromes, cerebral palsy (CP), epilepsy, and developmental delay, spanning a wide range of severity. These factors may have increased variance so much as to obscure a real benefit. Additionally, 13 different developmental exams were used, and only one child in the IAHP group was treated before age five. This is contrary to the IAHP method, which recommends treatment from an early age. It suggests that von Tetzchner's group did not understand the method well enough to make a valid replication. Finally, the parents felt strongly that the IAHP method was better, and this was highly statistically significant. However, this was not mentioned in the conclusion, which stated that "the substantial claims of superiority compared to other interventions made by IAHP…are not supported, but parents appear to be met in a positive manner in these programs."[6]

The current study seeks to correct the flaws of von Tetzchner's study. Instead of many and nebulous diagnoses, only one, Down syndrome, was used. Down syndrome can be verified either by physical examination or a chromosomal analysis. In von Tetzchner's study, the number of different developmental profiles used (13) is almost great as the number of subjects (17-18) in each group. In the current study, only a single developmental profile is used. All before-and-after developmental examinations were done by the professional staff of IAHP, using the developmental profile of the IAHP. The treatments were taught by IAHP staff to the parents. The number of subjects was greatly increased from 17-18 to more than 200. Variance between subjects, which can obscure conclusions, was further reduced by having each child serve as his own control.

Materials and Methods

The database consisted of a 25-year longitudinal cohort extending from 1990 to 2015, containing 248 children with Down syndrome. Of these, 24 were lost to follow-up, and eight had birth or examination dates that were unclear, making time calculations unreliable. Remaining for analysis were 216 of the 248.

Exercises

The program uses many developmental exercises, which have been detailed in books.[7-10] Important components include: movement exercise, progressing from crawling at an early age to running; passive exercises for those not able to crawl yet (patterning); early reading with flashcards; early mathematical education by counting dots on flashcards; balance and athletic activities; nutritional optimization (elimination, rotation, or other diets); and avoidance of antiepileptic drugs that hinder brain development. Functional IAHP methods to stimulate brain development are explained below.

Crawling on the floor is encouraged. A minimum of four hours daily is recommended. Developmental milestones in crawling are for the infant to elevate itself on the forearms, and then on the wrists; to lift up its head to see where it is going; and to develop convergent gaze. Close contact with the floor encourages convergent gaze development, which is necessary for reading because without it one has diplopia. Stabilizing the body develops arm strength, chest strength, and breathing strength and control, which is necessary for speech. Crawling demands significant athletic exertion from infants, evoking growth hormone, which is beneficial for brain development.

Patterning is teaching a child how a motor activity feels, or teaching the sensory portion of a motor movement. When teaching one's child to draw, one could place the pencil in the child's hands, and then move the child's hands to draw. Many parents teach their children how to ride a bike by placing the child on the seat and moving the bike passively, helping the child with balance. Most parents have done patterning.

If children have difficulty crawling, then patterning is appropriate. To teach the child to crawl by passive movement requires a team of three. The team moves the head and each limb in proper sequence. If one did not understand the purpose, patterning would appear bizarre. Crawling in a cross-pattern requires coordination of head, arms and legs. In IAHP experience, it promotes development.

Brachiation is moving across a jungle gym (ladder parallel to floor) while hanging from it by the hands. It recalls the movement of primates, before they descended from the trees to walk on the ground. It demands strength in the arms, accurate vision and hand placement, and balance. Swimming develops arm strength and breath control. Swimming stimulates brain development, especially at a young age.

Beyond crawling, children may walk, walk on uneven surfaces, climb and descend stairs, walk on logs, and run. These develop balance. Newborns are taught balance passively by swinging them through the air or moving them on a pad, replicating the movements airplanes make, such as pitch, yaw, roll, etc. Running is a strong stimulus for brain development. IAHP encourages all sports, dance, balance moves, and gymnastics. From the IAHP perspective, exercise is more about the brain than the limbs.

Many children with neurologic disabilities have small stature and small lung volumes. The children often do a treatment called "masking" for one minute per hour. Breathing from a special mask raises carbon dioxide, which is considered to stimulate lung development, chest volume, and cerebral vasodilatation. In IAHP's experience, masking may enhance chest size, stature, and head circumference.

Reading may be taught at ages 4-6 months, one word at a time. Two-inch bright red letters are printed on flashcards. This is because newborns and infants have poor ability to focus and converge. Their vision is blurry. The cerebral cortex, which interprets the images, is also under development. In this early stage, whole-word reading works best. Words are more concrete and practical, while letters are abstract. The children intuitively develop phonics while learning words. Early reading demands that the infant visual cortex develops, so as to perform at the level of an older child. Stimulating cortical development is the point.

Math is taught early by counting red dots placed randomly on a flashcard. While Arabic numerals are abstract, dots are concrete and are more easily understood by infants. This develops estimation, a right-brain form of math. Memorizing multiplication tables is an approach to math more like language—a left-brain approach. Thus, estimation develops a parallel neural circuitry for mathematics.

It is most important to make learning fun. Children naturally love learning. Parents have an urge to test the infant, but infants don't like being tested any more than adults do. Short teaching interludes (five words) with minimum testing are most effective.

Role of Staff and Caregivers

IAHP provides course work through which parents and caregivers are taught the therapy. The parents and caregivers are the therapists. IAHP staff teach the courses, counsel the therapist-parents, and perform the developmental examinations.

Developmental Assessments

The IAHP developmental profile is the Doman-Delacato profile. Each patient received a thorough developmental assessment by professional institute staff at initial examination and first follow-up. In each case a global neurologic age was determined. The chronologic ages were determined from the dates of the examination and the birth date. The ratio of global neurologic age (NA) divided by chronologic age (CA) were determined. The ratio of the global NA/CA was also determined at the first follow-up.

The median time from birth to initial exam was 16 months, and the average time was 26 months. The median time from initial exam to first follow-up was 8 months, and the average time was 13 months.

The Institutional Review Board of the IAHP approved the study.

Results

Some patients ordered materials and began some treatment, not wishing to wait for the initial assessment. In the data, one can see some children doing surprisingly well before IAHP treatment was formally begun. No Down syndrome patients were normal or better without some form of IAHP treatment. If some patients had not begun IAHP treatment before the initial assessment, the results of the study might have shown a stronger treatment effect.

Figure 1 illustrates one representative child who had a NA of 7.89 at first exam at age 12.96 months. The initial slope was 7.89/12.96=0.61. The slope of 0.61 means that the child developed at a rate of 6 months of neurologic progress per 10-month interval. At the first follow-up, the child had a NA=21.04 months at a CA=20.46 months. The slope of the second interval was (NA=21.04-7.89=13.15)/ (CA=20.46-12.96=7.5 months). The second slope (13.15/7.5=1.75) indicates that in the second interval, the child progressed at a rate of 1.75, or 17 months per 10-month interval. Thus, much more rapid developmental progress was made. For an individual patient, this figure illustrates the difference between slopes before and after IAHP treatment, which are compared in the paired T-test (see below).

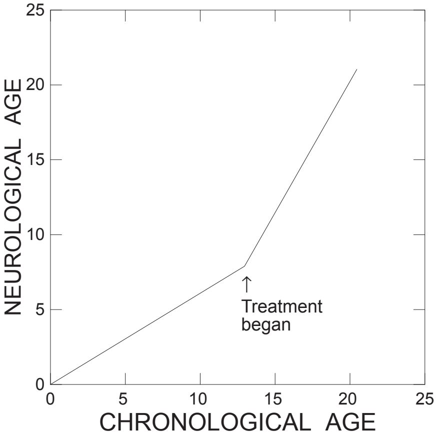

Figure 1. Rate of Neurologic Development of One Patient before and after IAHP Treatment

Figure 2 demonstrates that before treatment at IAHP, subjects had made about half as much progress as would normally be expected for their chronologic age. The figure is square, with time in months equal on X and Y axes. If neurologic progress in months were equal to chronologic time in months, it would be represented by a line from the lower left corner to the upper right corner of the diagram (slope=1.0). In Down syndrome with standard treatment (before IAHP treatment) the ratio of change (slope) in neurologic age (NA) over chronologic age (CA) had a mean of 0.55 with a mode of 0.5. These results with the developmental profile of the institute agree with what is generally known about Down syndrome. Generally, one would expect a median intelligence quotient (IQ) of 40 with the range of 25 to 70.

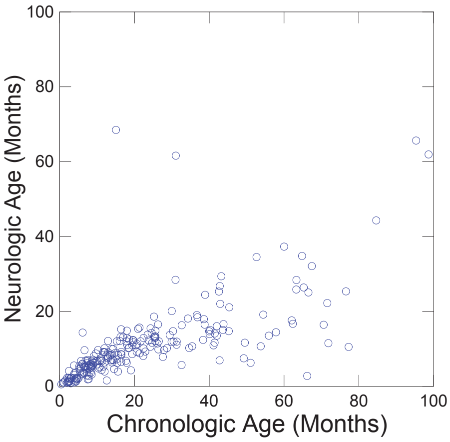

Figure 2. Neurologic Age vs. Chronologic Age at Initial Assessment

Figure 3 demonstrates that after IAHP treatment, the rate of change (slope) of neurologic progress per unit time more than doubled. The post-treatment average was 1.43, and the mode was 1.2. Note that when the first follow-up occurred at a very short interval after the initial exam, a line representing the data would have a much steeper slope. There are likely two reasons for this. One is that when stimuli are novel (learning something new rather than something old), brain development is promoted. A second reason is that if, but only if, the method did really make a difference, a short time interval accentuates the contrast between the standard method and the new method.

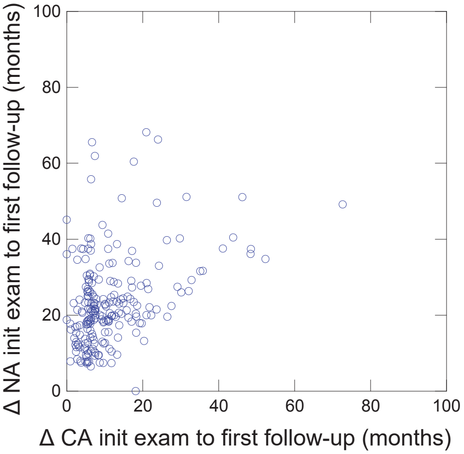

Figure 3. Change in Neurologic Age vs. Change in Chronologic Age at Follow-up Assessment

Figure 4 plots the slopes of the rate of change of NA/CA before IAHP treatment (when child was presumably receiving standard treatment) and after IAHP treatment. The frequency distribution of the rates of change is shifted to the right after IAHP treatment, towards more rapid development. A paired T-test was performed, comparing pre-treatment rate of neurologic progress in each patient with the post-treatment rate of neurologic progress in the same patient. The pre-treatment rate of neurologic development was subtracted from the post-treatment rate of neurologic development. If the pre-treatment progress was equal to the post treatment progress, this difference would be zero. If before IAHP treatment, a child made 5 months of neurologic progress in 10 months, and after treatment began made 14 months of progress in 10 months (more than doubling in the child's rate of development), the difference would be 9 months greater progress in 10 months, or 0.9.

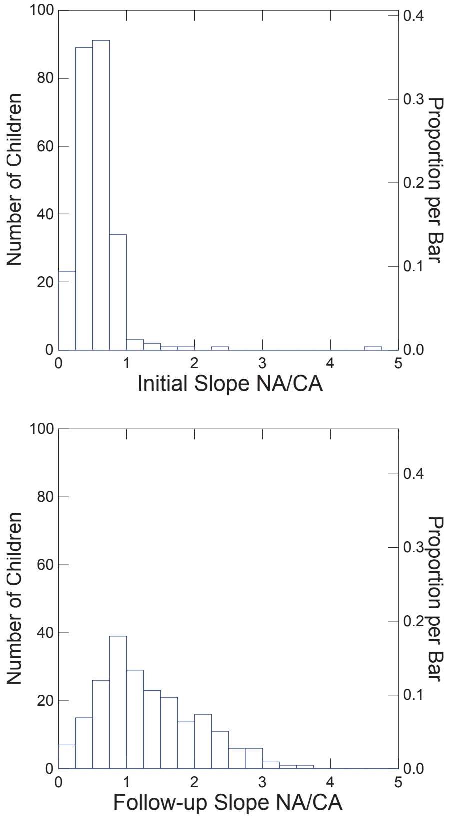

Figure 4. Rate of Change in Neurologic Age vs. Change in Chronologic Age at Initial Assessment (above) and Follow-up Assessment (below)

The mean difference was 0.87 months of neurologic progress per month. The 95% confidence interval for the difference was 0.75 to 1.0. These data indicate a strong beneficial effect of treatment. Because the confidence interval does not overlap zero, the results are statistically significant. The *P* value is $< 10^{-15}$.

Discussion

In the Middle Ages in Europe, literacy was very uncommon. Now most children in the Western world are expected to be able to read and write. The reason for the difference is that children now attend school six to eight hours per day. This previously unforeseen treatment (all children attend school) yields a previously unforeseen result (most children are now literate).

According to an old paradigm, mentally retarded children (now more often called intellectually or cognitively disabled) are uneducable and incurable. In the old paradigm, significant training would be a waste of time and effort. Many children were institutionalized. According to a newer paradigm, brain performance and intelligence are trainable. If a child has an IQ of 50, it means that in 10 months' time, only five months' progress is made. From the perspective that training improves performance, the definition of the problem also suggests the solution. This relationship makes the recommendation for intensified treatment obvious in a newer paradigm.

The effects of sensory stimulation and training on brain development have been studied in animals. Beginning in the 1960s, Rosenzweig et al.[11] spawned a large body of literature on the effects of environmental enrichment on the brain.[12] This term refers to functional methods to enhance brain development. Environmental enrichment is composed of complex inanimate and social stimulation including voluntary exercise. Sensory inputs may be auditory, visual, tactile, and/ or social.[13] Beneficial effects on brain development, seen across multiple animal species including humans, include enhancement of gross and microscopic brain morphology; enhanced biochemical effects such as neurotransmitters and neurotrophic molecules; enhanced physiologic processes such as long-term potentiation; and improved behavioral and cognitive processes such as learning, memory, problem solving, and social interactions.[12] Beneficial effects on brain development can correct or improve prior neurologic insults that result from sensory deprivation. They may remediate or improve neurologic injuries, developmental delays, and/or genetic syndromes (e.g. Down syndrome).[12]

Each of the components of environmental enrichment has effects on the brain. Exercise stimulates neural plasticity. This leads to enhanced neurogenesis, learning, and cognitive performance.[14] These enhancements are seen in the cerebellum, cerebral cortex, hippocampus, and globally.[14] Exercise enhances intelligence and academic achievement both in normal children and in those with mental retardation.[15] The benefit is increased when exercise is combined mental training.[16] Combined mental and physical training can enhance neurogenesis (neuron replication) and also neuron survival (limiting apoptotic loss of newly elaborated neurons).

Different types of sensory stimulation also promote neurogenesis, brain growth, cognition, and learning. Auditory stimulation, ideally including the mother's voice, stimulates the auditory cortex so much that one can measure increased thickness of the auditory cortex with cranial ultrasound.[17] Visual sensory deprivation has profound negative effects on brain development, and visual stimulation enhances brain development.[12] Tactile stimulation also enhances brain development. Stimulation of one sensory channel (e.g. tactile) stimulates development in other sensory (e.g. visual) and motor modalities.[18] In general, there is substantial cross-pollination, such that stimulation of one sensory input or motor skill enhances other sensory channels and motor capabilities.[12] These principles work across a range of species, in normal and pathologic conditions.[12] Development is a physiologic process, and can be manipulated, just like pulse or blood pressure.

The literature on environmental enrichment provides a strong foundation in animal research for IAHP methods. Adoption literature suggests environmental enrichment also works in humans. In some institutions and orphanages, there is an "institutionalization syndrome" composed of growth delays, neuro-behavioral alterations, low IQ, disorganized attachment, and impaired language abilities.[19] These result from neglect and diminished social and sensory stimulation. Clearly, enhanced caregiving can strongly mitigate or alleviate these effects of neglect.[19]

In one study, adoption from lower socioeconomic status to higher socioeconomic status caused IQs to improve from a mean of 77 to a mean of 98.[20] Five other studies confirmed thaadoption from lower socioeconomic status to higher socioeconomic status improved IQs and cognitive performance.[20] From these adoption studies, one can conclude that intelligence is not immutable, but can change. Functional stimulation (environmental enrichment) can effect a significant improvement in intelligence, development, and performance.

If a child suffered severe neglect and sensory deprivation, the child could be mentally retarded. If at age 2 he achieved one-year milestones, he would have a developmental quotient of 50 (1/2 x 100). If the child was transferred to an enriched or stimulating environment, he could make more rapid progress. During a second period, the child might make three years of progress in two years. During the second period, the child might have had a developmental quotient of 150 (3/2 x 100). This is called catch-up recovery. If at age 4 the child had four-year milestones, he would have a developmental quotient of 100 (4/4 x 100).

Some children were, in fact, severely neglected in Romanian orphanages.[21-22] One group had good results when adopted before age 2. Evaluation before adoption revealed severe global privation. Children suffered such severe neglect that they were mostly below the third percentile (mentally retarded). They had Denver developmental quotients of approximately 50. The Romanian orphan children were adopted into more loving and stimulating British families. When reexamined at age four, they had nearly complete recovery of cognitive abilities. They had intelligence quotients in the 90s (normal) after recovery. Thus, nearly complete recovery from mental retardation by means of environmental enrichment has been demonstrated in humans.[21-22] Even moderate mental retardation could have nearly complete recovery.

It was once thought that genetic, congenital, or neurologic conditions were incurable, but more recently this has been challenged.[12] In a mouse model of perinatal anoxic brain damage, environmental enrichment reversed developmental delays in inhibitory interneurons.[23] Similarly, in a rat model of cerebral palsy, environmental enrichment was able to prevent motor deficits.[24] After noise-induced impairment of the auditory cerebral cortex, environmental enrichment rescued cortical neuron function[25] and promoted recovery of degraded auditory cortical processing.[26] In rats with cerebral cortical malformations, environmental enrichment resulted in improved cognition.[27]

Studies in a mouse model of Down syndrome suggest that exercise and environmental enrichment enhance neurologic development and performance in this condition as well. In the Ts65Dn mouse, environmental enrichment led to more complex branching of the dendritic trees of neurons,[28] and exercise led to improvement in learning abilities and hippocampal neurogenesis.[29] Other studies showed that environmental enrichment improved cognitive abilities, synaptic plasticity, and visual functions,[30] and that it enhanced memory, cognition, visual system maturation, hippocampal neural plasticity, and brain function.[31]

In a human study, multi-sensory massage enhanced visual function and accelerated development in children with Down syndrome.[18] Prenatal and perinatal environmental enrichment enhanced or restored anatomy, behavior, learning, and memory in both animals[32-33] and humans.[34]

Figure 4 shows that there is more variance in patients using IAHP treatment than prior to treatment. This may be because both children and parents may make greater or lesser efforts at educational and treatment exercises. Also, in cases where follow-up was short, the novelty of a new treatment may accentuate the effect (Figure 3). When education is the treatment, teaching something new has greater effect than teaching something old. Novelty enhances the effect of environmental enrichment.

Strengths of this study may include measures to reduce variance. It is widely thought that standard therapy has no significant benefit over no therapy.[6] If similar measures were used to reduce variance, standard therapy might be shown to be superior to no therapy.

A potential weakness of this study is that all evaluations were done at IAHP. In future work, independent outside evaluation may strengthen the credibility of the conclusions. This method should also be studied with longer follow-up and across different diagnoses.

The rapid rate of improvement—more than doubling in many children—might seem hard to believe, but it is consistent with studies of adopted Romanian orphans and animal studies.

Environmental enrichment uses the concept of holistic cerebral stimulation, recognizing that to greater and lesser degrees, most areas of the brain are connected one way or another with most other areas of the brain. Depressing one cortical function tends to depress other cortical functions to some degree. Conversely, stimulating one cortical function tends to stimulate other cortical functions to some degree. This is illustrated in IAHP's experience that children, even those with profound brain injuries, can begin learning to read at age 2 or even earlier and should be given the opportunity.

Reading stimulates other cortical functions including speech. Rather than using speech as the foundation to learn visual language, one could just as easily use visual language as the foundation for speech.

Down syndrome has been thought of as primarily a chromosomal problem. The chromosomal paradigm focuses on genes triplicated by trisomy as a primary set of pathophysiologic mechanisms. Alternatively, Down syndrome could be re-imagined as a problem in developmental neurobiology. This re-imagination of Down syndrome changes the focus to different pathophysiologic mechanisms, and points toward different treatments.

Conclusion

Down syndrome children have much greater potential for development than many realize. Methods discussed here for environmental enrichment should be studied for their potential to enhance brain development in other conditions, and in normal children as well.

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From Birth Mothers to First Mothers: Toward a Compassionate Understanding of the Life-Long Act of Adoption Placement

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Debbie Garratt, R.N., M.Ed.**

ABSTRACT:
Objective: Women who place a child for adoption have historically been far less actively researched than the other individuals in the adoption triad (adoptees and adoptive parents). They often have unmet psychological needs related to the decision to place for adoption, the placement experience, and as they endeavor to move forward post-adoption. In this review an effort is made to provide a description and analysis of the professional literature on women's placement experiences, with attention to methodological challenges inherent in deriving valid results. Next an overview of the results of a mixed method pilot study on birth mothers' decision-making and adjustment is shared. Finally, the most pressing future research needs on the topic of adoption placement from the birth mother's perspective are outlined.
Data sources and extraction: Employing the following search terms: adoption, open-adoption, closed adoption, birth-mother, biological mother, relinquishment, and adoption placement, an exhaustive search for empirical journal articles, reviews, and edited book chapters was conducted yielding over 80 publications. Sources spanning a 50 year period (1974-2014) were identified via MEDLINE, PUBMED, and PsycINFO.

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** Executive Director, Real Choices Australia (Contributions: research design, survey development, data collection, editing of report).

Results: **Based on an in-depth analysis of the best available evidence on the psychological lives of women who choose adoption, an argument is made for more focused research attention and enhanced sensitivity to the unmet needs of birth mothers in our communities.**

Discussion: **As the experiences of birth mothers are more fully understood, more substantive and compassionate counseling before, during, and after adoption will become more feasible.**

Introduction

Adoption is relatively common in the U.S. with this family form personally touching the lives of nearly two thirds of the population. Results of the *National Adoption Attitudes Survey* published in 2002 revealed that 64% of the respondents endorsed having been adopted, adopting a child, placing a child for adoption, and/or having a family member or close friend directly involved with adoption (http://adoptioninstitute.org/publications/2002-national-adoption-attitudes-survey/). Despite this widespread familiarity, women who have made the life altering decision to place a child for adoption have been largely silenced in contemporary society, the professional literature, and even in popular press constructions of adoption. [1,2,3,4] The act of signing away all legal rights to a child is viewed by many as the point in time when the birth mother's involvement in her child's life logically ends; and birth mothers have historically been encouraged to move on as if the pregnancy, birth, and adoption never happened.

Adoption in the U.S. is generally perceived as non-normative and less preferable to biologically-based families.[5] As a result, all members of the adoption triad (adoptive parents, adoptees, and birth mothers) often bear the effects of being stigmatized.[5] Of all parties involved, however, the role of the birth mother has arguably been the most strongly stigmatized, with women who place for adoption the least supported.

A recent empirical examination of birth mothers represented in children's story books revealed widespread marginalization,[6] with only 2 of the 104 books analyzed from the perspective of women who place a child for adoption. Most books available to adoptees provide simplistic glimpses into the psyche of a birth mother and perpetuate stereotypes of her as single, poor, and unable, or unwilling to care for her child. As exemplified in the brief excerpt below from Jerome and Sweeney's study,[6] even in a book wherein the birth mother's perspective is utilized and the decision is portrayed as carefully considered, the adoptive parents are still presented as having so much more to offer than the birth parent, who has only love: *"So I began to search for the best family that I could find. I wanted your parents to be in love and in a good marriage, and I wanted them to have their own home. I wanted your family to be happy and fun to be around. I wanted your family to love you as much as I did."* Also of note is the use of the past tense, suggestive of the birth mother's love having ended at the point of placement.

Why are birth mothers' experiences so private and of so little apparent interest and value to mainstream society? What is it like to make this profound decision in the immediate and over time? The objectives of this article are threefold: 1) review the empirical literature pertaining to women's adoption decisions and experiences coping with the decision; 2) describe quantitative and qualitative data from a preliminary study of women who placed for adoption; and 3) identify the most pressing future research needs on the topic.

Literature Review

Approximately 50% of the annual 6.7 million pregnancies in the U.S. are unintended, with 82% of adolescent pregnancies in the unintended category.[7] The U.S. adolescent birthrate is currently the highest in the developed world, and as such actually surpasses the European Union adolescent birthrate by four times.[8] As an option in cases of unintended pregnancy, adoption is surprisingly uncommon in the U.S. with less than 3% of White unmarried women and less than 2% of Black unmarried women[3] deciding to place a child for adoption. These figures represent a marked decline from 50 years ago when 40% of unmarried White women placed for adoption.[9] The placement of newborns has become increasingly rare in the U.S., declining almost nine-fold since the early 1970s. Current estimates of domestic infant adoptions range from approximately 7,000 to 22,000 annually,[10] with various websites of adoption agencies often reporting estimates of approximately 18,000 (e.g., buildingyourfamily.com and babycenter.com). Between 1 and 5 million current U.S. residents are adopted,[11] and the number of adopted children not residing with either biological parent in 2009 was 1,782,000.[12]

Some have argued that widespread availability of elective abortion has resulted in fewer women choosing to carry to term and place for adoption; however the decline in adoption preceded the legalization of abortion in the U.S. suggesting the two options may be largely independent.[13,14] Other factors including less social stigma associated with single parenthood and more support programs for low income mothers among other possibilities seem to be more logical explanations for a shift away from adoption.

In the US, there are four general forms of adoption currently available. The first is *Closed Adoption* wherein no identifying information about the birth family or the adoptive family is shared between the two and there is no contact. The records are sealed and sometimes become available to the adopted child on his or her 18th birthday. In the second form, *Semi-Open Adoption (or Mediated Adoption)* information is shared between birth and adoptive parents; however confidentiality regarding individuals' full names and contact information is maintained. In this type of adoption, birth parents often participate in choosing adoptive parents and they sometimes meet prospective parents. Birth parents may request pictures and written updates after the adoption, although they don't normally have any direct communication with their children. In the third type of adoption, *Open Adoption,* birth and adoptive parents mutually decide to share their full names and correspondence information. Communication occurs directly and as often as desired. Finally, in *Identified Adoption,* birth and adoptive families choose each other on their own, coming into contact through personal relationships, advertising, or an attorney.

As Friedlander[15] has pointed out, *"viewing adoption as an event or circumstance, albeit a many layered one, rather than as a personality trait is a nontrivial distinction."* This she emphasizes is relevant for all triad members (the child, the birth parents, and the adoptive parents). There is no developmental endpoint in adoption, since feelings associated with the experience change as individuals navigate each life stage.[15] This is true regardless of the form of adoption from the above list that characterizes placement of the child. Professional recognition of the complexity of the adoption decision and awareness that birth mothers' abilities to achieve comfort requires integration and re-integration of the experience into one's personal identity throughout life, are vital to developing adoption protocols that honor and respect birth mothers.

Fravel and colleagues[16] measured the *"psychological presence of the relinquished child"* derived from interviews with a national U.S. sample of 163 predominantly White birth mothers and found that at an average of 7.7 years post-placement the adopted child remained psychologically present for the women both on special occasions and during routine living. The authors suggested that their data discredits the myth of birth mothers removing their children from their minds and moving on. They noted that the adopted child was psychologically present to some degree in every single woman's case. The results of this study underscore the need for a more comprehensive understanding of the life-long trajectories of women deciding to place for adoption.

Although never formally stated in public forums, there may be some fear that bringing birth mothers' lived experiences to the foreground will threaten the practice of adoption, when in fact ignoring birth mothers' experiences is likely to invite more damage. As contemporary adoption plans become more sensitive to the ongoing relationship that is experienced despite physical separation, and plans are developed to embrace and meet the needs of the birth mother, the likelihood of adoption placement working well for all involved will undoubtedly increase and fears surrounding it will subside over time.

Predictors of the Decision to Place a Child for Adoption

Wiley and Baden[3] point out that personal stories and direct communication with many birth mothers has revealed that the psychological distinction between a voluntary and involuntary placement for adoption is best characterized on a continuum as opposed to a dichotomy. They further note the degree of pressure or coercion a woman feels has not been examined closely as a variable in studies of birth mothers' adjustment. The feelings of coercion may be directly or less directly experienced from parents, partners, spouses, friends, and/or teachers, or such feelings may have their origin in perceptions of violating cultural norms by having a child at a young age and/or without a partner. The authors note: *"The distinction between the legal category of relinquishment (voluntary vs. involuntary) and the emotional experience of the birth parent(s) (totally voluntary vs. coerced) is important to make in both practice and research."* In this article the focus is on predictors of legal voluntary placement, as opposed to involuntary placement with awareness and sensitivity to the fact that "voluntary" placements may be colored by varying degrees and forms of external pressure. Indeed, available evidence suggests that for many women, placement of the child for adoption is the result of social and family pressure or force,[17,18,19] Deykin and colleagues[20] reported that pressure from families opposed to keeping a child, from physicians, and/or from social workers reflected the experiences of 69% of the respondents.

In a review published in 2005, Wiley and Baden[3] summarized the results of nine U.S. and Canadian studies related to factors that predicted the adoption decision. Well-established predictors were age, race, socioeconomic status, education, preference of the birth grandmother, vocational goals, the quality of the relationship with the birth father, and living arrangements. Wiley and Baden further noted that the literature has consistently shown that White women place for adoption at significantly higher rates than women of color, including African American, Mexican American, and Filipino American women. Wiley and Baden describe the phenomenon of *"informal adoption"* wherein single mothers share the parenting of their children with extended family members or they "gift" a child to a family. This type of arrangement seems to be more common among women of color and may explain the lower rates of placement.

Studies have also indicated that adoption plans are more likely to be made by single mothers from intact families of higher socioeconomic backgrounds, with higher academic achievement and more ambitious educational and career aspirations, as well as more goal-directed life plans.[11,14,21-24] Other less actively researched, but significant predictors of the decision to place for adoption include having been reared in a small town, more traditional attitudes about family life, and conservative attitudes toward abortion.[28,29]

Another factor that has been identified as related to the choice to place for adoption is the preference of the birth mother's mother.[11,23,30] Mothers are reported as more influential in decisions to place for adoption than peers and male partners.[31,32] Leynes[29] found that adolescent birth mothers who were less influenced by their male partners, were more likely to choose adoption. Finally, Resnick and colleagues' work[33] indicated that approximately 25% of both those who chose to place and those who chose to parent identified the father as the least helpful person in their lives relative to the decision.

Chippendale-Bakker and Foster[11] noted in their study that most women were motivated by a desire to provide a better life for their child and similarly Resnick and colleagues[33,34] identified the baby's best interest as a primary motivating factor. Other reasons for deciding to place for adoption reported in the literature include feeling unprepared for parenthood or not feeling ready emotionally, as well as inadequate finances.[20,35]

Foli[36] reminds us that the view of the unwed teenage mother as the prototype of women placing for adoption is more myth than reality with only about 25% of birth mothers fitting into this category. A more accurate typical case scenario according to Foli is a woman in her 20s who has other children.

Psychological and Behavioral Adjustment of Birth Mothers

Birth mothers who experience grief and difficulty in association with placing a child for adoption may specifically report feelings of loss, sadness/depression, guilt, remorse, and anger.[37-40] Symptoms of Post-Traumatic Stress Disorder (PTSD) and self-destructive behaviors, including substance abuse and eating disorders were reported by Jones,[41] based on in-depth interviews of 70 U.S. women who had placed a child for adoption 7-31 years prior. Jones also found that many of the women suffered from self-esteem issues involving feelings of powerlessness, worthlessness, and victimization. Subsequent marital problems have been reported with placement of a child for adoption as well.[20] In their recent review of the literature, Wiley and Baden[3] concluded that the following clinical symptoms are sometimes identified in birth parents: unresolved grief, isolation, relationship difficulties, and trauma. However, Wiley and Baden noted that there are also studies indicating that some birth mothers, who choose adoption fare better than those who decide to keep their infants on external criteria of well-being, such as high school graduation rates.

Feelings of loss are central to the separation between a mother and child through adoption and the experience has been compared to that which occurs in cases of perinatal death.[42] However, whereas the grief associated with perinatal death tends to resolve with time, in adoption the feelings of grief may intensify.[42] Typical aspects of the experience of placing for adoption that make it difficult to resolve negative feelings include a lack opportunities to express grief, inadequate support, and not having socially acceptable mourning rituals.[42] When grief is not expressed, women may develop a pathological reaction that is likely to include symptoms of deep depression.[42]

Roles[43] holds the view that the grief of birth mothers is similar, but not identical to other types of grief. She has identified phases leading to resolution in birth mothers beginning with numbness and denial, followed by eruption of feelings, acceptance, accommodation to and living with uncertainty, and re-evaluating and rebuilding. Several authors who have examined grief in birth mothers likewise emphasize the need to acknowledge and validate the loss in order to work through the grief process,[44,46] This may begin with the birth mother holding her child, explaining her reasons for choosing adoption, and verbalizing her wishes for her child's future.[47]

Brodzinsky[17] suggested that healthy grieving for birth parents is optimized when they discuss and express their grief in a nonjudgmental, supportive environment and are able to engage in a ritual marking or commemorating the loss of the child. Brodzinsky also noted that an opportunity for reorganization leading to understanding of the situation and the roles of everyone involved is beneficial to the final stages of grief work.

In Logan's[42] interview-based examination of 28 birth mothers wherein 68% of the women reported some form of mental illness (depression, nervous breakdown, manic depression, and other conditions), the factors found to be associated with psychological distress included lack of support from families and from the agencies involved, lack of counseling, suppression of feelings of loss, guilt, and shame, the presence of other significant life events, such as the experience of sexual abuse or a death, and achieving contact with their children and finding out that the child's life in the adoptive home had not been very happy. One woman in the study who experienced the adoption as highly traumatizing stated *"I'm angry that nobody told me that adoption wasn't the end of the problem – adoption was the start of a bigger problem. I lost my boyfriend, home, parents, myself. You don't just lose the baby. It left me numb, it left me feeling I was no good, it left me feeling absolutely bereft –.... It left me feeling like someone had died and I hadn't been allowed to go to the funeral....I couldn't talk about it. No one allowed me to grieve."* This study was not representative, as all the women had contacted an agency for after adoption services (help with locating a child, seeking information about the child, or advice on how to tell a subsequent child). Moreover, like many other studies on birth mothers' experiences, the investigation was compromised by the small sample, lack of a control group, and the retrospective nature of the data collection.

Condon[48] identified four unique psychological aspects of the experiences of birth mothers who place for adoption. First, many mothers feel the adoption is their only option due to financial hardship and pressure from family and professionals, with such feelings detracting significantly from the experience being fully "voluntary." Second, because there is always the possibility of reunion, the process of saying goodbye with any sense of finality is hindered. This obstacle to healing can engender disabling chronic grief reactions. Third, birth mothers often lack knowledge of the child leading to disturbing fantasies, such as the child being sick, sad, angry, or having died. Finally, women may see their efforts to acquire knowledge about their child as being blocked by an uncaring bureaucracy. Ninety percent of the women in Condon's study reported strong feelings of affection for the infant, both during late pregnancy and in the immediate post-partum period. None reported negative feelings toward the child. Average ratings of sadness and/or depression at the time of placement were between "intense" and "the most intense ever experienced." The amount of anger experienced at the time of placement was rated between "a great deal" and "intense" for the sample, and guilt was on average rated as "intense." Condon found that for many women, intense emotions did not subside with time and for some of the women he assessed, increases were detected across the years. The majority of those sampled by Condon said they had received little or no help from family, friends, or professionals. More than 50% used alcohol or sedative medication to cope after placing their child for adoption. Nearly all the women in this study reported that they coped by withdrawing and bottling up their feelings, with one third subsequently seeking professional help.

Research by Winkler and van Keppel[49] was undertaken to obtain participants from the entire range of psychological adaptation to placing an infant. Using television, radio, and newspaper advertisements, women who believed that "they had made a good adjustment to relinquishment" as well as "those who believed that their adjustment was poor" were requested to participate (N = 213). Methodological strengths included the following: 1) hypotheses grounded in theoretical concepts of social support, expression of feeling, stressful life events, and psychological reactions to loss and bereavement; 2) use of psychometrically sound assessment instruments; and 3) inclusion of a matched comparison group. The results revealed that on average those who placed a child for adoption exhibited less positive adjustment than the matched control group. Problems adjusting were linked to having inadequate social support networks, limited opportunities to express feelings, and a continuing sense of loss. Experiencing a sense of loss that extended up to 30 years was reported by approximately half of the sample of women who placed for adoption. Birthdays and holidays were identified as the most difficult times, and birth mothers generally believed access to information about the course of their child's life following adoption would have helped to ease their pain.

There are studies suggesting that adolescent women who place their infants for adoption do not fare worse, and may actually fare better compared to their peers who decide to keep their babies. For example, in a five-year longitudinal study by Winges et al.[39] comparing the lives of adolescent birth mothers, (116 decided to parent and 76 chose adoption), those who chose adoption were found to be more likely than parents to remain single and avoid a second birth across the five years. The two groups differed little in educational attainment, and there were no significant group differences in the psychological measures of well-being. Those who chose adoption were more likely to be employed; yet their earnings at the close of the study did not differ from those who chose to keep their infants. The authors concluded that the decision did not set the course for the participants' lives. McLaughlin and colleagues[50] reported no difference in the two groups relative to school enrollment at 6 months, high school graduation rates, and perceived quality of life, depression, self-efficacy, socioeconomic status, and religion.

Based on data from the National Survey of Family Growth,[51] adolescents who placed for adoption were less likely to live in poverty and were more likely to complete high school than adolescents who had a non-marital birth and chose to parent. As noted by Namerow and colleagues,[52] these findings were replicated in several studies published in the late 1980s and early 1990s using data derived from community agencies that served pregnant women (prenatal clinics, adoption agencies, and maternity residences.) Specifically, the results generally revealed that young women who placed for adoption, compared to those who parented, had more positive outcomes related to school enrollment, employment status, income, public assistance, and rapid subsequent pregnancies. However, on the more personal measures of psychosocial adjustment including self-esteem, personal efficacy, emotional support, life satisfaction, and optimism, the two groups were indistinguishable.[52] Another pattern in this early work noted by Namerow and colleagues was lower rates of satisfaction with women's pregnancy decision; but despite this differential, the majority of women in both groups across the studies were satisfied with their decision.

In another large scale investigation, the results indicated that among women who place for adoption as teens (under age 21), compared to those who elect to parent, at four years post-placement, the "placers" experienced more favorable outcomes than the "parenters" on a variety of socio-demographic and social psychological outcomes.[52] This study investigation involved interview-based data derived from 592 pregnant teens (54% parenters and 46% placers). They were interviewed at three points: during the last trimester of pregnancy, at 2 years, and at 4 years after the birth. Retention was quite high, with 89% participating in the first follow-up and 76% at the second follow-up. Women in the study were recruited from three primary types of programs: maternity residences (75%), prenatal clinics (17%), and adoption agencies (8%).

At four years after birth, placers were more likely than parenters to be legally married, and parenters were more likely to be cohabitating, separated or divorced. With regard to the measures of psychological well-being (measured only at the four year assessment point), the placers scored significantly lower on measures of depression and reported significantly higher levels of general positive affect. In addition, placers were significantly more satisfied with all life domains at four years post placement. Specifically, the placers scored higher than the parenters on the following satisfaction scales: life in general, financial situation, work satisfaction, quality of relationship with partner, and they reported more positive future outlooks relative to education, work, finances, marriage, and financial security.) The results were the same at two years post-birth with the exception of no significant difference between the groups relative to partner relationship satisfaction. Placers were further less likely to have received public assistance or to have experienced a subsequent abortion or birth. The only variable that favored the parenter group was satisfaction with their pregnancy resolution decision. Reported satisfaction was observed to be equal to 88% (2 years) and 90% (4 years) and 70% (2 years) and 78% (4 years) for the parenters and placers respectively. The authors concluded: "*The findings from this study clearly indicate that relative to parenting, resolving a teenage pregnancy by relinquishing one's infant for adoption is a positive choice resulting in more favorable outcomes on a broad variety of socio-demographic and social psychology outcomes.*" (p. 194).

A core difference between this study and other work indicating that an adoption placement decision operates as a serious risk factor for adverse psychological trajectories, may relate to the fact that a majority of the participants in the Namerow and colleagues'[52] study, who chose adoption were recruited from maternity residences (92%). This is a context wherein the women likely received a great deal of emotional support, effectively preparing them for the birth, physical separation, and post-placement bereavement and adjustment work.

A few other longitudinal studies have identified comparable rates of decision satisfaction between women who place for adoption and parent. Donnelly and Voydanoff[53] reported that the majority of women in both groups were firmly convinced they had made the right decision at two years post placement. The results of Kalmuss and colleagues'[54] study based on responses of 527 unwed mothers a year after placement or the decision to parent revealed comparable decision satisfaction rates with 78% of the sample indicating they would make the same decision again.

As indicated by Winges and colleagues,[39] women who decide on adoption may be more likely than women who do not, to have personal, social, or demographic characteristics that increase their risk for psychological difficulties. Conflicting results in the literature described above may therefore be due to insufficient controls for third variables. More research is needed to adequately assess characteristics of mothers who choose adoption, risk factors for psychological problems after relinquishment of a child, and to determine common mental health risks.

Respecting Birth Mothers' Experience through Open Adoption

The notion that maternal attachment can be averted by swift removal of the infant at birth and the avoidance of subsequent contact between mother and child is contradicted by recent research. Based on the view that open adoption may ameliorate much of the suffering experienced by birth mothers, researchers have examined the effects of open adoptions. Open adoption has gained a considerable amount of support in the U.S. in recent years;[55-57] and there is a marked trend toward endorsement for openness, primarily because of the benefits to the birth mother. Specifically, open adoption may reduce birth mothers' feelings of pain and loss, resulting in more positive psychological well-being.[58,59] Direct contact with the adoptive parents engenders trust that the child is safe and well cared for,[60] in addition to fostering a sense of pride in their placement decision.[61] Those in favor of open adoption further contend that adoptive parents will feel more secure because the birth parents have given them explicit consent to parent the child.[62] Proponents of open adoption also believe adoptive parents benefit from the knowledge of their child's medical history, cultural backgrounds, and the reasons for the birth mother's adoption decision.[62,63] However, for many years there was also an active voice against open adoption. Arguments against open adoption focus on three primary beliefs: 1) continued contact may impair attachment between adoptive parents and their adopted child; 2) adoptive parents will feel less in control and more insecure; and 3) without finality the grieving process will be more difficult and birth mothers will incur mental health risks.[64] The empirical evidence accrued in the professional literature and reviewed below has failed to substantiate the arguments against open adoption and clarity pertaining to the merits of openness in adoption is emerging.

Available published data has demonstrated that birth mothers tend to be much more satisfied with their decisions to place for adoption when there are opportunities for ongoing contact with the adoptive family; and post-placement psychological adjustment is more positive in cases of open adoption compared to closed adoption.[55,66-72] Contact and provision of information appears to serve to reduce guilt and fears regarding the child's well-being.

Henney, Ayers- Lopez, McRoy, and Grotevant[73] published results of a longitudinal study of birth mothers' experiences of grief and loss relative to the degree of adoption openness. Structured interviews of 169 birth mothers were conducted in two different waves (4 to 12 years post-placement and 12-20 years post-placement). The authors reported that at Wave 1 most of the birth mothers were experiencing moderate to high degrees of grief, and by Wave 2 a majority reported only feeling some or no grief. Birth mothers in fully open adoptions had lower levels of grief than those in confidential or closed adoptions at Wave 2.

Similar results were derived in an older study by Winkler and Keppell[49] based on the responses of over 200 women who had placed their first born child for adoption between 4 and 30 years earlier. These authors concluded that the effects of placement were often very negative and enduring, with approximately 50% of the sample reporting that their feelings of loss increased over time.

A recently published qualitative study by Clutter referenced earlier[8] involved an in-depth analysis of 15 Midwestern predominantly adolescent women, who had experienced an unplanned pregnancy and placed their infants through open adoption. The women were identified via an agency that kept birth mothers' needs at the forefront. All the women in this study chose the adoptive family after review of written materials, pictures, and often in-person interviews as well, and they all were pro-active in the development of an adoption plan. Among the desired adoptive family characteristics reported by the birth mothers were loving fun parents, stability, a stay-at-home mother, the ability to provide for needs and desires, and a spiritually strong family. The results revealed that many women described the decision as among the most difficult and best in their lifetimes. The benefits of open adoption outweighed challenges of pregnancy, birth, and emotional transitions. Birth mothers in this study often commented on feeling very much a part of the families who had adopted their children, feeling they were the recipients of friendship and unconditional love. One participant stated: *"Open adoption is such a great thing. It gives you a whole new family like I've changed my life because of this. I thought because I placed my son, I would have less reason to care but I have more reason because I have a whole crowd of people who care about me. We're all one big family now. You go from having nobody to having everybody."*

A large scale survey of 1,396 adoptive parents in California[75,76] revealed that adoptive parents were most satisfied with adoption when the level of openness remained consistent with the original adoption plan. Unfortunately adoption arrangements are not always legally enforceable, and more research is needed to address how often changes occur and what the possible effects are of altered birth plans for everyone involved.

A number of studies have been published using the survey data from the Minnesota-Texas Adoption Project.[68,72,77-79] Overall the pattern of results indicated that adoptive parents in open adoption were satisfied with the adoption process and adopted children in open adoption did not experience any more difficulties compared to adoptees in closed adoptions.[79]

Holleinstein, Leve, Scaramella, Milfort, and Neiderhiser[80] reported data demonstrating that open adoption was beneficial in fostering positive perceptions of birth parents by adoptive parents. Finally, Ge and colleagues[69] shared the results of a study employing 323 matched pairs of birth mothers and adoptive parents. These researchers specifically examined the degree of adoption openness (contact and information exchanged) and birth and adoptive parents' post-adoption adjustment at 6 to 9 months. Results clearly demonstrated openness was a significant predictor of satisfaction with the adoption process among both adoptive parents and birth mothers. Increased openness was positively correlated with birth mothers' adjustment as measured by both birth mothers' self-reports and the interviewers' observations.

Based on the results of their longitudinal investigation described earlier, Henney and colleagues[73] have developed a perspective on openness that incorporates sensitivity to individual women's unique situations, personalities, coping resources, and life stage. They see the level of openness as not necessarily unchanging in placement decisions and they caution:

> A "rush to openness" may not be beneficial for all birth mothers…Birth mothers' grief reactions are highly personal; the same amount of information about the adopted child – say, that the child had influenza but is now recovered – may be overwhelming to the coping resources of one birth mother who worries consistently about the child's health, but may be comforting to another birth mother who is relieved that the child is now well. Birth mothers' grief reactions are also highly contextual; information (or lack thereof) or experiences that may be helpful in one stage of the birth mothers' life may renew grieving in another. In the present sample, for example, the birth of subsequent children was a major life event for the birth mothers that for some renewed their feelings of loss and increased their grieving and for others was a milestone in their grief resolution. Thus, the provision of openness to birth mothers is not simply a one-time event or choice.

Pilot Study Results

With strong backgrounds in psychological trajectories of other reproductive decisions, the authors of the present report were highly motivated to hear women's stories in their own voices and they planned their first formal study of women who placed children for adoption. After receiving Institution Review Board approval, birth mothers were recruited by asking adoption agencies to post notice of the online survey on their websites and to pass on the recruitment flyer to any women who placed for adoption in their data bases. A Facebook page was also created announcing the study and directing birth mothers to the online survey. A research team of four undergraduate university students divided up states in the U.S. and created lists of adoption agencies with contact information. Next emails were sent to approximately 120 agencies with follow-up calls encouraging directors to pass on information regarding the study to any birth mothers, who may have been interested in participating.

Unfortunately the recruitment effort resulted in only 56 surveys. Problems identified included agency personnel not having the time or interest in assisting, sealed records wherein the adoption personnel no longer had contact information on birth mothers, and privacy issues precluding direct provision of contact information to researchers. The challenges involved in locating women who have been through an adoption experience are likely a primary obstacle behind the minimal research attention afforded to them, in addition to the stigma described earlier in this report.

In the sample of predominantly White women (95%), for the majority (63%), it had been 21 years or more since they had placed a child for adoption. The age range of birth mothers was from 17 to 81, with most of the women in their late 40s and 50s at the time they completed the survey. The sample was comprised of a majority of women who agreed or strongly agreed that their faith/spirituality was important to them (73%). With regard to marital status at the time of data collection, 62% were married, 19% were single never married, 15% were separated or divorced, and 4% were widowed. Finally, 17% had a high school education or less, 38% had some college, 27% had an associate's or bachelor's degree, and 17% had some level of graduate training or had earned a graduate degree.

Prior to describing the results, a caveat is necessary. Generalizations beyond this self-selected sample are precluded with the socio-demographic characteristics defining the sample likely quite discrepant from the population of women who choose to place for adoption in the US and elsewhere. Nevertheless, several insights deemed worthwhile to share were gained and may be of use to others as research on this topic develops.

The survey had a total of 166 items including background questions and only 60% of the women who started the survey actually completed it. No systematic differences in demographic backgrounds were observed between those who completed and did not complete the survey. Due to the limited response rate and high number of incomplete surveys, the researchers selected only 32 items related to the larger themes of this review to provide a snapshot of the responses received. The sample data for these items is provided in Table 1. The data generally indicate that a significant proportion of the women sampled had a considerable amount of decision ambivalence, were not provided much information regarding how they might expect to respond emotionally post-placement, reported feeling unsupported throughout the process, and experienced a mix of positive and negative emotions related to placing their children for adoption.

Table 1: Percentage of Birth Mothers Agreeing or Strongly Agreeing with Placement Decision and Adjustment Variables (n=34)

Placement Decision		
1.	I was comfortable with my decision to place my child for adoption:	50%
2.	If I could go back in time, I would not place my child for adoption again:	44%
3.	Deciding how to resolve my unplanned pregnancy was one of the hardest decision is of my life:	68%
4.	If I had made my decision entirely on my own, I never would have chosen to place my child for adoption:	38%
5.	Others made me feel I would be selfish to parent my child:	37%
6.	I placed my child for adoption to make others happy:	39%
7.	I wish there had been just one person who offered me the support I needed to keep my child:	58%
8.	The counselors at the adoption agency seemed cold and uninterested in me:	28%

9.	At the adoption agency I was provided with information regarding the emotional or psychological adjustments I would face after placing my child for adoption:	34%
10.	Once I made the decision to place for adoption, I was allowed considerable input into identifying suitable adoptive parents for my child:	35%
11.	I had choices regarding how open an adoption I wanted to pursue:	38%
12.	My partner pressured me to place our child for adoption:	16%
13.	My parents pressured me to place my child for adoption:	50%
14.	The amount of time I spent with my child after his/her birth felt comfortable to me:	40%
15.	No one seemed to care very much about me during the birth:	54%
16.	I felt the decision to place my child for adoption was not my own and I resented it:	43%
Post- Adoption Adjustment		
17.	I was jumpy and generally anxious:	35%
18.	I relied on alcohol to escape troubling emotions:	32%
19.	I experienced bouts of extreme sadness:	82%
20.	I felt alone and unloved:	76%
21.	I was prone to angry outbursts:	35%
22.	I had low self-esteem:	65%
23.	I was worried I would never be able to have another child:	35%
24.	I felt dissatisfied with the amount of contact I had with my child:	55%
25.	I found myself longing to be near my child:	76%
26.	I knew my child was safe, loved, and well cared for:	54%
27.	Life improved after I placed my child for adoption:	26%
28.	I felt proud of my decision to give my child a better life:	66%
29.	I felt ashamed due to my decision to place my child for adoption:	50%
30.	My view of myself changed positively as a result of giving birth and placing my child for adoption:	47%
31.	I was able to fulfill my education/career goals after placing my child for adoption:	41%
32.	Placing my child for adoption was a maturing experience for me:	70%

There were four open-ended questions designed to delve deeper into women's unique experiences of placing for adoption. The length of responses varied from a sentence or two to several paragraphs. In the space below we provide a cross section of responses to each question with the aim of illustrating the broad range of experiences evidenced. The above themes that emerged from the Likert scale data were reiterated in the open-ended question responses along with a few others including the following: 1) changes in feelings over time, sometimes shifting to more suffering and other times to more perspective, contentment, and closure; 2) turning to spirituality in order to find peace with their decision. Perhaps what stands out most significantly is that for many women adoption was a lonely journey wherein they often encountered just the opposite of what they felt they needed: judgment, emotional distance, and even disdain from those most closely involved, as opposed to the compassion, understanding, and nurturing support they longed for. Moreover, those who seemed to experience the most peace surrounding placement of their children for adoption were those who had some level of continued involvement with their children. Sentiments favoring open adoption and honoring the promises made to them at the point of placement were also voiced.

1. Please tell us about your experience with adoption.

- Too much to say for the space and time. It was both a painful and wonderful experience. Our daughter was born 2.4.1982, Christian placement, closed adoption. Healthy pregnancy, healthy delivery with minor complication after…really blessed with supportive family and friends. Yet the course is very lonely for a birth mother regardless of her support system. My boyfriend was supportive and certainly relieved at the time. There was grief, and it would come in waves. I do not have strong memories of that first year. I think I just was taking steps to go forward. We were blessed to share a reunion with our firstborn when she turned about 25 years; remarkable how whole she was emotionally, physically and spiritually - but that's the message of redemption! We have an ongoing relationship with her and her hubby, we've met some of her family, and share holidays and even the births of our grandchildren. Not without its pain and struggle, but really an amazing journey.
- I accidentally got pregnant at age 29 and was in an emotionally abusive relationship with an alcoholic. At 7 weeks pregnant, he borrowed my car to run to the store and I woke up at 1 am and my car was still not home. He came home at 2:30 a.m., drunk. I told him to leave, and my parents had to come remove him from my house. That was my wakeup call; that this would be the person helping me raise my child.... and that was certainly not what I wanted for her or me. I looked into abortion but for whatever reason it wasn't the right decision for me. I called Caring for Kids and met with them later that week and started making an adoption plan.
- It broke my heart, yet I knew it was the right decision at the time. I begged to keep my child! I loved him. Wanted him! My Pastor found a family who wanted to adopt my child. They agreed to send me pictures, updates and to aid in our reunion when he turned 18. I wanted to care for him in the hospital and bring him to the adoptive parents or a neutral person. I wasn't allowed to tell anyone I was pregnant. My mom was so ashamed of me, embarrassed by me that she made me move to Florida to live with my father whom she hated!

- The only way I made it thru the pregnancy without getting attached to her was by telling myself I was having a baby for them. I knew how hard it would be to go thru all 9 months without having them to be ready for her to be born. I had 3 other children already and knew I could not care for her financially or emotionally. I wanted her to have a father to raise her. I wanted her to live a normal life, not in my chaotic life.

2. Has the adoption experience been what you expected?

- I had no idea. The counselor was great to bring some insight. He was gentle, truthful, and non-manipulative. I anticipated grief, and relief. I did not know what to expect from myself, wondered if I was strong enough. It was everything anticipated, and then I found grace far beyond my natural, and healing has been a process. God has been faithful to meet me at every turn.
- I was pretty well prepared for the adoption experience. I wasn't prepared for how I would feel 5 years down the road. I regret it more now than I did then. It's hard to remember that who I was then is not the same as the person I was now.
- I thought my parents, my pastor, and the adoptive parents cared about me and my son. I trusted them to help me. They lied to me, covered up information and betrayed me. I felt ashamed, embarrassed, alone with no one to talk to. I was basically told to forget my son and never speak of him again! I thought I'd be happy with my decision, proud about doing the right thing! But I was very sad, confused, hurt and missed my son very much! I wanted him back but knew he was where he needed to be. I thought I would go on with my life like my parents, pastor and friends said yet, I never fit in again with any of my friends or my family! I was always an outsider after the adoption. No one to talk to. No one could understand my heartache and pain! After 5 years the adoptive parents stopped sending me pictures and updates! I was devastated! They never shared information about me to him or helped us to re-unite either like they were suppose to. I've never trusted anyone again.
- The pregnancy time with her parents went well. All we did and all that was said and promised really cemented us together. When she was born until the adoption was final all was great. They sent pictures and updates constantly. At the six month point, they cut us off. No pictures, no letters. They told me I was a surrogate and that they thought I was selfish for not letting go emotionally.

3. Is there anything that could have been done to help you feel more supported during the pregnancy or afterward?

- Even though I didn't want to place my child for adoption I think if I would have had counseling and some sense of control (choosing the family and even meeting the family) I wouldn't have experienced such long–term emotional difficulties.
- Yes, I would have chosen to go through an adoption agency and had help making a post–adoption contact agreement. Having an adoption counselor

afterwards permanently would have been good. I stopped going after a while because it was very hard to talk about the things that her parents were doing to our relationship.

- It would have been nice if the hospital staff didn't judge - they were very rude to me—they didn't have a clue as to my situation and didn't care to find out —I was an 'open book' and would have told them all.
- Support from family or professionals.
- A supportive mom and family.
- Programs to help me keep her. My own money.
- Acceptance by my parents and siblings. Counseling would have helped.
- Open adoption records would now help.
- I do wish I would have had some more support post adoption like birth mother support groups. I did feel alone and had to learn about the grieving process as I went through it.

4. Is there anything that you would like to add?

- I love my son. And never wanted to let him go.
- I had a very positive experience. I am happy with all of it. I have never regretted my experience. I think it made me a better, stronger person.
- Adoption was the best decision I could make at that point in my life for my child.
- It was a very sad and hard time for a 17 year old.
- I believe the system was cruel, disabling and coldly ugly, the system served to make unmarried mothers feel dirty and shameful.
- I would love to meet my daughter.
- I'm just so thankful that I didn't get an abortion. The child I placed for adoption is my world and I'm so thankful to be able to see him happy and grow up.
- Better not to get me started -smile. It's a subject I'm passionate about. I would love to find ways to awaken the beauty of adoption in our communities and especially faith communities to become the broadcast in the life movement about the beauty of life choices in our cause and not the hate of abortion.

As noted by Wiley and Baden[3] terminology related to women who place for adoption has changed over time and has included *"natural parent," "biological parent," "genetic parent,"* and *"real parent,"* with the accepted terms today being *"birth parent," "birth mother,"* and *"birth father."* Interestingly a few of the women who participated in our study described discomfort with the term *"birth mother"* and voiced a preference for *"first mother"* or just *"mother."* The women expressed sentiments indicating that the term *"birth mother"* minimizes the meaning of their lives in the children's lives, reducing their presence to a time-limited role ending at the point of birth. Further, some of the women responding to our survey voiced a strong aversion to terms including "gave up" and "relinquished." Although our data collection effort did not yield sufficient data to conduct sophisticated quantitative analyses, we do believe bringing these opinions to light represent a contribution to the field, as these terms are currently commonplace in the adoption literature. Below is an example of one woman's concerns in this regard.

> Of the earlier questions, it was written about giving up your child. Those words have such a negative ring to them. Please don't ever say that or write that. We don't ever use those words in our pregnancy center. I didn't give up my child. I gave him a better life, one that I couldn't provide. We say chose adoption, place your child for adoption or make a life plan for your child thru adoption. I think those negative words are part of the reason adoption sometimes is looked upon negatively.

Clearly contemporary nomenclature does not incorporate the very deep feelings many birth mothers experience for their children, bonds that may endure for a life-time. The often boundless love of birth mothers includes the act of placing a child for adoption to insure their happiness and security, despite what may be very powerful innately driven desires to keep the child with them. The selfless nature of adoption placement does not end with the act of signing the papers, but continues for the rest of women's lives as women often forgo needs they may have for proximity to enable the child to thrive in his or her adoptive home. In the testimonies we collected, the overarching desire women expressed was for their children to know that they love them.

Future Needs and Concluding Remarks

When we step back from all the empirical work in an effort to wrap our minds and hearts around the psychological consequences to birth mothers of placing for adoption, a number of methodological and theoretical limitations become undeniable and are discussed below. Nevertheless when the literature in its totality is examined, the picture that is emerging is one of long-term loss for many birth mothers. The biological and psychological bond is not easily severed for what may be a majority of women, and indeed it may not in reality be severable. Addressing the denial of a bond that endures across time and space in conjunction with more sophisticated empirical investigations of the complexity of birth mothers' emotional connectivity to their children, should lead to a healthy reframing of adoption and improve delivery of adoption services.

Data collection and analysis efforts on this topic have been wrought with problems. In their 2005 review of the published literature, Wiley and Baden[3] underscore the importance of remembering that long-term research tends to over-represent birth mothers who continue to struggle with the loss of their child for years after the placement. Sampling bias results from research participants tending to come for treatment with clinical samples used, and those who volunteer in more generalized data collection efforts may be more inclined to have unresolved feelings. To provide an estimate of just how serious the sampling bias issue is, Wiley and Baden[3] noted that five out of the eight studies they identified and described in their literature review included clinical or self-selected samples from adoption support groups or organizations. Another significant methodological problem evidenced in the literature on birth mothers is insufficient use of standard assessment instruments. In the review by Wiley and Baden,[3] they point out that only two studies exclusively used standard instruments.

Future research should incorporate substantive data and statistical controls for variables related to the mothers' backgrounds (e.g. age, ethnicity, socioeconomic status, psychological problems prior to adoption, and other life challenges) in order to more effectively tease out the independent effects of adoption placement. As illustrated earlier in this article, many women who choose not to parent do so for reasons related to life stressors and/or psychological variables that may factor into post-placement assessments, if not controlled. At this point in the development of the literature on birth mothers, it is not entirely clear the extent to which post-adoption assessments of mental health challenges are directly attributable to the event, represent a continuation of pre-existing psychological difficulties, or the placement acts as a catalyst for exacerbating already present mental health challenges. Given the diversity of women who choose to place for adoption, all three trajectories likely define the real life experiences; however with more sophisticated quantification we will gain a clearer understanding of the power of adoption placement in women's lives.

Ten years ago, Wiley and Baden[3] voiced the need for larger non-clinical samples, more active use of standardized assessments, increased prospective data collection efforts, and movement away from exclusive reliance on self-report data in order to reach more generalizable conclusions. They also issued a call for research that addresses the complexity of the experience and incorporates sensitivity to the cultural diversity of women united by this reproductive decision. These researchers conclude their extensive review by noting: *"Moving beyond a trauma paradigm, however, to incorporate an epidemiological stress and coping model for the study of the birth parent experience and incorporating a multicultural perspective in all research and practice with birth parents would allow counseling psychologists to set a powerful agenda for research and practice in the field of adoption in the 21st century."* Unfortunately since the publication of their review, the topic has not received the amount of scholarly attention it deserves. Large scale, nationally representative, longitudinal studies will undoubtedly only become possible when governmental funding agencies acknowledge the need for this work and make such data collection initiatives a priority. As described under the section of this report addressing the results of this study, data collection begins with efforts to find women who placed for adoption and they are a population that is difficult to locate. Creative strategies for locating birth mothers are needed, and larger scale general population surveys should include items related to having placed for adoption.

To compliment more sophisticated quantitative studies, there is significant need for in-depth qualitative analyses wherein women are provided little prompting and are encouraged to share whatever they feel inclined to share regarding their lives before, during, and following placement. From extensive analysis of open-ended interviews, researchers and theorists will gain a much fuller appreciation for the range of individuals' experiences. They all share the willingness to bring new life into the world without many tangible self-benefits, and our understanding of this population will benefit greatly from developing a clearer understanding of their strengths, the many positive qualities that led them to the decision, enabled them to survive the separation, and continue with their lives. As birth mothers are better understood as complete human beings with many strengths, the knowledge gained can be employed pro-actively to counter negative stereotypes and reduce stigma.

At the most fundamental level, what is needed is improved theoretical models to guide data collection. A plea for theoretical development was voiced by Henney and colleagues[73] in 2007:

> A vital need in the field of adoption is for a contemporary theory of birth mother adjustment across the lifespan, particularly regarding resolution of grief and loss. Indeed, there is not a satisfactory definition as to what "grief resolution" should look like in a birth mother. Must the birth mother show no signs of suffering or sadness regarding the placement for her to have resolved her grief, or is this perhaps a misunderstanding of the nature of birth mother grief? Can we truly expect the loss of a child to adoption to be "resolved" in this sense, or will the resolution look different – like birth mothers who are still sad and perhaps remorseful, but who have built a "safe place" for that grief in their lives? (p. 887)

Available theories have tended to assume one of two extremes: 1) adoption as a minor disruption in people's lives, with little to no bearing on their future functioning; and 2) adoption as a traumatically dark experience in women's lives, robbing them of future peace and joy. The reality for most women electing adoption is likely carved out somewhere in between the two conceptualizations.

Information gathered from this cohort of women clearly indicates that current theoretical frameworks are specifically inadequate relative to describing the lived experiences of mothers who lose a child to adoption. In academic and professional circles words that feel offensive to mothers are commonly used and descriptions of the grief or loss experienced does not provide the depth of explanation for their suffering or acknowledge the potential life-long impact. Development of a theoretical framework that views the loss of a child through adoption from the perspective of the mother is necessary. The authors therefore propose the next step in answering the question *"what are the experiences of mothers who decide to place a child for adoption actually like, and how do they manage their situations both behaviorally and psychologically?*" is to undertake a Grounded Theory (GT) investigation.[74] GT, developed by Glaser and Strauss in the late 60s, is a systematic methodology employed in the social sciences wherein a substantive theory about a phenomena is directly constructed through the analysis of data. The theory that emerges is "grounded" in the data.

Common methods used when conducting a GT study include participant observation, analysis of artifacts, and interviewing. Participant observation involves researcher immersion in the daily lives of those being studied. When the observation occurs in the participants' natural setting it is commonly referred to as fieldwork. Researchers using a GT approach may also learn about a group by collecting and studying artifacts such as written protocols, charts, educational materials, etc. that are used by members of the group under investigation. Data used to develop theory is perhaps most typically derived through extensive interviews with participants. The use of very generally framed questions (as described above) enables the most genuine results to emerge. Given how little is actually known about the breadth and depth of women's experiences in the realm of placement for adoption, GT seems ideal for authentically developing theory about the impact of the decision on the lives of women. In GT, theory arises directly from the data without the imposition of outside theoretical concepts, such as in this case, maternal loss, grief, or trauma.

Until we have a well-formulated theoretical model with the explanatory power to capture a wide range of personal experiences, any efforts to develop and deliver the services women need during the decision, placement, and post-placement stages will remain limited and highly constrained. Moreover, amending existing policies and developing new policy based on the limited understanding we have available on birth mothers' emotional lives in 2016 would be irresponsible and unlikely to meet the most pressing needs of the majority of women in this population.

The need for more substantive and compassionate counseling before, during, and after an adoption placement has been voiced repeatedly in the published literature.[3,14,15,81] However, until more investigations with larger, nationally representative samples, using reliable and valid measurement tools, with the sensitivity to gauge the fullness of women's responses have been conducted, understanding the needs of this diverse population will remain limited. Moreover, the development of effective therapy protocols is constrained by the insufficient knowledge base.

Although the psychological experiences of birth mothers have not historically been a priority in research or in clinical practice, there is growing sensitivity at least among adoption agencies in the US. This relatively recent shift was articulated by Johnson and Faasse[82] in a publication produced by the National Counsel for Adoption:

> In recent decades, as licensed social workers, licensed private adoption agencies, and other skilled professionals have taken over the practice of adoption, there has been an increased focus on assisting birth parents in their feelings of grief and loss. As the understanding of birth parents' issues has continued to grow, so has our understanding of the impact of the adoption decision and resulting emotions and grief for birth parents. Today, no competent adoption professional would suggest to a pregnant client that it would be possible to simply resume her life and forget the child she placed for adoption. Most adoption agencies now provide extensive pre- and post-placement counseling and other support services for birth mothers.

Although Johnson and Faasse identified some positive change regarding adoption professionals' understanding of the psychological needs of "birth parents" this is somewhat misleading, because there has been virtually no systematic attention given explicitly to the experiences of birth fathers in the academic or professional literatures. Birth mothers' emotions have historically been obscured by the primary focus on the practical and psychological needs of adoptive parents and adoptees; however birth fathers in contrast have been utterly ignored. Research is needed to examine all facets of the paternal experience (before, during, and after the decision to place for adoption).

For long-term needs, women who continue to have adjustment issues over the course of many years typically turn to mainstream clinical practices, find support from an emerging presence on the internet in the form of blogs for sharing experiences, and there are an increasing number of weekend retreats available. With regard to the latter, Caring for Kids (http://cfkadopt.org/) offers retreats for birth mothers at any point in their journey. As described on their website:

> Our retreat encourages the building of a support network and resources among those who attend. Not only is the retreat for birth mothers, it was designed and is facilitated by birth mothers as well. The facilitators work their hardest to ensure the retreat is a safe, welcoming environment where birth mothers will have the opportunity to express their thoughts and explore their adoption journey without fear of judgment. The program emphasizes providing birth mothers with valuable tools to help them continue growing as a person and cope with their adoption in a positive way.

By systematically analyzing the challenges birth mothers face when placing a child for adoption in the context of relational and community supports, and with the understanding that birth mothers rarely if ever completely "give up" their children, many improvements will be ushered into the realm of possibility. First, women will be able to make more informed, less pressured decisions wherein they feel supported in a choice that they truly own and are comfortable with. Second, trained professionals will be able to assist women in developing adoption plans that most effectively meet their personal needs and desires. Third, services from fully-informed and well-trained professionals will be available to foster healing in women who encounter difficulties at various points in their lives post-placement. Finally and most importantly, it is hoped that information will be derived to help women positively integrate the experience of placing a child for adoption with feelings of love and connectivity that begin rather than end at birth.

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Hippocratic Medicine and the Myth of Moral Neutrality: Notes on “Cultural Loss” and its Effects on the Practice of Medicine

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At its heart, medicine is primarily a moral activity. No-one is obliged to take the physician’s advice thus the physician helps the patient to decide what they ought to do. But that word ought cannot be derived from physical facts. Physical facts never tell us what to do. Some actions are so deeply rooted in tradition that we can assume agreement but they were originally derived from theology or philosophy they cannot be derived from physical science.

A. The practice of medicine developed in a Judeo-Christian cultural ethos.

But the basic foundation was laid by Hippocrates in the 4th Century BC. Hippocrates foresaw what was needed for the practice of medicine:

1. Physicians who believed they would be accountable to God for all their actions.
2. A moral consensus existed within medicine.
3. Total rejection of killing within medicine because physicians who kill are necessarily less trusted and Trust is therapeutic.
4. Tacit recognition of conscience rights.

None of these gems needed to be expressed bureaucratically. They constituted who we were. Moral neutrality was unthinkable as well as incoherent as will be discussed later. (cf Polanyi) Physicians were bound by an Oath, which invoked the gods and represented a deontological document describing the actions required of a good physician.

For the first time, this Physicians’ Oath codified an ethical standard for the art, which, first of all, transcends the vicissitudes of societal law and, further, which specified a professional dedication to the sanctity of life and a trust-based relationship between doctors and their patients.[1]

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[1] http://www.ahregistry.us/history-and-meaning-of-the-oath.html

B. Beginning in the late middle-ages erosion of this ethos coincided with the beginning the scientific age.

Ockham is the key influence: only what is appreciated directly by the senses can be known. Thus at a stroke all the immaterial goods such as love, justice, truth and mercy were removed from the public square. Ockham did what no one else had yet done: he transposed a metaphysic of individual existence where duties were owed because man was made in the Image of God into a new concept where physical facts were dominant. Destructive though it was of natural theology, it helped to liberate natural knowledge from the control of theological concepts. (Leff in *Medieval Thought* p286)

Prior to Ockham, the intellectual world embraced Aristotle's metaphysics, which answered the question of why something exists by centering on four causes of being: the material, formal, efficient, and final cause. Take as example, a human being.

The material cause of human beings is the substance they are made of. Thus the material cause of a human being is the carbon, oxygen, nitrogen, trace minerals, etc, of which the human being is composed.

The formal cause of a human being is the design of human beings, the particular DNA directed arrangement of elements into cells and tissues and functions which are human as distinct from any other living organism. The efficient cause is the means of expressing this design. Efficient causes answer the question of how an idea is expressed in material ways. The final cause is the purpose of the designer, that purpose for which the human being was designed.[2]

With Ockham began the current modern view that only the material and efficient causes can be explored directly by the senses. The rest are just words. Reductionism was the result. The old four causes were reduced to considerations only of materials and techniques.

Moral facts were replaced by physical facts. Soon the idea of moral facts was lost completely and eliminated from the modern discussion of public policy.

C. Embracing reductionism as the only acceptable worldview for intellectual discourse eliminated consideration of virtue.

Without a consideration of efficient and final causes, truth and justice had no firm foundation. The Christian understanding of the virtues was lost to both scholarly and political discourse. Instead, choice, equality and tolerance were put in dominant positions. Since there was now no consensus on the meaning or purpose of human existence, nor the accountability of human beings to anyone other than themselves, moral decisionmaking was now irrelevant to guide actions. The question of what "should" be done was superceded in importance by the question of what "can" be done.

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[2] http://www.willamette.edu/~sbasu/poli212/AristotleonCause.htm

D. Consideration only of what is possible rather than what is prudent has had dramatic effect on medical ethics in the last four decades.

1. The primary commitment to the patient as made in the image of God was replaced by utilitarian concepts.
2. Abortion and euthanasia are the inevitable consequence.
3. The law becomes the pursuit of power rather than the pursuit of justice as Leff discussed in his classic 1979 paper in the Duke law review.

E. With the loss of moral consensus we must expect to have a struggle to retain our understanding of moral reality any public institution.

For 2000 years the medical world had a moral consensus through the Hippocratic tradition, but, sadly, today there is no possibility of agreement about abortion, infanticide, euthanasia. For some, these things are morally obligated services, for others they constitute murder. We are on the brink of needing two separate systems of medical care based on different moral systems. We have no longer a moral consensus as the basis for professional conduct.

F. Only arguments made on the basis of justice and democracy can expect to be heard.

No-one wants a doctor without moral integrity. But we do not agree about the nature of morality except perhaps that we ought not to do to others what we do not wish to be done to us. No-one therefore has the right to destroy the moral integrity of another person, including the moral integrity of the physician.[3]

In a rights based society with patient-centered practices of medicine, it is the duty of a democracy to protect every view of morality, both of patients and of medical practitioners who have moral or religious objections to particular treatments and services.[4]

Moral neutrality is not an option for doctors. We have only to ask the question why should I be morally neutral for the concept to fail. Some limited form of morality is necessary to answer the question, such as because moral neutrality is sensitive, kind, tolerant etc.

We need to understand the idea of subsidiarity, because it offers a way forward. The essence of the idea is that where two or more moral positions compete the duty of the government is to provide funds on agreed principles at the level where moral agreement exists. For example the provision of abortion and euthanasia cannot be provided by a large number of people because of their moral position whereas for the others the opposite is true. It seems that we need to face the fact that purely bureaucratic solutions are not sufficient. We need to argue for its application.

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[3] http://www.hippocraticregistry.com/?page_id=1955

[4] http://www.hippocraticregistry.com/?page_id=1955

The Freedom of Divided People: Not “Rights to Religious Life or Expression” (or Any of the Formulations It Will Prove So Easy to Resist) But the Most Basic Rights in the Constitution

Edward Tingley, Ph.D.*

The Tradition of “Freedom for the Thought that We Hate”

Christians today, in your country and mine, believe that we are living in a culture that has rejected traditional morality and all it rests on, while at the same time thinking that we can *make moral arguments to guarantee the acceptance of traditional morality.* This makes no sense. Do we believe that our morality and the beliefs and philosophy that undergird it have been rejected or not? Pick any issue of division you wish: the right to live as a person who believes in a divine order, or in an absolute morality, or in the sanctity of life, or in traditional sexuality, etc. – this cannot depend on convincing those who reject these things that, about each one, it is *we who are right.*

Think about it: pacifists have a *right* to conscientious objection, which they did not win by convincing anyone that military service is wrong. Public acceptance of conscientious objection does not hinge on *demonstrating the wrongness of killing in war,* since most of us do not agree that it is wrong. Pacifists have never even proved (nor have they had to) the *equal power* of the pacifist argument; in the eyes of most people it is not equally powerful but weak. Nevertheless we accept the conscientious objector. The people who count the pacifist argument inferior might even find it morally repugnant, like the District Court judge who said, “You cannot be a half-way citizen.... You must do what our Constitution requires of all American citizens – promise to serve that flag and defend

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it with your life, if necessary."[1] But you can believe in the importance of self-defense and still accept the conscientious objector. The pacifist whose case that judge saw was ultimately (retrospectively) vindicated, when the Court finally said that, *according to the Constitution,* she had the right to *believe what she believed* and even *to live accordingly.*

> If there is *any principle of the Constitution that more imperatively calls for attachment than any other it is the principle of free thought* – not free thought for those who agree with us but *freedom for the thought that we hate.*[2]

On what is that freedom based? Not on convincing your opponents that you are right.

Dissent over belief is an American right – ask any liberal. To be a dissenter or an objector there has to be a norm: a generally accepted position on what is right, to which you object. Objecting means non-involvement: you will not be contributing what others think it is your duty to contribute (bullets in the war, say) – but let's spell this out as this is a key point. In the eyes of these others who hate your pacifism, pacifists impose a burden on society; they come at a social cost, which is *not providing* the flying bullets that the average person thinks public safety depends upon, a view that that average person can make excellent arguments for. *But in the light of liberty that cost is nil.* That there are fewer soldiers lifting rifles – or (looking both back and forward) fewer people to pay the Anglican clergy and fewer believers in the Trinity (in 18th-century Virginia), or fewer opportunities to receive abortions, or fewer providers of 'compassionate care' in the form of euthanasia, etc. – is a perfectly acceptable *result,* an understood *given,* where dissent and liberty are the tradition.

So why do we hear so little about this? Because liberty is always ignored. It is obvious why it is ignored by any party (Anglican Christians in 18th-century Virginia, abortion advocates today) whose favoured interests are not served by it (an entirely expected forgetfulness that the First Amendment arose to correct). But we are not hearing it today in the defence of rights of conscience. Why is it not said that the *non-provision of legal and demanded services* is not an aberration but a perfectly familiar aspect of liberty? If a person chooses to defend conscience rights on a different basis – say, by debating the

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[1] Austin Cline, "Feminist, Author and Lecturer, Rosika Schwimmer, Denied U.S. Citizenship Because She's a Pacifist," Skepticism.org, http://skepticism.org/timeline/october-history/9280-feminist-author-lecturer-roskia-schwimmer-denied-us-citizenship-because-shes-pacifist.html.

[2] Notably, in 1929, a dissenting position, being the dissent of Mr. Justice Holmes in *United States v. Schwimmer* (1929), No. 484, http://caselaw.findlaw.com/us-supreme-court/279/644.html. In 1926 Rosika Schwimmer had been denied citizenship on account of her pacifism. When she, with the American Civil Liberties Union (the group that has sued Christian hospitals for their refusal to perform abortions), appealed that decision in the Circuit Court she won, but her case went to the US Supreme Court, and *U.S. v. Schwimmer* ruled eight to one against her. Yet it was Holmes's understanding of the Constitution that would prevail. In 1946 the Supreme Court overturned that ruling in *Girouard v. United States*. Gary Hartman, Roy M. Mersky, and Cindy L. Tate, "Loving v. Virginia," *Landmark Supreme Court Cases: The Most Influential Decisions of the Supreme Court of the United States* (New York: Facts On File, 2004), 328; Lee R. Remington, "*United States v. Schwimmer*, 279 U.S. 644 (1929)," http://uscivilliberties.org/cases/4643-united-states-v-schwimmer-279-us-644-1929.html; Veronica Neffinger, "ACLU Sues Christian Hospitals for Their Refusal to Perform Abortions," ChristianHeadlines.com (18 December 2015), http://www.christianheadlines.com/blog/aclu-sues-christian-hospitals-for-their-refusal-to-perform-abortions.html.

value of religion, or the moral duty to obey God, or by calling on the stingy protections of Religious Freedom acts (where your right will simply be weighed in the balance of whether the socially demanded services *will be provided*) – the implication is that you have *no right* to conscience. (Before any talk of civil disobedience, first force the issue of these *enunciated rights,* which are amply defended in American law.)

In the face of the challenge to conscience the first thing to do is to speak about liberty, not argue the value of religion or the wrongness of abortion (crucially important activities in the right setting, but an uphill battle here that will have a sad outcome). It would be a tragic thing, were the profound wisdom of the American tradition of liberty to be ignored in favour of stepping up activity in the "culture war," in which people fight over their differences. Liberty is not a value held *on one side* of the divide.

Pick Up the Constitution and Use It

A country of divided people is still one country, and, I should like to say, moreso in America than anywhere else. Though I am not an American I cannot help but look at this social division that many people are calling catastrophic from an American perspective, because America looked division in the face at its very Founding without much fear.

What division? Some say the division facing the Founders was hardly divisive at all – not at all the kind of seismic rupture you are seeing now. Yet set that question aside and consider the kind of principles those "lesser" differences then reigning set into the First Amendment. Are these ideas not big enough for today's crisis?

Return to the issue of the present moment: the challenge to religious freedom. This challenge must be brought to an end, but how? One failing strategy is to argue by way of principles and ideas that half the country has already jettisoned in shaping its new moral identity, one of which is the value of religion. Is there not something important and unique about religion that is worth speaking up for? Indeed there is, but if it is your plan to stop the unjust lawsuits, threats, and regulations lined up for you, you will have to actually change the minds of the people bringing those suits – people who *question* the license traditionally given to religion.[3]

It seems highly important in a conflict to remember that wars are won by delivering blows to which your opponent says, "Ow!" – blows that the opposition knows are blows. But when a Christian argues that his Constitutional right to religious freedom ought to be respected, or that the supreme importance of religion justifies such respect, a large contingent of the opposition that *knows nothing about religion* feels no pinch whatsoever. Brian Leiter has written a book to argue that there should be *no exemptions* for Christians, period (no exemptions, religious or otherwise, to "general laws with neutral purposes," unless an exemption shifts no burden or risk onto others). *Why Tolerate Religion?,* his book asks, raising (note this language) "one of the most enduring puzzles in political philosophy and constitutional theory – why is religion singled out for preferential treat-

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[3] Says Douglas Laycock, "Scholars from all points on the spectrum now question whether there is any modem justification for religious liberty." Douglas Laycock, "Sex, Atheism, and the Free Exercise of Religion," *University of Detroit Mercy Law Review* 88:407 (2010-11), 423.

ment in both law and public discourse?"[4] A great many readers find Leiter's logic to be compelling. "The overall effect is a very impressively argued case," says *Library Journal;* "Students and scholars likely will be citing Leiter's clear and powerful arguments for many years," says *Choice* (which called the book an Outstanding Academic Title). The "compelling" argument that Americans are obligated to respect the First Amendment's protection of religion is not felt to be compelling at all by a crowd of people on the other side of this dispute. That argument just gets the opposition going.

By all means, fight the battle: show that there is a justification for the First Amendment's protection of religion[5] – but changing the mind of an opponent requires some common ground and it has been the purpose of modern philosophies to *get off* your common ground. ("What is philosophy today ... if it is not ... the endeavor to know how and to what extent it might be possible to think differently...."[6]) What ground do you really have that you could pin your opponent to? (Some argue that "natural law" arguments stake out precisely such ground, but, speaking as a philosopher, I should like to observe that the new pragmatic and postmodern philosophies, crafted to *replace* the old ones, justify *rejecting* any natural-law argument that leads to an uncongenial conclusion. So, if logic be damned, just how will you pin down your foes with arguments: how will these natural-law arguments make hay when their blades are lifted at the moment of business?)

Today philosophies *proceed on the basis of how to escape the past,* and you will no more remove resistance to religion by awakening the opposition to religion's importance and bringing it back to respect for faiths than, in James Madison's day, you could remove a Baptist's resistance to state Anglicanism by converting that Baptist to the Episcopal church. *The whole idea of freedom of thought,* as a fundamental right, stood on the *recognition that Americans are free to think. (Relative to others, to dissent.)* You may decide that there is a God, and you may live as in your eyes that understanding of reality demands. ("The

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[4] Brian Leiter, *Why Tolerate Religion?* (Princeton University Press, 2013), 4, 14-15. This articulates the de facto Religious Freedom Restoration Act standard. About this standard Laycock writes, whenever a RFRA case can be parsed as a case of discrimination – of "religious bigotry," a free pass to impose your values on other people – then it will lose, because in cases of "discrimination the religious side always loses." Douglas Laycock in conversation with Dylan Matthews, "Why a Pro-Same-Sex-Marriage Law Professor Supports Indiana's Religious Freedom Law," Vox.com (31 March 2015), http://www.vox.com/2015/3/31/8319415/indiana-religious-freedom-discrimination.

[5] Ryan Anderson, for instance, argues that Leiter "misconceives religion" (Ryan T. Anderson, "A Leiter Case for the Superfluousness of Religious Liberty," Libertylawsite.org (25 November 2012), http://www.libertylawsite.org/book-review/a-leiter-case-for-the-superfluousness-of-religious-liberty/). But what would it take to correct that "fatal flaw in his argument," unseating Leiter's challenge? Surely Anderson must reply: *proper instruction in what religion is.* But can that lesson be given? Must we be made to *understand* "the thought that we hate" and then *tolerate on that basis?* Is it not rather the case that Leiter must, in fact, accommodate the thought that he hates even while it looks ridiculous, the reason for which he hates it?

[6] Michel Foucault, cited by Barry Allen, *Truth in Philosophy* (Cambridge, Mass.: Harvard University Press, 1993), xiii.

right to believe a religion but no right to act on it would be a hollow right indeed."[7]) Freedom of thought is your common ground. A divided America is still America: in fact, a divided America is everyday America, just what the newly born United States very soon understood itself to be.

Freedom of thought is an altogether powerful principle, raised up in billboard fashion in your founding documents, where it is too loud and clear to be interpreted away. (In Canada these same principles – which, I insist, *are in our law too* – are there in a much more latent way. I really have to insist that they are there, prompting others to counter-insist that they are not, and you enviable Americans *do not have this problem.*)

Laycock writes, "The religious community cannot take religious liberty for granted. It needs to expend a lot more energy defending the right to religious liberty,...."[8] Plainly, this energy should be *effective.* Get it in motion at that place in America that is intact (a divided America is divided, not destroyed), and that is the ground and tradition of freedom of thought.

It is simply not true, as Pat Buchanan once put it, that "We are two countries now ... morally and socially and culturally and theologically, and cultural wars do not lend themselves to peaceful co-existence. One side prevails or the other prevails."[9] That is not accurate: if there is an "American heresy" that is surely it. America is one country, always divided in serious ways, as a home to people with profoundly different fundamental commitments – yet people who have no choice but to stand by the American blueprint, because you can be sure that these people *will not deny* the right of that Baptist, that pacifist, that unbeliever to believe as he does. Though people repeatedly fail to practice the principles that they uphold (in that respect Barack Obama, a trampler of liberty, and John Adams, who had his critics jailed, are not so different), it is principles *that they indeed uphold* that they are violating, and you do not have to convert a man to what he already believes.

No American is an opponent of the principle of freedom of thought, which in a very pivotal way is what conscientious objection and religious objection really are. It may be that things are so bad that one part of the Constitution has to be shored up by another, but if that is the case, it should certainly be done.

Why It Is Fine to Be Disliked (in America)

The common ground you share with those who oppose you is the Constitution that guarantees "Freedom for the thought that we hate." It is worth paying attention to just who is saying this: liberals and heroes of liberalism like Justices Holmes and Brandeis, whose once controversial opinions have all become law. Pay attention to these extraordinary words.

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[7] Douglas Laycock, "Religious Liberty and the Culture Wars," *University of Virginia School of Law* 8:29 (2013), https://www.youtube.com/watch?v=xXtRRRVZ57U&index=47&list=WL.

[8] Laycock, "Sex, Atheism, and the Free Exercise of Religion," 429.

[9] Pat Buchanan in *Cultural Marxism: The Corruption of America* (c. 2010), a documentary directed by James Jaeger.

> Those who won our independence ... believed liberty to be the secret of happiness and courage to be the secret of liberty. They believed that *freedom to think as you will* and to speak as you think are means indispensable to the discovery and spread of political truth.... But they knew that order cannot be secured merely through *fear of punishment* for its infraction; that it is *hazardous to discourage thought....*
>
> — Justice Louis D. Brandeis[10]

> *The makers of our Constitution ... recognized the significance of man's spiritual nature, of his feelings, and of his intellect.* They knew that only a part of the pain, pleasure, and satisfactions of life are to be found in material things. They sought to *protect Americans in their beliefs,* their thoughts, their emotions, and their sensations. They conferred, as against the Government, the *right to be let alone* – the most comprehensive of rights and the right most valued by civilized men.
>
> — Justice Louis D. Brandeis[11]

> Struggles to *coerce uniformity of sentiment* in support of *some end thought essential to their time* ... have been waged by many good as well as by evil men. *Ultimate futility of such attempts to compel coherence* is the lesson of every such effort.... It seems trite but necessary to say that the *First Amendment to our Constitution was designed to avoid these ends by avoiding these beginnings*.... We can have intellectual individualism and the *rich cultural diversities* that we owe to exceptional minds only at the price of *occasional eccentricity and abnormal attitudes.* When they are so harmless to others or to the state as those we deal with here, the price is not too great. *But freedom to differ is not limited to things that do not matter much. That would be a mere shadow of freedom.* The test of its substance is the *right to differ as to things that touch the heart of the existing order.* If there is any fixed star in our constitutional constellation, it is that *no official, high or petty, can prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion* or force citizens to confess by word or act their faith therein.
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> — Justice Robert H. Jackson[12]

"The principle of free thought" eloquently elaborated above is a cherished idea in the America your opponents stand for, and you should be talking to them about it.

Christians should stop trying to be loved; you can be perfectly happy being hated. The thought that is hated Americans indeed hate, but *America* sweetly smiles upon it. In the defense of your rights as Christians – of both rights of conscience and rights of religion – it makes profoundly good sense to stop asking the opposition to *understand your rightness,* to hear you out and *see that you are right* to act on conscience, *right* to be religious, *right* to reject abortion. Your opponents are very poorly equipped for the job you are giving them. These arguments of yours are the very ones that your opponents have elaborated a whole world-view to bury. (Do you not suppose that what you see

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[10] Brandeis in *Whitney v. California* (1927), https://www.law.cornell.edu/supremecourt/text/274/357 (italics added here and throughout).

[11] Brandeis dissenting in *Olmstead v. United States* (1928), https://www.law.cornell.edu/supremecourt/text/277/438.

[12] Jackson in *West Virginia Board of Education v. Barnette* (1943), https://www.law.cornell.edu/supremecourt/text/319/624.

as a departure from traditional morality might throw a wrench into old-time moral reasoning?)

Be happy to be "wrong" (and hated for it), and do not miss the opportunity to say that you have the right. Tell your opponent *he is wrong* and *he has the right too!* Take every chance you are given to remind people that America is that kind of place and do all that you can *not* to give the impression that America has to be *your vision of America,* because it is that zero-sum game that is forging the chains you soon might be wearing. If it is your America that has to win, that is the thinking that has people all over the country designing your bondage.

Until America adopts an official philosophy (*never* is when that will happen), being "wrong in their eyes" is business as usual and your American right. Being "wrong in their eyes" is as much a *moral badge of honor* as being "wrong in *your* eyes" is for them, and America is just that place where friends and family members can despise each other's reasoning and carry on with dinner.

> Almighty God hath *created the mind free,* and manifested his supreme will that *free it shall remain* by making it altogether insusceptible of restraint; that *all attempts to influence it by temporal punishments, or burthens, or by civil incapacitations,* tend only to beget habits of hypocrisy and meanness, and are a departure from the plan of the holy author of our religion, who ... chose not to propagate it by coercions ... but to extend it by the influence of reason alone.
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> — Thomas Jefferson[13]

> [By] the *liberty of conscience* ... granted [in the Constitution] adequate security is also given to the *rights of conscience and private judgment.* They are by nature *subject to no control* but that of the Deity and in that free situation they are now left. Every man is permitted to consider, to adore, to worship his Creator in the manner most agreeable to his conscience. *No opinions are dictated,* no rules of faith prescribed, *no preference given to one sect to the prejudice of others.*
>
> — John Jay[14]

In America you can think for yourself and reach your own conclusions, and they will be (make no mistake about it) the conclusions that your neighbor thinks monstrous (when New Englanders granted Catholics the right to worship, what they thought these Catholics were kneeling to was the Antichrist).[15] But that is the beauty of America.

Why Federal Powers *Cannot* (Not *May Not*) Decide Moral Questions (Abortion, Marriage, Etc.)

What is the freedom of thought of Americans *based on?* The America built on the foundation of the Declaration of Independence, and the bodies of its defenders, and the Constitution of the United States is a home for *human beings, functioning as* human beings.

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[13] Thomas Jefferson, "A Bill for Establishing Religious Freedom," 1777, cited in James H. Hutson, ed., *The Founders on Religion: A Book of Quotations* (Princeton, N.J.: Princeton University Press, 2005).

[14] John Jay, "Charge to the Ulster County Grand Jury," 1777, cited in Hutson.

[15] Steven Waldman, *Founding Faith: Providence, Politics, and the Birth of Religious Freedom in America* (New York: Random House, 2008), 51.

Freedom of conscience, as Roger Williams put it in 1644, is "Soul Libertie," room for the soul to live as it was made to.[16] *Conscience* is the *operation of the human soul,* not merely that sector within it that is conscious of guilt.[17] Williams wrote that "the government of the civill Magistrate extendeth no further then over the bodies and goods of their subjects, not over their soules."[18] *Freedom of conscience,* then, defends a space in which to use the soul or mind just as it was made to be used, free of interference, each person assuming responsibility for the pivotal decisions of his or her life.

Here is how it shows up in the *Virginia Declaration of Rights* of 1776 (penned by George Mason and James Madison), in which "All men are equally entitled to the free exercise of religion, *according to the dictates of conscience;*... it is the mutual duty of all to practise Christian forbearance, love, and charity, towards each other"[19] — above all in the charity of acknowledging one's neighbors (whatever they might come to believe) as human beings equipped with powers of mind, concerned with their own welfare, and vested with a responsibility for their own fate.

What "idea of America" is implied in this? Here it is described in 1776 by Samuel Adams, cousin of the future second President: "Driven from every corner of the earth, *freedom of thought and the right of private judgment in matters of conscience* direct their course to this happy country for their last asylum."[20]

And here is John Adams in 1825, advocating "liberty of *conscience* on *all subjects* and ... the right of *free inquiry* and *private judgment* in *all cases,....*"[21] The scope of "all subjects" and "all cases" is plain, and the word "private" here directs us to that place within every human being where our "judgments" about this range of belief are made (this term "judgment," repeatedly used by these men, being the standard English term then used for all determinations of true and false).

Why attach this importance to being free to *affirm* (that is, within *you) only what you truly believe?* Because it so happens (this is an incontrovertible fact) that a man judges the truth of a thing *for himself,* and because America was *conceived as* a place that would want and welcome this *real man,* that is how it has to be. The laws of such a land will allow these citizens *to use the powers of judgment they possess as human beings,* and will not obstruct them when those judgments fail to advance (or pointedly evade) the

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[16] Roger Williams, *cited in* John M. Barry, *Roger Williams and the Creation of the American Soul: Church, State, and the Birth of Liberty* (New York: Viking, 2012), 4.

[17] Those who are parsing "conscience" in this way are not paying attention to the American tradition of this concept, where 'conscience' is a synonym of the workings of the human mind in forming judgments about *the world,* not just right and wrong. ("With Newman we should see *conscience* as a 'stern monitor'. It is the faculty of rational moral judgment by which we are capable of distinguishing right and wrong and conforming our conduct to truths about what must and must not be done." Anderson, "A Leiter Case for the Superfluousness of Religious Liberty.")

[18] Williams, cited by Barry, 336.

[19] Michael W. McConnell, "Establishment and Disestablishment at the Founding, Part I: Establishment of Religion," *William & Mary Law Review* 44:5 (2003), 2119-20.

[20] Samuel Adams, Speech in Philadelphia, 1776, cited in Anthony Lewis, *Freedom for the Thought That We Hate: A Biography of the First Amendment* (New York: Basic Books, 2007), 183.

[21] John Adams, Letter to Thomas Jefferson, 1825; *cited in* Hutson.

purposes of any "higher class" of citizen (the majority, perhaps, or those "on the right side of history") whose outlook has been confused with the American way.[22]

When all these thinkers speak about freedom of conscience what they are saying is that *only a human being can think human thoughts:* the state (other than the one that "is" these people) cannot think *any* thoughts, make *any* determinations, hold *any* opinions. This is the affair and the business of human beings alone, in their communities. That people be permitted to conduct their business and *live as people,* assuming those powers of mind and that responsibility that are *theirs,* and then be left to act, with integrity, in the world that *they have freely recognized,* is in fact to *let them live* as "Nature's God" ordained (a plan that man has had a sorry history of obstructing). That is the extraordinary American plan.

It does not follow, however, that a great undertaking brings no complications. Does freedom of thought mean that any person who, like the conscientious objector, *cannot help but believe* that some activity forbidden by a state law (abortion, say) is in fact a "humanitarian good" has an immediate exemption from the law? The Framers could have set in place no such principle, since this would have effectively deprived them of the entire understanding of law that they were free to embrace, the system of law that they, by their conscience, believed in: law as "commanding what is right and prohibiting what is wrong" (Blackstone). Any standing exemption for all dissenting individuals would bring that tradition to an end.

But wasn't tolerance of dissent a key? Free thought, rights of conscience, soul liberty, is not a license to do as you like in accord with your beliefs; it is freedom *not to participate* in the way of life set up in the law, where that would violate, as others can plainly see, your most fundamental commitments. It is freedom to be left alone for *not joining in* with the majority (who have the liberty to set up their own state laws) in some activity of that character – the conscientious objector being a perfect example. The status of "conscientious objector" allows him to *abstain;* it is not a license to undermine the laws. He is free to fight for pacifism and turn the whole country pacifist if he can, but in the democratic manner — "by the influence of reason alone" (Jefferson). And this brings out the "upper storey" of soul liberty: above the dissenting individual is the state, enacting the laws "of the people," but above the people there is no *superior force* to make those people and that state fit its laws to the dissenter. As was suggested in words quoted above from Justice Brandeis, this is a dimension of conscience linked with the Declaration of Independence.

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[22] "In the liberal tradition, the government's role is ... to protect the right of the people to pursue their own understanding of the truth, within the limits of the common good. That is the difference between 'the full and free exercise of religion' (Madison's formulation) and mere 'toleration'. Toleration presupposes a 'dominant group' with a particular opinion about religion (that it is 'false', or at least 'unwarranted' [citing Leiter]).... Religious freedom does not proceed from any official presuppositions about religious truth. It allows everyone, believers and unbelievers alike, the right to form their own convictions about transcendent reality and to live in accordance with them,..." Michael W. McConnell, "Why Protect Religious Freedom?" (review of Leiter), *Yale Law Journal* 123:3 (December 2013), http://www.yalelawjournal.org/review/why-protect-religious-freedom#_ftnref135.

"While we are contending for our own Liberty," said Washington, "we should be very cautious of violating the *Rights of Conscience in others,....*"[23] What has happened to that wisdom?

> Never before in American history have we attempted to make illegal, under any circumstances, well-known, core religious practices of the largest religious groups in the country.... With respect to the contraception mandate and with respect to same-sex marriage we have made in certain contexts illegal the practices of nearly half the population, of Catholics and Evangelicals. That's new, that's unprecedented....[24]

What the First Amendment does is to forbid the federal government, which has no soul in which to form beliefs (only people have beliefs), from imposing upon those people some "beliefs" of its own. It can have no beliefs. (The beliefs of America are in the Constitution and the Declaration.)

Whatever difficulties these matters bring, they are yours.

As a last word, it is worth noting that the promise of liberty was a promise made not just to Americans but to the world. "This country has already had the honor of setting an example of civil freedom," said James Iredell (considered in his day "the ablest defender of the Constitution"), "and I trust it will likewise have the honor of teaching the rest of the world the way to religious freedom also."[25] Those outside your borders, clipped and crimped by the same depredations as you but who cannot call on these ideas as part of their tradition, pray that this is so, and we are watching to see whether the American people can keep this brilliant promise.

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[23] Washington, cited by Waldman, 65.

[24] Douglas Laycock, "When Rights Collide?: Religious Liberty, Equality, and the Fallout from Hobby Lobby," American Constitution Society, 2015, https://www.youtube.com/watch?v=4aq8UmwzGOQ&index=42&list=WL.

[25] Iredell, cited by Denise A. Spellberg, *Thomas Jefferson's Qur'an: Islam and the Founders* (New York: Knopf Doubleday, 2013), 177.

Becoming a Healthy Physician: The Transformation

Noreen Z. Johnson M.D., Haywood J. Robinson, M.D.

We are former abortion providers who now live in College Station, TX. We have been working in the pro-life movement for thirty years in various ministries. Our practice now resides in a former Planned Parenthood abortion clinic. We are followers of the Lord Jesus Christ. Without His sacrifice and forgiveness, we could not stand before you today to testify to his saving reconciliatory, redemptive, and transforming power. We are saved by His grace through faith. Our lives testify that the enormous challenge of becoming a healthy physician and maintaining that state requires supernatural diligence and persistence in purpose through the power of the Holy Spirit.

The contemporary world view that frames the mode and method by which we minister medicine has deviated far from the standards set by traditional Hippocratic practice. The time honored values of millennia past, and our Judeo-Christian values, are no longer the pattern by which medicine is practiced today. The precious lives of our patients, both born and preborn, have been devalued. It is becoming increasingly difficult to advocate for the well being of our patient and to implement humanitarian compassionate care. Our charge to practice on behalf of our patients, to do them no harm, requires courage and a commitment to be "transformed" and set apart in this sea of dehumanization, and in the culture of death. In our personal experience, deep spiritual transformation was a prerequisite to initiating and maintaining the priority to care for our patient's needs despite the pressures from prevailing secular worldview. Our Hippocratic view of patient care was and is a reflection of our spiritual foundation. If we are rooted and grounded in love, compassion and altruism, then this is what will be manifested in our care for others. However, if there are issues in our lives that are associated with unresolved spiritual, emotional and mental injury, this too will affect our care of our patients.

Our purpose as physicians is to enhance and preserve life. Well then, how is it that physicians perform several thousand abortions in the U.S. daily? How did we get to this point in medicine that human life is devalued in such a grotesque fashion? The basic tenets of the Hippocratic oath are clear: Patient confidentiality, no sexual relations with patients, no euthanasia, and no abortions. These standards stood for a long time. But now the medical profession is turning away from Hippocratic tenets. Here we are in 2016, with euthanasia, abortion, healthcare rationing, selling baby parts, etc. As physicians, we are acting as if we are God. But we are taking life that we can't give. What caused this change? Human sinful nature that wants to possess and control God's power over life and death. And what can reverse it? Only the Truth. That is what changed us.

Consider our case. We were heart-hardened abortionists who had been performing thousands of abortions for many years. How were our hearts changed? It was by God's supernatural power working through His people, speaking the Truth. And that is what you are called to do. The people in medicine who know the Truth can transform medicine and our culture with God's power. Often, God uses a small minority to attain great victories, that's because God is a majority all by himself!

What is our challenge landscape? Our challenge is to reach the heart of the abortionist, to reach the heart of ACOG, etc. We know it can be done. When we were involved in doing abortions, we were isolated individuals. We were itinerant abortionists, traveling city to city killing preborn children. We lived in an isolated environment with a hardened heart. Many of our colleagues have tormented lives, weighed down with chemical dependency. They don't want contact with humanity, they' re not accountable or associated with the local community. It will require supernatural intervention to reach them and help them to become healthy physicians. "We are transformed by the renewing our minds" (Romans 12:2). We need to have the mind of Christ (1 Cor 2:15-16). When Jesus was crucified, the centurion knelt at the cross and said, "Surely this is the son of God." We need this revelation for our innocent preborn children.

Noreen and I, when we understood the Truth, were convicted of the wrongness of taking other human life in abortion. We experienced forgiveness. After that first step of forgiveness, God took us on a journey of healing, transformation, and reorientation, like the transformation of Saul to Paul. We are blessed to now be a part of pro-life ministries, pregnancy help centers, 40 days for Life, Life Education and Resource Networks, AAPLOG and Centurions.

As black physicians, we have pondered the irony of the history of abortion. *Roe vs. Wade* was passed in 1973. Could it have been averted? On that Supreme Court was the first black justice, Thurgood Marshall. He was most famous for winning *Brown vs. Board of Education.* This decision overthrew *Plessy vs. Ferguson*, which legalized "separate but equal," segregating schools. Mr. Marshall recognized justice from a racial/personal paradigm, but he totally missed the point from a broader human paradigm.

Physicians usually don't go to medical school with the intention of performing abortions. The choice to perform abortions is an insidious process that is nurtured in the secular environment of medical school and residency. A subtle indoctrination that disregards the humanity of the fetus. If the student allows himself to witness and then participate in an abortion, there is virtually no turning back. The seduction of financial gain and the lust for power over life and death feed the spirits of greed and idolatry. After the physician experiences the financial rewards provided by doing abortions, it is easier to develop that "die hard" conviction that a woman has the right to choose to kill her preborn child by abortion. Especially in these days when there are so few doctors performing abortions, the abortion doctor often sees himself or herself as a benevolent savior and defender of a woman's right to choose abortion. It is so easy to enter this delusionary state, rationalizing to him or herself that he or she is serving the needs of women, and filling a necessary void in women's healthcare.

There are three victims who suffer the consequences of an abortion. The baby, the mother, and the doctor. Of course it is obvious the baby loses his or her life as he or she is dehumanized to be just "products od conception." The mother also is dehumanized. When we did abortions, we deliberately avoided making eye contact with her for fear of awakening any human compassion brought by anguish we could see in her eyes. We did not allow her or ourselves to form a doctor-patient relationship. She had been dehumanized to just another number on our list of abortions that day. But what we and other abortion doctors did not realize is that we ourselves had become dehumanized in the process. We had lost human compassion and sensitivity. We had become morally and ethically bankrupt.

Think for a moment about what it is like to be an itinerant abortion doctor. He or she-goes from clinic to clinic and often from state to state performing abortions. He or she is not a part of any medical society and lacks respect among colleges and members in the community in which he or she lives. His personal and family life are frequently wrecked by broken and damaged relationships. He or she masks low self-esteem with alcohol or other substances to numb the pain of life.

The question is, how can one impact and change the mind of an abortion provider? What is the most effective method to communicate an alternate view to physician abortion providers? Putting it bluntly, how does one touch someone whose heart is hardened and whose mind is deluded?

The scientific debate over when human life begins is long settled. It acknowledges the genetics that human life begins at fertilization. How does one change the delusionary belief of a medical provider who thinks that it's o.k. to terminate the life of a pre born human being based on "wantedness" by the mother. Supernatural intervention is needed.

We can attest to the power of prayer. Pray for abortion providers you know personally, and those working in your community, but also pray for all abortion providers and clinic workers. The testimonies of those who have made the transformation from death to life have often been in response to prayer.

Another avenue is relationship building. This may be difficult since darkness tends to avoid light, but one should always welcome opportunities to demonstrate love and extend cordiality to abortion providers. Love always wins, "Love covers a multitude of sins."

Be involved in prolife activities and activism that gives opportunity for visibility and ministry. Speak the truth in love. Be accurate in presenting abortion-related information. Do the necessary research and document and compile the facts.

Finally, testimonies from former abortion providers, abortion clinic workers, women who regret or who have suffered consequences from abortion, always carry great impact. Those abortion providers who will listen can be transformed, and begin the path to healing and restoration…… We are living proof.

Safe Sex Belief and Sexual Risk Behaviors Among Adolescents: Project YOURLIFE

Jokin De Irala, M.D., Ph.D.*

Introduction

Project YOURLIFE is an international study on what youth think and feel about relationships, love and sexuality that also studies their leisure time activities as well as some characteristics of their family education. The general objective of this project is to improve the lifestyles and health of school-attending adolescents in relation to their affectivity and sexuality.

International data on the socio-cultural context, family education, lifestyles and opinions that young people have concerning affectivity and sexuality as well as the analysis of how these variables are associated with each other will give better insights for future evidence-based public health recommendations.

The study began with surveys taken by representative samples of school-attending adolescents in the Philippines, El Salvador, Peru and Spain. Results published so far using data from approximately 11,000 adolescents in peer reviewed journals can be found at the research project website (http://bit.ly/1OQs1Wh).

The project now uses online survey tools to make data collection more efficient and schools worldwide will be invited to participate. Participating schools will request their students to take an anonymous online survey and will receive a summary of school-specific results in PowerPoint slides. These results can be used for educational purposes among teachers, parents and students. The project, in turn, will utilize this data from schools worldwide to perform international analyses, proper statistical adjustments and public health recommendations.

Objectives

The primary objective of the YOURLIFE project is to achieve a better understanding of how the socio-ecological context of schooled adolescents and what they think and feel about relationships, love, and sexuality, influence their sexual health.

The specific objectives of the YOURLIFE project are:

1. To study the adolescents´ knowledge, attitudes and behavior related to sexuality and thus identify misconceptions as well as risky attitudes and behaviors that

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may put them at an increased risk of acquiring sexually transmitted infections (STIs) or unplanned pregnancies.

2. To examine the reasons for having or not having sexual relationships and the circumstances associated with such reasons.
3. To identify the worldwide social factors associated with particular knowledge, attitudes and sexual risk behaviors using data taken from schools in different countries and with different socio-demographic characteristics.

Examples of recent results obtained by this project

A recent paper published using this data is one concerning the effect of safe sex beliefs and sexual risk behaviors among adolescents[1] (http://bmj.co/1bVtfOD).

A cross-sectional analysis was performed using representative samples of high school students in the Philippines, El Salvador and Peru. Participants completed a self-administered questionnaire where they were asked about the risk of HIV transmission if one has sex using condoms. They were also asked to indicate whether they had ever had sexual relations and whether they used a condom in their first sexual relation. The sample was composed of 8994 students, aged 13–18.

One out of seven adolescents believed condoms are 100% effective (safe sex believers). These adolescents were 82% more likely to have had sex than those without such a belief, after adjusting for confounders (OR=1.82; 95% CI 1.51 to 2.21). On the contrary, no association was found between risk perception and condom use. Subgroup and sensitivity analyses produced similar results.

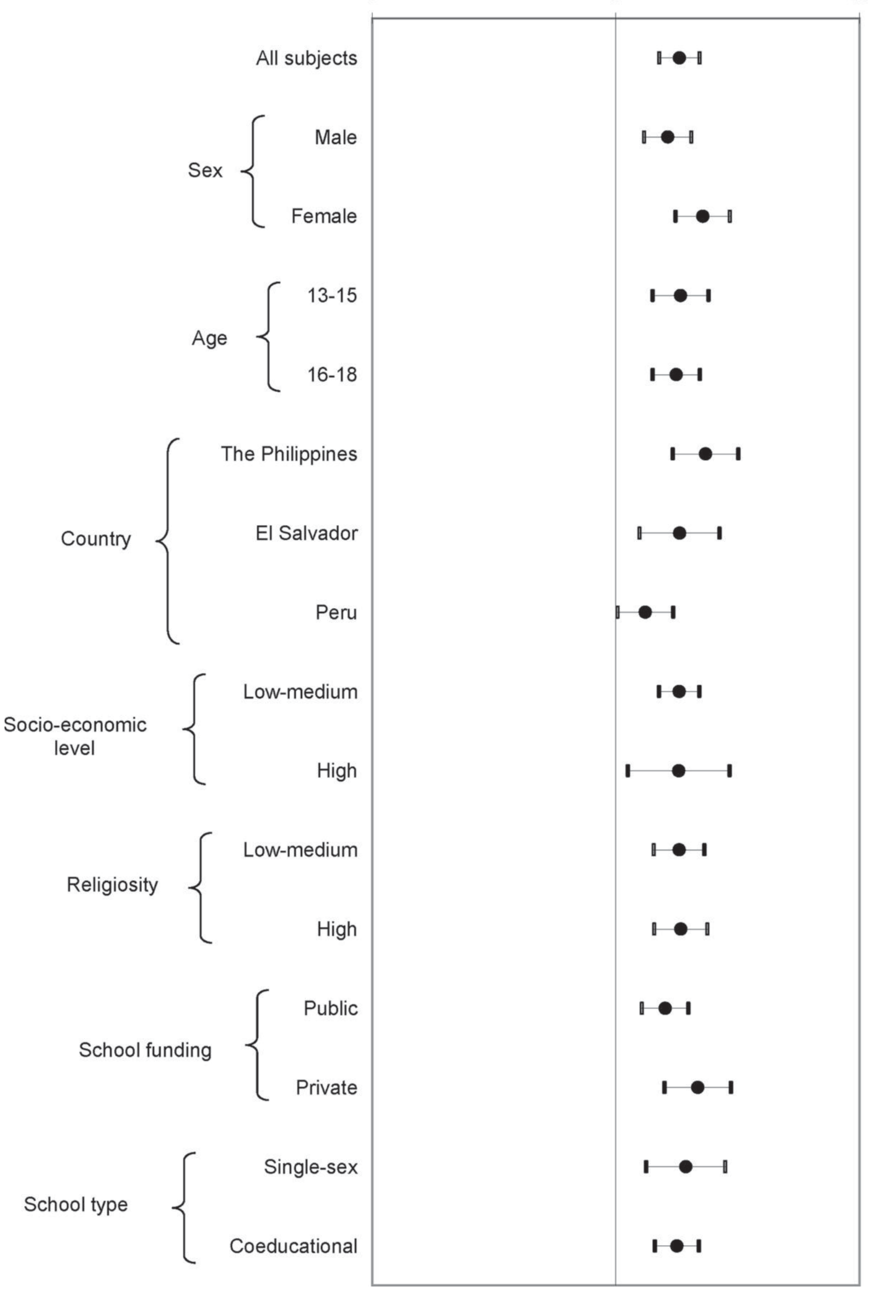
Subgroup analyses were performed by repeating the model that adjusted for different independent variables associated with sexual initiation. They were performed within separate categories of sex, age, country, religiosity, socio-economic status, school funding and type (Figure 1).

The OR for the association between the main independent variable (safe sex belief) and sexual initiation was consistent across all subgroups. In all the subgroups, the adjusted OR and the 95% CI were always above one (indicating a more frequent sexual initiation among adolescents with safe sex beliefs).

To the best of our knowledge, this is the first study conducted specifically to evaluate the phenomenon of risk compensation related to safe sex beliefs and that has used the same questionnaire and the same data collection protocol in three different developing countries from Asia, Central America and South America. These results reasonably suggest that there could be an association between safe sex beliefs and sexual initiation. Longitudinal studies are needed to better understand this possible association as it could influence guidelines of sexual health promotion.

If risk compensation associated with the belief that condoms are 100% effective is confirmed, then public health authorities, the media, educators and parents could be expected to review how promotional messages regarding condom use is being conveyed to the youth, and deliberate how such messages could be more safely conveyed in the future.

Figure 1. Odds Ratios (ORs) of having had sex for respondents with a safe sex belief, versus respondents without a safe sex belief, across different subgroups. Odds Ratios (and 95% CIs) are adjusted for sex, age, country, socio-economic level, religiosity, school funding and school type. Note: logarithmic scale representing ORs from 0 to 10.



Previous results obtained by this project

The main findings regarding sexual health are:

1. Filipino youth obtained information about sexuality mainly from friends (69.6% for girls and 57.5% for boys), although they valued parents' opinions more than those of their friends. The topics most discussed with parents were for girls: girls' physical changes (59.9%), pregnancy (41.7%), how to manage feelings/emotions (46.1%) and dating the right person (36.8%); for boys: how to manage feelings/emotions (33.5%), dating the right person (26.0%), pregnancy (23.9%) and STIs (21.7%). Most participants desired to know more about how to manage feelings/emotions, STIs and contraception.

   Almost half of respondents were not aware that condoms are not 100% effective in preventing STIs or pregnancies (42.9% for HIV -Human immunodeficiency virus- risk, 43.7% HPV –Human papillomavirus- risk and 40.6% for pregnancy). The belief that condoms are 100% effective was associated with being sexually experienced (OR=1.59; 95%CI 1.09–2.33).[2]
2. In the Philippines, El Salvador and Peru, the reasons most frequently reported for deciding to have first sex were: external pressure, being carried away by sexual arousal, thinking they were in love, wanting to have fun, feeling like it, and finally, wanting to know what it was like. The prevalence of subsequent regret for having had sex was 12.6-31.7% in the three countries studied. An association was found between some reasons given for deciding to have first sex and subsequent regret, such as partner's insistence (OR=1.90; 95% CI: 1.38–2.63), going through an "uncontrolled situation" –for example during "petting"– (OR=1.68; 95% CI: 1.26–2.23) or having seen sexual images in films or magazines immediately prior to that first sexual experience (OR=2.07; 95% CI: 1.46–2.92).[3]
3. In El Salvador, sources of information about sexuality, as well as the messages received from friends and parents, had a great influence on sexual behaviour. The factor most associated with having initiated sexual relationships was friends' and siblings' acceptance of having sex (OR=1.7, 95% CI: 1.3-2.2 and OR=1.8, 95% CI: 1.2-2.7). Protective factors associated with not having had sex were parental supervision (OR= 0.5, 95% CI: 0.4-0.7), messages from friends that encourage abstinence (OR=0.7, 95% CI: 0.6-1.0), messages from siblings that encourage abstinence (OR=0.7, 95% CI: 0.5-0.8) and messages from parents favorable to marriage (OR=0.4, 95% CI: 0.3-0.6).[4]
4. When the mean ages of first sexual intercourse and the proportions of youth sexually experienced at different ages were analyzed in El Salvador, Peru and Spain, data showed that the use of mean age of sexual initiation can be misleading, especially when the percentage of sexually active youth at each age is not specified. For example, it was found that the mean age of first sexual intercourse was 14.8 in El Salvador, but only 13.8% of 14 year old El Salva-

dorian participants had had sex; in Peru the mean age was 14.3 but 9.6% of 14 year old Peruvian participants had had sex, and in Spain the mean age was 16.3 but 21.7% of 16 year old Spanish participants were sexually initiated. We therefore encourage the utilization of the percentages of youth at different ages who have already initiated sexual relationships instead of using the mean age of sexual initiation. This will reduce confusion, help avoid erroneous interpretations of information, and provide a much-needed additional source of support to young people. All of these factors in turn give public health policies that seek the delay of sexual initiation in youth a better chance of succeeding.[5]

Invitation to participate

The YOURLIFE study is based on a self-reporting questionnaire specifically designed for adolescents and developed at an easy reading level. It is based on previously validated questionnaires used in several national and international surveys conducted among adolescents.

Project YOURLIFE is now available for the participation of English-speaking schooled adolescents worldwide. All the project information, participation procedures and ethical requirements are explained in the project website (http://projectyourlife.com). Three different online questionnaires are available worldwide for schooled adolescents aged 13/14, 15/16 and 17/18. The surveys are free of charge and are available in Spanish, English, and will be subsequently available in other languages as the project expands. Schooled adolescents aged 13/14 can also be invited to participate in a subsequent follow-up survey upon reaching the ages of 15/16 or 17/18 and schooled adolescents aged 15/16 can be invited to participate in a subsequent follow-up survey upon reaching 17/18.

This prospective analysis of the data will allow improved control of the phenomenon of reverse causality typical in cross-sectional studies and thus allow a better understanding of how some variables in younger participants could be associated with specific outcomes when they are one or two years older. A set of matching variables will enable the pairing of two questionnaires of the same person at different ages and will preserve the anonymity of the adolescents.

Interested schools would request participation after having read and accepted the ethical requirements of the project. They would then receive a specific web link where students can access the questionnaire. Within a few weeks the school receives a detailed and tailored report on the questionnaires' overall results both on pdf documents and on PowerPoint slides. This will enable schools to use their results in specific educational programs targeting teachers, parents and/or students. Any issue detected by the survey and that warrants the school´s attention as educators of adolescents may be addressed. The survey could also be used by schools to monitor changes in their students if they were to implement educational programs based on previous results, as the survey can be applied to the same students at different ages.

Researchers worldwide are also invited to participate in the analysis of data with our research team. Post-master's or doctoral opportunities are available for researchers that are interested in working with this international data (see the "publish with us" section at http://bit.ly/1OQs1Wh).

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Management of Very Early Adolescent Pregnancy

Byron C. Calhoun, M.D.*

ABSTRACT:

Background: Very Early Pregnancy ($\leq$ 15 years at delivery) is suggested as a risk factor for adverse pregnancy outcome including low birth weight (LBW), preterm birth (PTB), small for gestational age (SGA) infants, stillbirth, and neonatal mortality.

Objective: To systematically review the risk of an infant being born LBW/PTB/SGA/stillbirth or neonatal mortality among patients $\leq$ 15 years of age.

Search strategy: Medline, Embase, CINAHL, and bibliographies of identified articles were searched for English language studies.

Selection criteria: Studies reporting birth outcomes to mothers $\leq$ 15 years of age with an appropriate control group of older gravidas.

Data collection and analysis: A single reviewer collected data and assessed the quality of the studies for biases in sample selection, correct age cohorts, confounder adjustment, analytical, outcome assessments, and attrition.

Main results: Forty-six studies were located with very early adolescent pregnancy. Of these, only 21 papers had the correct age group ($\leq$ 15 years) with a comparison cohort. The studies found in the very early adolescent pregnancy:

- Increased risk of SGA
- Increased risk of LBW < 2,500 gms
- Increased risk of PTD < 37 weeks
- Decreased risk of DM
- Decreased risk of cesarean section
- Decreased risk of use of pitocin/active phase length
- Conflicting risks for Preeclampsia/VLBW/Episiotomy/instrumental delivery rates

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***Conclusions*: Very early adolescent pregnancies ($\leq$ 15 years) do not have universally grim outcomes as normally quoted. Very early adolescent pregnancies have decreased risk of cesarean delivery, DM, and of active phase disorders. Further, many of the adverse outcomes may be ameliorated with earlier, adolescent-focused, and improved antenatal care.**

***Key words*: very early adolescent pregnancy ($\leq$ 15 years)**

Background

Arguments exist regarding the association between very early adolescent pregnancies and adverse outcomes.[1] Whether the association is causal or associated with the poorer social situation of adolescent mothers remains at issue.[2] Many studies from the developed and developing world have reported that teenage pregnancies are at increased risk for preterm birth (PTB), low birth weight (LBW), and small for gestational age (SGA).[3-17] Other studies have not confirmed the LBW and PTB association[18-21] or the SGA association.[16,20] Some studies also demonstrate increased risk for maternal death, early neonatal death, and anemia.[3-4,6-7,12] This concern is heightened, particularly due to the information that approximately 12% of adolescent pregnancies are in females < 14 years of age.[22]

Other studies note that the very early adolescent pregnancies have decreased morbidities. Specifically these pregnancies demonstrate decreased rates of cesarean sections,[6-9,15-18,21] gestational diabetes mellitus,[6,16] rates of lacerations,[16] and risk for third trimester bleeding.[6] Satin et al. 1994 demonstrated a decreased rate of use of Pitocin and an increased vaginal delivery rate.[9] Leppalahti et al. 2013 found that very early adolescent pregnancies had an increased vaginal delivery rate.[17] These findings are thought to be related to a younger age with less obesity, hypertension, macrosomia, and tobacco or substance abuse.

Due to this conflicting data we asked the following questions:

1. Are very early adolescent pregnancies ($\leq$ 15 years of age) at increased risk for adverse pregnancy outcomes compared to older gravida pregnancies?
2. Are very early adolescent pregnancies ($\leq$ 15 years of age) at decreased risk for operative delivery (cesarean section) and other pregnancy associated morbidities?
3. Are there interventions that might ameliorate adverse outcomes in the very early adolescent pregnancies?

Material and Methods

Medline, Embase, CINAHL, and bibliographies of identified articles were searched for English language studies for very early adolescent pregnancy articles from inception of Medline until January, 2016.

Objectives

To systematically review risk for adverse outcomes among very early adolescent pregnancies:

1. Are very early adolescent pregnancies at increased risk for adverse pregnancy outcomes compared to older gravida pregnancies?
2. Are very early adolescent pregnancies at decreased risk for operative delivery (cesarean section) and other pregnancy associated morbidities?
3. Are there interventions that might ameliorate adverse outcomes in the very early adolescent pregnancies?

Criteria for Considering Studies for This Review

Observational studies that assessed the association between any adverse pregnancy outcome and very early adolescent pregnancies compared to an older gravida cohort. The older gravidas included all women > 15 years of age and included multiple cohorts with varying age groups. All outcomes of LBW, PTB, SGA, diabetes, preeclampsia, eclampsia, cesarean section, vaginal delivery, neonatal mortality, maternal mortality, postpartum morbidities, anemia, third trimester bleeding, induction rates, labor abnormalities, and lacerations were included. A study was included if it provided adequate information on outcomes with very early adolescent pregnancies and its effects on the outcomes of interest. Only information available from the publications was included and no authors were contacted. Studies published were included only if there was a comparative cohort. Studies published solely as an abstract were not included.

Types of Studies

Observational cohort studies with matched, unmatched, or historical controls; longitudinal studies; and case-control studies were included. Reports of data from national or local vital statistics not published as peer-reviewed articles were not included.

Types of Participants

Participants included women who had any delivery, including stillbirths, to ascertain any complications with delivery with the very early adolescent pregnancies and the comparison groups of older gravida pregnancies.

Assessment of Exposure

Maternal pregnancy of very early adolescent pregnancies was elicited from the history based on the date of birth of the gravida. Further details on maternal characteristics were gleaned from the medical records, hospital records, administrative databases, national databases, or vital registries.

Search Strategy for Identification of Studies

Electronic databases (Meline, Embase, CINAHL) were searched from inception until January, 2016 for all published studies in the English language. The search items were modified according to database requirements. The reference lists of the identified articles were reviewed to locate further eligible studies. The articles were evaluated initially based on titles and abstracts by the author (BCC) using a study relevance format. Selected articles were retrieved in full and were assessed for eligibility by the author (BCC). Search terms used were: *very early adolescent pregnancies ($\leq$15 years of age), preterm birth, SGA, LBW, Very Low Birth Weight (VLBW), preeclampsia, eclampsia, stillbirth, gestational diabetes, teenage pregnancy, maternal mortality, neonatal mortality, and labor abnormalities.*

Methods of Review

Data from each eligible study were extracted without modification of original data onto custom-made data collection forms by the author. Information of confounders adjusted and adjusted risk estimates (adjusted odds ratios) were added if available. The methodological quality of the studies was evaluated using a pre-defined checklist. Both unadjusted and adjusted values were included when available. For categorical measures, odds ratios (OR) were reported and for continuous measures, weighted mean differences (WMD) were used. Summary estimates with 95% CI were noted.

Results

Description of Studies

The results of the search, the study selection log, and the number of studies reported are as follows: Twenty-one papers were included in this review.[1-21] Twenty-four papers were excluded.[23-47] Fifteen due to the wrong cohort being compared to the very early adolescent pregnancy;[23-37] three excluded due to relationship to substance abuse/depression;[38-40] two excluded for too small a sample size;[41-42] two for policy papers not clinical outcomes;[43-44] one for using only estimates not actual data;[45] and one due to skeletal maturity only.[46] Baseline characteristics of included studies are reported in Table 1.

Methodological Quality of Included Studies

The results of the quality assessment are reported in Table 2. Most studies had a low to moderate risk of bias. Studies were unlikely to suffer from recall bias since the data was obtained from delivery databases.

Data from Individual Studies

Data from each study were presented in table format in Table 1. Only those studies that reported statistical significance to $p \leq 0.05$ or statistically relevant OR's/RR's were included.[1-21] Adjusted OR's were evaluated where available.

Comment

In this systematic review of twenty-one studies, we identified significantly increased unadjusted and adjusted odds of increased risk of SGA, LBW < 2,500 gms, and increased risk of PTD < 37 weeks very early adolescent pregnancies. However, we also found a decreased risk of DM,[6,16] decreased risk of cesarean section,[6,9,15-16,18,21] and decreased risk of use of pitocin/active phase arrest[9,18] in the very early adolescent pregnancies. We found equivocal data regarding preeclampsia, VLBW < 1,500 gms, and episiotomy/instrumental delivery rates in very early adolescent pregnancies.[3,6-9,11,13,15,17,19-21] The impact of very early adolescent pregnancies on SGA, LBW < 2,500 gms, and PTD < 37 weeks should not be ignored. However, these outcomes must be weighed in terms of the decrease in DM, cesarean sections, and decrease in use of Pitocin and/or instrumental delivery.

The major strength of this analysis is the review of all relevant studies from inception of Medline, Embase, CINAHL, and bibliographies of identified articles were searched for English language studies for very early adolescent pregnancy ($\leq$ 15 years) articles. One selection bias is that no non-English articles were queried. The other strength of the article is the use of large cohort studies available to ask the pertinent questions regarding very early adolescent pregnancy and use those articles with reported statistical significance only.

The main limitation to this study is that the majority of the studies were unmatched, cohort studies with variable control groups. Some used older adolescents > 15 years of age (16-20), and some used mature women > 21 years of age. However, the increased risks to very early adolescent pregnancy for SGA, LBW < 2,500 gms, and PTD < 37 weeks did not vary based on the age-based comparison cohort used.

Therefore, we conclude that outcomes in pregnancy in the "very early adolescent" are not as grim as portrayed. Certain significant morbidities, such as preterm birth, are *increased* and may be manageable with routine obstetrical care (particularly early onset care). Other significant morbidities are *decreased*, including cesarean section, GDM, and use of Pitocin/arrest disorders, and therefore must be included in the discussion of the issue. Earlier and focused prenatal care may ameliorate the effects of adverse outcomes in the very early adolescent pregnancy.[42]

Outcomes may be influenced by modification of risk taking behaviors (tobacco/EtOH/illicit drugs), early entry into prenatal care, and, focused care, specific to the needs of very early adolescent patients. Further study on the impact of focused clinics, enhanced prenatal care, and risk reduction for tobacco/EtOH/illicit drugs should be considered in the care of very early adolescent pregnancy.

Table 1. Characteristics of included studies

Author	Year of Study	Place of study	Population/ Number	Setting	Exposure assessment	Confounders
1. Gibbs et al.	1964-20110	International/multi-country	Multicenter	Systematic Review	Delivery records	Parity, maternal age, ethnicity, socioeconomic status, drug use, alcohol use
2. Taffa et al.	May-Jun 2009	Ethiopia	295	Cross-sectional survey	Delivery records	Parity, matnernal age, socioeconomic status,
3. Malabarey, et al.	1995-2004	USA	300,627	Population Cohort study	Birth registry	Parity, maternal age, ethnicity, prenatal care
4. Chen et al.	1995-2000	USA	175,019	Retrospective Cohort Study	Birth registry	Parity, maternal age, ethnicity, socioeconomic status, drug/EtoH use
5. Fraser et al.	1970-1990	Utah, USA	134,088	Retrospective Cohort study	Birth registry	Parity, maternal age, ethnicity, marital status, prenatal care, educational level
6. Conde-Agudelo	1985-2003	Latin American women	33,000	Retrospective Cohort study	Birth registry	Parity, maternal age, educational level, CHTN, weight gain, marital status, tobacco abuse, marital status, antenatal visits
7. Gilbert et al.	1992-1997	California, USA	31,232	Cohort study	Birth registry	Parity, maternal age, ethnicity, preeclampsia, eclampsia, pyelonephritis

Table 1. Characteristics of included studies-Continued

Author	Year of Study	Place of study	Population/ Number	Setting	Exposure assessment	Confounders
8. Eure et al.	1985-2000	Atlanta, Georgia (Emory University)	2,930	Retrospective cohort study	Obstetrical birth registry	Maternal age, ethnicity, prenatal care, STD's, drug abuse, living with others
9. Satin et al.	1988-1991	USA/Parkland Memorial Hospital	1,622	Cohort study	Birth registry	Maternal age, parity, ethnicity, Pitocin augmentation, preeclampsia
10. Alves et al.	2009	Brazil	1,476	Cross-sectional study	Public health database	Maternal age, race, marital status, schooling, type of delivery, birth place
11. Hampton et al.	1985-1990	USA/University of Mississippi	995	Retrospective cohort study	University of Mississippi database	Maternal age, race, parity, prenatal care, preeclampsia, eclampsia, HELLP
12. Olausson et al.	1973-1989	Sweden	831	Population-based cohort study	Swedish Medical Birth Registry	Maternal age, education, prenatal care, complications in pregnancy
13. Althabe et al.	2010-2013	Kenya, Zambia, India, Pakistan, Guatemala, Argentina	370	Prospective population based multicountry	International birth registry	Maternal age, parity, education, socioeconomic status, BMI
14. Bacc et al.	1989	Maputo, Mozambique	362	Retrospective cohort	Clinical delivery records	Maternal age, parity

Table 1. Characteristics of included studies-Continued

Author	Year of Study	Place of study	Population/ Number	Setting	Exposure assessment	Confounders
15. Traisrislip et al.	1992-2013	Thailand	298	Retrospective cohort analysis	Hospital delivery database	Maternal age, parity, prenatal care, pre-existing medical complications, preeclampsia, eclampsia
16. Perry et al.	1985-1992	USA/New Jersey	239	Prospective cohort study	Hospital delivery database	Maternal age, partiy, maternal weight gain, BMI, pre-existing medical complications, anemia
17. Leppalahti et al.	2006-2011	Finland	84	Retrospective cohort study	Finnish national registry	Demographic factors, parity, maternal age
18. Lubarsky et al.	1990-1992	USA/University of Tennessee, Memphis, TN	35	Matched cohortt	Hospital database	Parity, age, prenatal care, insurance status, marital status
19. Hidalgo et al.	2002	Ecuador	201	Prospective case controlled study	Hospital database	Socioeconomic status, age, parity, prenatal care
20. Berenson	1992-1994	USA/University of Texas Galveston	147	Cohort study	Hospital database	Age, parity, ethnicity, socioeconomic status, tobacco, alcohol, illicit drugs, STDs
21. Hoque et al.	2004	Natal, South Africa	90	Retrospective comparative study	Hospital database	Age, parity, socioeconomic status

Table 2. Quality assessments of included studies

Author	Type of Study	Selection bias	Exposure assessment bias	Outcome assessment bias	Confounding factor bias	Attrition bias	Analytical bias	Overall risk of bias
1. Gibbs et al.	Systematic Review	Low	None	None	None	None	Low	Low
2. Taffa et al.	Cross-sectional survey	Moderate	Moderate	None	Low	Low	Low	Moderate
3. Malabarey, et al.	Cohort study with unmatched current controls	None	None	None	None	None	Low	Low
4. Chen et al.	Cohort study with unmatched controls	None	None	None	None	None	Low	Low
5. Fraser et al.	Cohort study with unmatched	None	None	None	None	None	None	Low
6. Conde-Agudelo	Cohort study with unmatched concurrent controls	None	None	None	Low	None	Low	Low
7. Gilbert et al.	Cohort study with unmatched concurrent controls	None	None	None	Low	None	Low	Low
8. Eure et al.	Cohort study with unmatched concurrent controls	None	None	None	Low	None	None	Low
9. Satin et al.	Cohort study with unmatched concurrent controls	None	None	None	Low	None	Low	Low

Table 2. Quality assessments of included studies-Continued

Author	Type of Study	Selection bias	Exposure assessment bias	Outcome assessment bias	Confounding factor bias	Attrition bias	Analytical bias	Overall risk of bias
10. Alves et al.	Cross-sectional study	Low	Low	Low	Low	Moderate	Low	Low
11. Hampton et al.	Cohort study with unmatched concurrent controls	Low	Low	Low	Low	Low	Low	Low
12. Olausson et al.	Cohort study with unmatched concurrent controls	Low	Low	Low	Low	Low	Low	Low
13. Althabe et al.	Cohort study with unmatched concurrent controls	Low	Low	Low	Low	Moderate	Low	Low
14. Bacc et al.	Cohort study with unmatched concurrent controls	Low	Low	Low	Low	Low	Low	Low
15. Traisrislip et al.	Cohort study with unmatched concurrent controls	Low	Low	Low	Low	Low	Low	Low
16. Perry et al.	Cohort study with unmatched concurrent controls	Moderate	Low	Low	Low	Low	Low	Low
17. Leppalahti et al.	Cohort study with unmatched concurrent controls	Low	Low	Low	Low	Low	Low	Low

Table 2. Quality assessments of included studies-Continued

Author	Type of Study	Selection bias	Exposure assessment bias	Outcome assessment bias	Confounding factor bias	Attrition bias	Analytical bias	Overall risk of bias
18. Lubarsky et al.	Cohort study with matched concurrent controls	Moderate	Low	Low	Low	Moderate	Low	Moderate
19. Hidalgo et al.	Cohort study with matched concurrent controls	Moderate	Low	Low	Low	Moderate	Low	Moderate
20. Berenson	Cohort study with unmatched concurrent controls	Low	Low	Low	Low	Low	Low	Low
21. Hoque et al.	Cohort study with matched concurrent controls	Low	Low	Low	Low	Low	Low	Low

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Behavioral Methods of Family Planning: A Comparative Study of Efficacy and Safety of Fertility Awareness Based Methods and Birth Control Pills

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Background and Purpose

Published reports indicate that *over 100 million women worldwide* use the birth control pill (Oral Contraceptives, or OCPs).[1,2] However, in a national study conducted by the Battelle Centers for Public Health Research and Evaluation, rates of discontinuation of some birth control methods were as high as 90%, and had averages between 40-61% (depending on marital status) for women who were followed over a two-year period.[3] This suggests that women are searching for new methods, perhaps with fewer side effects or better effectiveness rates. Studies show up to *60% of women* would be interested in using Fertility Awareness Based Methods (FABMs) if given information.[4] Both FABMs and OCPs entail behavior modification on a daily basis, so the efficacy and side effects of FABMs and OCPs were chosen for comparison during this study.

Most commonly reported unintended pregnancy rates for FABMs and OCPs are based on low quality retrospective surveys. A popularly cited review from J. R. Trussell and colleagues reports typical use failure rates of 24% for FABMs and 9% for OCPs.[5] These numbers are based on estimates of the probability of pregnancy drawn from the 1995 and 2002 National Surveys of Family Growth.[5,6] There are at least three major problems with these surveys. One is that these are lower quality retrospective surveys based primarily on patient recall, with the data collected via a series of phone surveys. Another major problem is that 86% of the purported FABM users surveyed identified the calendar rhythm method—a much older and less effective method—as their prima-

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ry form of contraception. Then, the rates for all types of FABMs were pooled together, including some methods which are not even classified as FABMs by trained providers. This "lumping together" of all FABMs including "rhythm" masks important differences in effectiveness among the variety of modern methods; a fact acknowledged by Trussell, the author of this estimate.[7,8,9] The third major issue with this review is that the rates of effectiveness were adjusted to account for the researchers' assumption of underreporting of abortion. As a result of the issues with these popularly cited statistics, we sought to design objective criteria with which to evaluate the primary literature available for FABMs and OCPs, in order to understand both the quality of the studies available as well as the true effectiveness rates.

Methods

In total, three major search engines (Medline, PubMed, and EMBASE) were used with keyword searches to identify relevant articles. For FABMs, 30 articles from 1980 on were included in the study.[6] For OCPs, 47 articles from 2000 on were included in the study. (The year 2000 was chosen in part because studies from earlier decades had used higher dose hormone formulations which were proven to be unsafe for women, and the trend in later years has been towards seeking lower dose hormonal formulations to provide the same efficacy with fewer side effects[1]). Strength of Recommendation Taxonomy (SORT) criteria[10] were established first for the FABM review[6] and then adapted for the OCP review (Adapted SORT). The adaptation was based on fundamental differences between FABMs and OCPs such as lack of a "learning phase" for OCPs. The purpose of the SORT and Adapted SORT criteria was to provide a framework to determine the level of evidence for individual studies.

Two independent reviewers scored each of the identified articles for the FABMs and the OCPs reviewed. Major discrepancies in scores were resolved by sending the articles in question to a third reviewer for a tie-break score.

Results

For the FABMs reviewed, there were 56 maximum possible points with the SORT criteria. The scores ranged from 31-55 points, and 10 of the 30 articles (30%) were found to earn a SORT Level 1 status (qualified by earning a positive score in all of the critical criteria).[6]

For the OCPs reviewed, there were 42 maximum possible points with the Adapted SORT criteria. The scores ranged from 18-41 points, and 5 of the 47 articles (11%) were found to earn a SORT Level 1 status.

The SORT criteria for the FABM articles included the following categories.[10]

1. Tracking of sexual activity
2. Prospective or retrospective status of the study
3. Sample size
4. Duration of follow-up
5. Survival analysis and statistical methods used

6. Detection and recording of pregnancy
7. Effectiveness rates for typical and correct use of method
8. IRB approval
9. Geographical location(s) of population studied
10. Diversity of population
11. Sexual behavior or other method use in conjunction with the method studied
12. Client profile and
13. Any counseling, learning phase, or instruction needed for the methods.

The Adapted SORT criteria used many of the same core criteria but excluded the categories of learning phase, counseling, and prospective pregnancy intentions (it was implied that women seeking OCPs had no intentions of pregnancy within the duration of the studies).

Of interest, it was found that every major FABM had at least one robust study which earned SORT Level 1 status in this review. These major methods are: Billings Ovulation Method® (BOM), Creighton Model, Two Day Method SymptoThermal Method, Marquette Model, Standard Days Method and Lactational Amenorrhea Method.

Of the OCP articles reviewed, the following five formulations earned SORT Level 1 status in this review: Triphasil, 21/7 Regimen, 24/4 Regimen, Extended Regimen, Ascending Dose Extended Regimen (ADER).[11-15]

Additional Findings

Over the course of the review, other findings of interest surfaced as observable patterns. Cited advantages for FABMs included sense of empowerment of the women in the studies, enhanced understanding of fertility, cost-effectiveness, environmental friendliness of methods, enhanced communication between couples, use of methods as a diagnostic tool, lack of medical side effects, and freedom from drugs and devices. Cited advantages for OCPs included improved cycle regularity and control, decreased dysmenorrhea, improvements in acne and seborrhea, improvement in mood and sense of well-being, reduction in bloating and water retention, and autonomy in managing cycles with flexible regimens.

A stark contrast was noted in the literature in regards to the reporting of adverse events associated with methods reviewed. For the FABMs, there were no adverse physical effects reported in the literature with any of the methods. For the OCPs, there were adverse events reported in every article reviewed, and these adverse events spanned every organ system.

We also identified potential conflicts of interest. For the FABM articles, 43% of the articles had reported potential conflicts of interest, the majority of these (30%) were that one or more of the authors of the studies were trained in and/or developed the FABM that the article studied. For the OCP articles, 83% of the articles reported potential conflicts of interest, with the majority of these (68%) being that the pharmaceutical company manufacturing the OCP being studied directly funded the study.

Discontinuation rates were higher for the OCP studies than for the FABM studies. For the highest quality studies (Level 1), dropout rates were less than 20%. However only about 10% of the OCP studies were SORT Level 1; whereas one-third of the FABM studies were SORT Level 1. The remaining OCP articles commonly report large drop-out rates. High discontinuation rates may skew statistical analysis of effectiveness rates, particularly when the reasons for discontinuation are not known (ie women are lost to follow-up). This is a point to keep in mind when discussing effectiveness rates for either of the methods.

In regards to effectiveness rates, another finding was that only 28% of the OCP articles included tracking of participants' use of barrier methods or other secondary contraceptive methods. In contrast, 73% of FABM articles included this tracking information.

Conclusions

We conclude that it is possible to make objective comparisons of effectiveness rates between FABMs and OCPs based on SORT and Adapted SORT criteria. There are reported advantages to the use of both FABMs and OCPs, with the major difference being that the OCPs also come with a significant number of reported adverse medical effects. We anticipate that this review will serve as a call for greater uniformity of approach to the study of the available methods of family planning, and for an elimination of the sources of bias currently evident in much of the literature.

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Family Structure and Child Well-Being: Dads Make a Difference

Alma L. Golden, M.D.

Objectives:

- Review current trends in family structure.
- Identify research and demographic findings that link child well-being to family structure.
- Recognize the health benefits of fathers.
- Examine the role of physicians and community organizations in addressing family environments.

Many of social concerns are associated with personal and familial patterns. Educational attainment, obesity, cardiovascular disease, mental health problems, substance abuse and violence have all been recognized for their strong links to family experiences and routines. A number of years ago a clinic noted that there were significant "drop-outs" from their obesity program. On closer evaluation, some similarities were noted with the "drop-out" group: they we likely to have experienced a difficult childhood, and often abuse.

The Adverse Childhood Experiences Study (ACE) developed out of the obesity clinic observation. Kaiser Permanente and the Centers for Disease Control began a study that followed 17,000 patients. The information obtained is enlightening but not surprising. Seventeen risk areas associated with abuse, neglect and household dysfunction were identified. The more risks, or adverse childhood experiences, experienced by a person, the greater the possibility that they would have social, emotional or cognitive impairment. The impairments often led to high risk behaviors (drugs, sex, school failure, etc.) which increased the incidence of significant illness or disability.

The information about this progression is not new. All of us have watched neighbors, friends and loved ones endure abuse or dysfunction, then succumb to social or mental health problems leading to poor choices and disease. The connections are "official research findings" now.

Health Promotion: the next big question is: "how can we intervene?" or "how can we improve health?" For years health promotion believed that the cure to smoking or asthma or diabetes or drug use was through *education*. If we just let people know "this is your brain" and "this is your brain on drugs," people are smart enough that they will just do what is right.

When education failed to modify health behaviors, we thought the magic bullet was *motivation*. If we align the messaging with the values of the person, or we scare them, or we promise good things as a result of good decisions, surely people will make good choices.

Education and motivation can change a few patterns, but short-term behavioral changes in around 10-15% or the population are considered a good outcome. Health promotion advocates recognized that promoting health *skills* might improve outcomes. But even with the combined efforts of education, motivation and skills, condom education programs were failing to significantly modify patterns, even when the issue is potentially life and death, as noted in many of the HIV/condom programs.

Support Systems: What does determine health behaviors? The root of most personal patterns is the family. The routines of sleep, the patterns of tooth care, the choice of foods, daily activity patterns, and models of communicating and coping with stress are all "caught" not "taught." When a society fails to support the support system that creates health patterns, it should not be surprised that health patterns fail.

Health Interventions Do Not Predict Wellness: Relationships Predict Wellness Because Relationships Support Sustained Behaviors.

The Paradigms of Baby Boomers:

- Marriage is old fashioned and confining.
- Open relationships are healthier and more conducive to personal development.
- Fathers are nice but not necessary.
- It is better to live with a single mother than with unhappy married parents.
- The kids will be okay; they are flexible.
- Financial disparities are the reason for differences in health and school achievement.

In other words, Baby Boomers created skepticism regarding relationships. Although these paradigms were untested theories, the concepts were institutionalized and used as foundations for adolescent medicine, welfare programming and child rearing practices.

Those paradigms changed the world:

- Marriage occurs approximately 6-7 years later, and to fewer people: half the number of marriages compared to 1960.
- Women have fewer children and bear them later.
- Single mothers give birth to many of our children: over 40% of infants are born to single women.
- Fewer children live with married biologic parents and more live with cohabitating couples.
- The concept of "family" has been re-defined.

The baby boomer paradigm believed that these changes would improve the quality of life for both parents and children. However the ACE study demonstrates the opposite. Children are more likely to face serious difficulties when they come from disrupted families. The presence of committed mothers and fathers significantly reduces health threats and adverse health outcomes.

"Family Structure and Children's Health in the United States." NHIS Series 10, number 246, December 2010 is the CDC publication released on a weekend during the Christmas holidays in 2010. No press release accompanied the publication. For several months this massive report was unknown. Although 244, 572 households were surveyed and 630,884 people were included, and millions of tax dollars were used, the report has not been discussed in the public square and the results have not been used to improve health policy.

First, the document examines the *family structures* that our nation's children experience. 48% live with married biological parents. The remainder are with extended families (19%), single mothers (14%), blended families (9%), single dads (2%), with the remainder residing in foster, cohabitating or other arrangements.

Does family structure correlate with health behaviors and outcomes? The study had some interesting findings. Some conditions, such as hay fever, otitis media and asthma appeared to be relatively unchanged across family types, while other conditions varied greatly. Children who live with their married biological mother and father have fewer headaches, fewer reported developmental problems, and lower rates of emotional and social problems. These findings correlate with the observations of the Adverse Childhood Experiences study.

Married, high-school educated, biologic parents were less likely to have report problems for their child with access to:

- Routine well-child services
- Prescription and medications
- Medical home
- Dental services
- Vision services

These findings imply that children are more likely to develop good patterns of health maintenance if a father and mother are actively involved.

Emergency room usage is also significantly lower in children living with both parents. Perhaps two committed parents are more likely to team manage a sick child at home without resorting to a trip to the emergency department. Sick children of married parents are also more likely to see their own primary care doctor than children living with other family types.

Married biological fathers who live with the biological mother are the strongest predictor of improved health for children. Relationships predict health because relationships support sustained behaviors.

Behavioral, developmental and emotional health outcomes appear most sensitive to variations in family structure. The causation is not defined: Did the child have an adverse health status that created union dissolution? Or did union dissolution exacerbate the child's health problem? It is clear that children with the greatest behavioral and emotional needs are most likely to live apart from their dad.

One of the most notable quotes from the CDC report on Family Structure was "Children in nuclear families were generally less likely than children in the remaining family types to have a learning disability or ADHD regardless of parent's education, income, poverty status, place of residence, or region." In other words, dads make a big difference in all socioeconomic and geographic groups. The rates of "severe emotional or behavioral difficulties" or "not well behaved" are twice as high in children who do not have dad at home.

Multiple large studies confirm wide-ranging *benefits of a married biological father* in the home. In addition to the emotional and behavioral benefits, academic achievement, learning difficulties, fathers are associated with decreased problems due to:

- Violence: victimization and perpetration
- Behavioral, developmental and emotional patterns
- Child abuse and neglect
- Sexual exploitation of children and young teens
- Risk behaviors: teen pregnancy, substance use, criminal behaviors

Since the rates of *poverty for single mothers* is five times the rate for married couples, many have believed that income patterns are the real source of problems for children in "non-nuclear" homes. Studies of cohabitating couples have demonstrated that cohabitating men typically earn about 50% of married fathers. Step-parents may have a similar total income, but funds available to the child may be significantly lower due to the demands of outside child support or a lower commitment of the non-biological parent to spending money on a child.

The Scandinavian countries have attempted to *equalize the incomes* for single mothers. As noted by Dr. Sara McLanahan in her research review found in the September 2012 journal, *Social Forces*, "even in the very generous Nordic welfare states…children living with single mothers had fewer material resources, less parental support and poorer health than those living with two original parents."

In summary, married biological fathers are:

- The strongest predictor of academic success, educational completion
- Associated with fewer behavioral risks, increased mental health
- Associated with enhanced financial stability
- Important to teaching decision-making and mastering challenges

The impact of fathers extends into adulthood. Missing fathers are associated with:

- Lower rates of college completion
- Fewer sources of extended family support and encouragement
- Increased reports of stress as young adults
- Lower rates of trust in intimate relationships
- Financial and personal burdens of care for aging parents

What have we learned that the Baby Boomers got wrong?

- Marriage is beneficial for men, women and (especially) children.
- Cohabitation is often of low trust, stressful, and more prone to violence and dissolution.
- Kids do best with involved fathers.
- "Good enough" marriages produce better outcomes than divorce.
- The kids are NOT flexible, and may not be okay.
- Family structure and stability are more important predictors of outcomes than finances.

What should physicians and health providers do to support married dads at home?

- Know the facts about family structure and teach parents about their impact on health.
- Promote Dads support in all aspects of their children's medical, educational and spiritual care.
- Ask Dads to come to appointments; give specific assignments in the care of their children.
- Prescribe parenting, relationship education and other services in community or faith groups.
- Identify and strengthen extended family support.
- *MEALS together WITHOUT media!*

Fathers are critical to development, character, health, academic success and social competencies. Families form functional citizens, as noted by Eberhard Berthge regarding Dietrich Bonhoeffer:

"The rich world of his ancestors set the standards for Dietrich Bonhoeffer's own life. It gave him a certainty of judgment and manner that cannot be acquired in a single generation. He grew up in a family that believed the essence of learning lay not in a formal education but in the deeply rooted obligation to be guardians of a great historical heritage and intellectual tradition."

Resources

Family Structure and Children's Health in the United States: Findings from the National Health Interview Survey 2001-2007, *CDC Vital and Health Statistics* 10:246 December 2010.

Family Pediatrics, Report of the Task Force on the Family, 2003, AAP.

Child Trends Briefs on Family Issues.

Why Marriage Matters, Second Edition, 2005 Institute for American Values.

Other journals and demographic reports.

Please see me for additional information and journal references.

Endogenous Tissue Regeneration and Restoration, Maximizing Our Human Potential: An Ethical Alternative to Human Embryonic Stem Cells

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Objectives:

- Review the types of stem cells used in preclinical research and clinical trials.
- Discuss pharmacologic strategies that facilitate endogenous repair, stem cell upregulation and functional restoration following injury (emphasis on hearing loss as an exemplar).
- Brief review of adult CNS stem cell clinical trials and their success to date.
- Identify clinical trials using hESC and why this approach advances neither the science or society.

Overview:

For the first time in history, elderly (≥ 65 years old) adults outnumber young (< 5 years old) children. As medical care improves and fertility rates decline, society in general is aging and increasingly vulnerable to neurodegenerative diseases which seek disease modifying and, more recently, neuro-regenerative therapies and cures.

Since the 1998 discovery that neurogenesis is operant in adult humans, there has been an explosion in our understanding of how to exploit this process for repair of the central nervous system (CNS). Initially, human embryonic stem cells (hESCs) were advanced as the primary means for achieving cell replacement and regenerative tissue repair. More recently (2006), the ability to re-introduce a pluripotent state in differentiated adult cells was established, using genes important to embryonic stem cell function. Induced pluripotent stem cells (also known as iPS cells or iPSCs) are a type of pluripotent stem cell that can be generated directly from adult cells. In 2012 John Gurdon was awarded, jointly with Shinya Yamanaka, the Nobel Prize for Physiology or Medicine "for the discovery that mature cells can be reprogrammed to become pluripotent."

Since these discoveries, the number of neurorestorative CNS clinical trials has been steadily increasing. In periodically reviewing the CNS clinical trial space (2010, 2012 and 2015), the ratio of cellular: non-cellular (primarily growth factors) regenerative approaches remains at ~ 2:1. This has been increasingly dominated by autologous stem cell approaches with few ongoing CNS hESC clinical trials, although the absolute number of hESC trials has increased from 2 in 2010 to 8 in 2015 (N= 3 stroke, N= 3 ALS and N= 2 spinal cord injury). Sponsors of CNS hESC include ReNeuron (CTX), StemCells Inc (HuCNS-SC®), NeuralStem (NSI-566) and InVivo (HFB 2050 line). The scientific reason for this increase is unclear, especially given the wide range of adult autologous and allogenic stem cell options in development and the lack of a therapeutic advantage for hESCs. Other companies such as Q Therapeutics, Life Technologies, Novogenix and ReNeuron are suppliers of hNSC. Academia is also a key participant is these activities, as universities and academic medical centers are the primary sites for conducting most research on human disease, including trials using hNSC. Should they remain agnostic to this strategy?

Going forward, the field of hearing loss is particularly poised for the introduction of therapeutic clinical trials that build upon and augment the successes of devices (e.g., hearing aids and cochlear implants). While devices are clearly a therapeutic advance, they do not perform well in "real world" noisy environments where speech discriminator is more challenging. Hearing loss represents one of the most neglected human diseases, affecting up to 10% of the entire world and is increasingly associated with the development of other significant pathology such as dementia and depression. The number of Americans with hearing loss has evidentially doubled during the past 30 years. Hearing loss, primarily sensorineural hearing loss (SNHL), disproportionally affects the youngest and the oldest segments of society. The prevalence of newborns with congenital hearing loss is ~ 1:500 and approximately 14.9% of U.S. children have low-frequency or high-frequency hearing loss of at least 16-dB hearing level in one or both ears. In both noise-induced and age-related SNHL, the earliest pathology is at the inner hair cell-auditory neurite ribbon synapse, with hair cell and spiral ganglion neuron death a later consequence. Therapeutic approaches to the treatment of hearing loss includes symptomatic therapies targeting the ribbon synapse (e.g., ion channel) and restorative approaches for both the ribbon synapse (e.g., neurotrophins) and the inner ear hair cells (e.g., restoring the cochlear architecture with the ATOH-1 gene). In 2015, our group published the first therapeutic clinical trial for presbycusis in subjects with mild-moderate age-related hearing loss in which an oral AMPA (glutamate subtype) positive allosteric modulator was studied. Neurotrophin approaches in animal models have primarily targeted BDNF (brain-derived neurotrophic factor) and NT-3 (neurotrophin-3) or small and large (e.g., monoclonal antibodies) that serve as agonists at their respective ligand receptors, TrkB and TrkC.

Challenges of delivering potential therapeutics to the inner ear include penetration of the blood-cochlear barrier and the pros and cons of drug delivery via the middle ear (e.g., round window) versus directly to the inner ear via delivery to the perilymph. The latter has both the appeal of certainty of drug delivery (especially important for large molecules and gene therapy) and the drawback of violating the inner ear space with the inherent potential of altering the existing anatomy/cell architecture.

In summarizing the current scientific approach to neurorestoration, we struggle with the future today. How does one view the morality of embryonic stem cell research? There is an enormous amount of discussion about the potential for embryonic stem cells to cure many human diseases, although there is no evidence to date for this. Nonetheless, does the potential for a cure provide a solid moral rationale for the destruction of a human embryo in order to use these cells for some perceived "greater good"?

Is the scientific "defense" in support of cloning or the use of human embryonic stem cells a valid argument? Does science afford us all the answers we need? I would suggest that it is only the complementary use of science and faith that allows one to have a sound and unchanging moral compass.

The "re-programming" of a human cell to have it produce other cells in an order and a sequence that could result in a human being (cloning), is a very distinct possibility. A single cell, previously not considered a human life, could under these circumstances be manipulated to create a human being. The suggestion that life could (let alone should) be created other than by God's design raises one of the world's greatest moral dilemmas that goes beyond the scope of this discussion but which involves the linkage of human free will and freedom to the truth as well as a consideration of whether the limits of what science is capable of doing will define the moral compass of that society.

Similarly, does mankind have the right to destroy human embryos in the hope that the "harvested" stem cells may be of future scientific or medical value? If you believe in the protection of all innocent human life from conception until natural death, how does an individual or society rationalize the destruction of a human embryo in order to produce a certain body part, chemical or collection of cells? Where does this authority come from? Does mankind only recognize itself as the ultimate moral authority?

Conversely, is there sufficient focus on the use of stems cells obtained from adult sources? Although infrequently discussed, it is a medical fact that adult stem cells have cured dozens of diseases while no cure has ever been produced as a result of research using embryonic stem cells.

Science becomes a threat to mankind when it sets no value on human life or fails to recognize its existence. "A society will be judged on the basis of how it treats its weakest members and among the most vulnerable are surely the unborn and the dying" (Pope John Paul II). Although science has demonstrated unparalleled advances, it must recognize a higher standard than merely its own capabilities. For science to function without moral oversight would result in nothing less than the implosion of that society.

In the words of Albert Einstein, "science without religion is lame, and religion without science is blind."

In this "Age of Enlightenment," faith and science have come to be viewed as incompatible. However, faith and science have to come together again, *without* merging into each other. They are complementary. The very existence of our society depends on it.

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Insertional Mutagenesis and Autoimmunity Induced Disease Caused by Human Fetal and Retroviral Residual Toxins in Vaccines

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Objectives

- Understand vaccine manufacturing and cell substrate residual contaminant levels.
- Gain knowledge regarding species specific insertional mutagenesis and autoimmunity.
- Understand the relationship of these pathological processes to current childhood disease epidemics including autistic disorder, leukemia, lymphoma, intellectual disability, schizophrenia and bipolar disorder.

Introduction

Major concern of vaccination regarding childhood diseases in terms of Insertional Mutagenesis and Autoimmunity

The potential consequences of injecting our children with human fetal DNA contaminants include two well-established pathologies:

1) Insertional mutagenesis in which fetal DNA incorporates into the child's DNA causing mutations.

2) Autoimmune disease triggered by the human fetal DNA in vaccines leading a child's immune system to attack his or her own body.

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Vaccines

United States manufacturing process and vaccine history of using human fetal cell lines:

- In January 1979, the rubella manufacturing switch from animal based to the human fetal cell line WI-38 was approved by the FDA. A newly approved monovalent rubella vaccine and a trivalent mumps, measles and rubella vaccine both utilize the WI-38 fetal cell line for manufacturing.
- In November 1987 a human fetal cell line manufactured polio vaccine was FDA approved, which was discontinued in the US after 1991.
- In 1989, a second dose of trivalent fetal manufactured vaccine against mumps, measles and rubella was recommended for children at 12 months or older, and a measles vaccination compliance campaign was launched that doubled trivalent fetal manufactured mumps, measles and rubella vaccination rate.
- In 1995, a vaccine against chickenpox that was manufactured using the human fetal cell lines WI-38 and MRC-5 was approved by the FDA.

In general, a vaccine is a vial that contains a virus or a subunit of a virus, a liquid buffer, and contaminants from the cell line that was used to manufacture the virus. Some vaccines also contain preservatives or adjuvants, such as thimerosal or salts of aluminum. The viruses to be used in the vaccines are manufactured in cells or cell lines because they are too large to be made economically through synthetic means. Therefore, the manufacturers take advantage of the natural way that viruses replicate by infecting cells or cell lines with the virus and then harvesting the virus after it has replicated itself thousands or millions of times over.

Concerns regarding human derived cell lines for manufacturing

A cell line originally comes from a live animal or organism (the primary cells), but then genetic modifications are made in many cases to the primary cells such that they become long-lived and can be grown in the laboratory for years and even decades without having to go back and get more primary cells from the animal or organism. When the source that the cell line was ultimately made from was an electively aborted fetus, the manufacturers call these “human diploid cell lines.” Currently, if you see these words on the package insert of a vaccine or a drug, or listed in the ingredients of a cosmetic, the cell line was derived from an electively aborted baby. For example, HEK293 was derived from the kidneys of an aborted fetus and immortalization was accomplished by transformation with Ad5 E1A and E1B gene functions (adenoviral DNA). MRC-5 or WI-38 are examples of two fetal cell lines used for vaccine manufacture that were derived from embryonic lung that have not been immortalized and possess only a finite life span (~50 population doublings).[1]

WHO/FDA guidelines and threshold

In early guidance meetings, regulatory agencies and experts initially argued for a recommended limit of 10 pg contaminating cell substrate DNA per dose,[2] which was later on relaxed to 100 pg in 1986 (World Health Organization Study Group; Geneva).[3] After another change based on a WHO meeting in 1997, the currently recommended maximal amount of residual cell-substrate DNA per dose in a vaccine produced in a continuous cell line is 10 ng.[4] Neither limit was based upon empirical study or data to justify the guidance.

Excerpt from the FDA Briefing Document September 19, 2012 (p 25):

> Vaccines and Related Biological Products Advisory Committee Meeting
>
> The value of 100 pg of host cell DNA per vaccine dose remained the recommended standard for a decade. However, the issue was revisited in 1997 for several reasons. First, vaccine manufacturers could not always meet this level of residual cell-substrate DNA for some viral vaccines, such as with certain enveloped viruses. Second, more information was available as to the oncogenic events in human cancers, where it has been established that multiple events, both genetic and epigenetic, are required.*[5-9] And third, for continuous non-tumorigenic cell lines such as Vero, the major cell substrate that was being considered at the time, the presence of activated dominant oncogenes in these cells was unlikely. The outcome of the 1997 WHO meeting was that the amount of residual cell-substrate DNA allowed per dose in a vaccine produced in a continuous cell line and one administered by the parenteral route was raised from 100 pg to 10 ng.*[10] (*reference numbering changed for this publication)

Fragmentation of fetal derived DNA

The same FDA Briefing Document (2012) advises (p 17, 18):

> The oncogenic and infectious risk of residual DNA in vaccines can be reduced by the implementation of manufacturing steps designed to lower the amount of DNA, decrease the size of the DNA, and/or to reduce the activity of residual DNA by chemical treatment or gamma irradiation. … Current recommendations are that the level of residual cell-substrate DNA should be ≤10 ng per dose and a median DNA size of 200 bp or lower.
>
> Summary: Although current testing recommendations include evaluation of the oncogenicity of host cell DNA and cell lysates in vivo, *the oncogenic and infectious risk of DNA is primarily addressed by lowering the amount of DNA*, decreasing the size of the DNA (by nuclease digestion), and/or by reducing the activity of the DNA (by chemical treatment or gamma irradiation).

Content of human fetal DNA in several vaccines above WHO/FDA threshold

The only monovalent rubella vaccine available in the U.S. until 2011 (discontinued), was manufactured using the human diploid cell line WI-38 and contaminated with greater than 150 ng cell substrate DNA (sum of dsDNA and ssDNA) per dose, fragmented to approximately 215 base pairs in length. 150 ng of DNA is equivalent to the total amount of DNA in over 22,000 cells. Additionally, this vaccine was contaminated with fragments of the HERVK retrovirus. Another example is a hepatitis A vaccine that is manufactured using the human diploid cell line MRC-5 and is contaminated with more than 300 ng cell substrate DNA (dsDNA + ssDNA) per vaccine dose.[11] The chickenpox vaccine available in the US is contaminated with greater than 2 µg fetal MRC-5 DNA, according to the manufacturer's measurements.[12]

Recommendations to fragment the contaminating DNA were based on concern that an entire cancer causing gene might be present among the fetal DNA contaminants. However, science has demonstrated that in contrast to the integration of large DNA gene lengths, integration of short DNA fragments has been shown to be much more efficient. Integration is maximal when fragments are between 100 and 1000 base pairs in length.[13-14] Therefore, the recommendations to fragment the contaminating DNA may have increased the danger of the contaminants.

Fetal DNA vaccine contaminants have the potential to cause Insertional Mutagenesis

Mammalian cells can take up extracellular DNA fragments by receptor mediated endocytosis. Uptake is most efficient at low concentrations of extracellular DNA[15] and peaks 2 hours after addition of the DNA fragments to cell culture.[16] In the extracellular concentration range of 0.1 to 7 µM, oligonucleotides (small bits of nucleic acids) readily enter cultured cells through receptor mediated uptake,[17-20] reaching intracellular and nuclear [17, 21-23] concentrations which equal or exceed that of the extracellular medium within 2-4 hours.[24] Empirical experiments have shown that addition of placental DNA fragments of 500 base pairs in length contributed approximately 4% of a cell's genomic content per hour of incubation — roughly 40-50% of fragmented DNA added to cell culture will be taken up by a cell and 10-20% of the added DNA will be delivered to the nucleus, demonstrating the rapidity with which DNA can enter a cell.[15]

Insertional Mutagenesis and Autism Spectrum Disorders

Contaminating fetal DNA fragments might be inserted into a child's genome causing subsequent mutations during the normal process of double strand break repair (DSB). Indeed, it has been demonstrated that genes involved in DSB are differentially expressed in ASD.[25] Faulty DSB is known to be involved in many diseases.[26] DSBs occur both in somatic and germ line cells, and can be programmed, such as in somatic cells for immunoglobulin hypermutation and class switching, or the result of DNA replication, spontaneous DNA hydrolysis or cellular metabolism.[27-28] Toxins and chemotherapeutics can be inducers of DSBs in somatic cells. In the case of various lymphomas, we know that the addition of a toxin or chemotherapeutic induced DSB on top of a programmed class switching DSB leads to cancer.[28] In summary, this research reveals that the genetic susceptibility of some children to the development of ASD is due to the genes involved in DSB being differentially expressed (i.e. not normal). Together with the presence of recombination hotspots in genes that have been associated with ASD, these differentially expressed DSB genes constitute an underlying predisposition to development of ASD as a result of insertions of fetal DNA. Thus, children with this genetic condition (abnormal DSBs) are extremely susceptible to such insertions.

Meiotic recombination (MR) involves highly regulated pathways of double strand break (DSB) formation and repair. MR occurs at clustered sites within the human genome, termed recombination hotspots, the vast majority of which are located outside of genic regions,[29] presumably to reduce the potential for lethal results after MR. Interestingly, sites of MR/HR (homologous recombination) have been demonstrated to be further susceptible to additional DSBs and mutations.[30-32] Over 350 genes have been associated with autism spectrum disorders. Genomic anomalies include common genetic variations,[33] changes in chromosomal structure,[34] and rare mutations.[35] Recently, *de novo* deletions and duplications have been identified in up to 10% of simplex autism spectrum disorders, indicating environmental influences on the genetics of autism spectrum disorders.[36-37] 10% may well under-represent *de novo* mutations (DNM) as methods are limited to detecting large *de novo* CNVs (copy-number variations) and do not fully capture smaller mutations.[38] Furthermore, each specific mutation is found in only a very small percent of cases, highlighting the complexity of genomic impacts on autism spectrum disorders and the challenge of understanding the *de novo* mutation process. Network mapping is revealing downstream links between these diverse genomic mutations and autism spectrum disorders phenotype,[39] yet we do not understand the process by which diverse genomic sites are targeted for mutation. However, recombination hotspots are concentrated in the genes that have been associated with autism, and may contribute an underlying susceptibility to mutations in those genes when presented with fetal DNA fragments.[11,40] Altered double strand break formation and repair pathways (DSB) may be a commonality among the extremely diverse genetic mutations observed in autism spectrum disorders. Unfortunately, the focus of concerns amongst scientists in academia, in industry and at the FDA has been on the potential of residual DNA for oncogenicity or infectivity, not on the potential for the induction of subsequent gene mutations following genomic insertion of DNA fragments, although this danger was indeed discussed during a 1999 FDA workshop entitled "Evolving Scientific And Regulatory Perspectives On Cell Substrates For Vaccine Development."[41] Numerous studies have established the ability of species specific DNA to accumulate intracellularly and insert into a host's genome at an appreciable rate, especially as DNA fragments in the form of very small chromatin-like particles (natural "DNA nanoparticles").[42-43]

Insertional mutagenesis and other neurodevelopmental disorders

Beside autism spectrum disorders epidemic, there are also apparent epidemic levels of other early onset neurodevelopmental syndromes such as childhood onset schizophrenia (0.4% of population affected),[44] and bipolar disorder.[45-46]

The continued or rising prevalence of these early onset neurodevelopmental diseases despite the reduced reproductive fitness associated with them implies important non-heritable genomic and environmental components to the diseases.[47] Accumulating evidence from family-based exome sequencing approaches published over the past several years points to the importance of *de novo* mutations in these diseases that include simplex autism disorder and autism spectrum, schizophrenia and intellectual disability.[48-56] Hundreds of rare, *de novo* mutations have been identified in individuals with autism disorder or intellectual disability that are related by involvement in large functional networks of genes.[50,57] In the case of schizophrenia, this network involves the glutamatergic systems, and in the case of autism disorder the network involves genes which are important for the formation and function of synapses. The literature is divergent with regards to whether DNMs are found at a higher rate with disease versus the general population. While the rate of DNMs is not uniformly reported as elevated compared to non-diseased children,[58] the DNMs in these diseases are consistently found in exons or critical coding regions of genes that would lead to premature stop or non-functional proteins.[50,51,59] Other investigators, such as Awadalla, found an excess of DNMs in autism and schizophrenia,[49] and the DNMs identified by Hamdan et al., which disrupted protein function in children with intellectual disability were not present in healthy controls.[60] In contrast to the slight increase in DNMs found in children with neurodevelopmental disease, *de novo* genomic insertions and deletions are significantly increased in childhood onset schizophrenia or autism disorder compared to healthy controls (0% versus 10%).[51,55,61]

Vaccines containing HERVK

Human endogenous retrovirus K (HERVK), a contaminant in some of the chickenpox and measles/mumps/rubella vaccines[62] is a retrovirus that integrated into human germline cells relatively recently in human evolution and is inherited in a Mendelian fashion as an endogenous retrovirus. Such retroviruses are generally inactive. Thus, experts have considered the presence of endogenous retroviruses in the human genome to be innocuous. However recent evidence has shown that HERVK can be reactivated[63-66] or even maintain its activity in present day humans[67] and integrase activity from homologous HERVK sequences has been reported.[64] Active HERVK integrates preferentially in transcription units, in gene-rich regions, and near features associated with active transcription units and associated regulatory regions.[68]

Recent evidence has shown that HERVK transcripts are elevated in the brains of patients with schizophrenia or bipolar disorder[69-70] and in the peripheral blood mononuclear leucocytes of patients with autism spectrum disorders.[71] This retrovirus has also been associated with several autoimmune diseases.[72-74] HERVK is in the same family of retroviruses as the MMLV[75] virus used in a gene therapy trial, in which inappropriate gene insertion led to subsequent additional somatic mutations and cancer in 4 of 9 young boys.[76] The HERVK gene fragment present in vaccines more likely than not codes for the integrase or the envelope protein, thus is active and induces gene insertion[64] or neuroinflammation.[77-78]

Example of Insertional Mutagenesis in patient cases

In an early gene therapy trial, the experts with the FDA's Gene Therapy Division estimated that the risk of retroviral and human DNA fragment induced mutations and cancer was 1 in a trillion. Tragically, when they gave the retroviral and human DNA fragments to boys with SCID disease in a gene therapy trial, 4 out of 9 (44%) of the boys developed leukemia.[76] 44% is a lot higher than the FDA's estimated risk of 1 in a trillion.

Autoimmunity

Cause (fetal human DNA fragments)

Scientists have found that children with autistic disorder have antibodies against human DNA in their blood that non-autistic children do not have. These antibodies may be involved in autoimmune attacks in autistic children.[79-81]

Exposure of a child to fragments of human fetal (primitive) non-self DNA could generate an immune response that would cross-react with the child's own DNA, since the contaminating DNA could have sections of overlap closely similar to the child's own DNA.

Antibody measurements in the serum of autistic versus healthy age and sex matched controls demonstrated significantly higher percent positivity of serum antineuronal antibodies (62.5%) than healthy controls (5%). Moreover, the frequency of the presence of these antibodies was significantly higher in female children with autism (90%) than male autistic children (53.3%; 60 males and 20 females; ages range between 6 and 12 years.)[79]

Increased by number of administered vaccines with fetal DNA contaminants and frequency of injections thereof

With the current ACIP and statewide vaccination recommendations, children may be exposed to as many as 7 or more fetal DNA contaminated vaccines before they are 2-3 years old, compared to only 2 vaccines containing fetal DNA in the early 1990s. During the period from birth out to three or more years, human brain development is an active process, with neural circuits being established, pruning of unused dendritic synapses going on, and nerve cell death occurring on a massive scale.[82-83] During periods of intense brain cell death such as this, DNA not otherwise found extracellularly would be present and serve as the target for autoimmune attacks, originally triggered by exposure of a young child to the fetal DNA fragments found in vaccines.

Summary

1. Contaminating DNA levels in the rubella, mumps-measles-rubella, chickenpox and some hepatitis A vaccines available in the US well exceed the current World Health Organization guidance of less than 10 ng cell substrate DNA per vaccine dose.
2. The DNA of the aforementioned rubella vaccine was fragmented into short pieces of approximately 215 base pairs (in average) in length, a length ideal for cellular uptake and genomic integration.

3. Some of the chicken pox and measles/mumps/rubella vaccines are also contaminated with fragments of the Human Endogenous Retrovirus K (HERVK), a retrovirus that invades the genome of its host, can be re-activatable and which can facilitate the integration of stray DNA into the host's genome.
4. Short DNA fragments are known to integrate into the genome in a species specific manner and can lead to mutagenesis and/or genomic instability as well as an autoimmune response.
5. The vaccine schedule exposes young children to insertion of fetal DNA fragments during a time of significant brain development.

The dangers of retroviral fragments as well as residual human diploid DNA are an unstudied risk to vaccine recipients, and yet, the overwhelming body of scientific literature clearly demonstrates the high likelihood of autoimmune and/or insertional mutagenesis dangers from these contaminants. This is an issue that undoubtedly cries out for serious epidemiological and scientific investigation. SCPI is currently conducting a study to provide further clinical proof for autoimmunity caused by fetal DNA found in vaccines (see Addendum at the end of this publication for additional details).

Recommendations

- *Disclosure* of fetal DNA quantities in vaccine package insert.
- *Alternatives* that are already available and manufactured in other countries.

Vaccines can be safely and effectively manufactured in animal, insect or plant based cell lines, eliminating the dangers of residual human DNA and retroviral contaminants:

A rubella vaccine available in Japan, which is based on Takahashi strains of live attenuated rubella virus, *is produced on rabbit kidney cells*. A single dose of this vaccine has been recently proven to retain immunity for at least 10 years when rubella was under regional control.[84]

Addendum

Further clinical proof or currently conducted studies for autoimmunity and insertional mutagenesis caused by human fetal DNA found in vaccines

Autoimmunity

During the past several years multiple scientific publications have demonstrated that approximately 40% of children with simplex autism have immune responses to neural tissue and more importantly, to human DNA that typically developing children do not have.[79-80, 85-87]

SCPI is currently conducting an Institutional Review Board approved observational clinical trial, in collaboration with Dr. Karin Burkhard, M.D., to determine whether children with autism also have immune responses to the specific human fetal contaminants found in the suspected childhood vaccines. Dr. Burkhard is a psychiatrist in Hauppauge, NY, who received her medical degree from the Geisel School of Medicine at Dartmouth and has been in clinical practice for more than 20 years. We have already enrolled 20 autistic and 20 typically developing children for this study, which will determine the immunity for each individual child to the following:

- general human DNA,
- the specific human fetal DNA from cell lines MRC-5 and WI-38, and
- their own DNA (autoimmunity)

Evidence for immunity to the human fetal DNA contaminants as well as autoimmunity to the children's own DNA will provide compelling proof for the dangers of using human fetal cell lines to manufacture vaccines due to the reasons presented in this publication.

Insertional Mutagenesis

It seems reasonable that the fetal contaminants in vaccines could cause a disease like cancer, because cancers are known to start due to a mutation in just one cell, but how could a mutation in one cell cause a diffuse neurodevelopmental disorder like autism?

Cancers such as lymphoma and leukemia are known to be clonal. Clonal means that all of the cancer cells arise from a single mutated cell. Typically, the originating cell will have a mutation that gives it a survival advantage over other cells. While it makes sense that a single cell could take up the human fetal DNA contaminants found in vaccines, undergo insertional mutagenesis and lead to cancer, it seems less obvious how a single cell could lead to a diffuse neurodevelopmental disease like autism. Well, the field of hematology has shown that our blood system is largely clonal.[88-89] We have trillions of blood cells in our bodies, however, it turns out that just a very few blood stem cells are active and make all those trillions of blood cells.

How could a mutation in a hematopoietic stem cell (HSC) cause problems in the brain? Glial cells found in our brains are generated from the differentiation of HSCs in our bodies. HSCs circulate periodically and then return to the bone marrow. While circulating, one of these stem cells could readily take up human fetal DNA fragments causing insertion into the cell's DNA and a mutation, as small fragment homologous recombination has taught us, readily happens in blood forming stem cells.

What this means is that while we have millions of stem cells, in most people only 7 or 8 stem cells are actively making all the trillions of blood cells in our bodies. In many people, only 1 or 2 stem cells make up to 90% of the trillions of blood cells in our bodies, which means a mutation in a single blood stem cell, which typically gives the mutated cell a survival advantage as seen with cancer, could result in 50% or more of our blood cells carrying the same mutation. Furthermore, the glial cells that populate our brains can be replaced during life with new glial cells from the blood. If those replacing glial cells are formed by a mutated blood stem cell, then the glial cells in the brain could carry a dominant mutation. Mutated glial cells in the brain could cause a diffuse abnormal immune activity in the brain, and glial cells are also known to be critically important for nerve cell signaling.

Thus, a mutation in a single blood stem cell is quite probable when children receive human fetal DNA contaminants in their vaccines. Such a mutation would give that cell a survival advantage, and that mutated cell could produce trillions of mutated blood cells that would subsequently populate the brain's glial compartment and lead to diffuse abnormal brain function in these children. This mechanism appears to be the cause of simplex autism in about 60% of children, while the other 40% appear to have an autoimmune mediated regressive autism.

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Gender Identity Issues in Children and Adolescents

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Infants are assigned a gender in various ways. Most often assignment is made in the delivery room where it is common to hear "It's a boy!" or "It's a girl!" Prenatal genetic testing allows for pre-delivery determination. Ultrasound assessment of genitalia in the second and third trimester is also used. And to the parents and close family friends, facial and familial characteristics make some offspring unmistakable: "that's my boy - a spittin' image of the old man."

There are disorders of development of sexual identity. Some of these disorders have a physical basis, and some have a psychological disorder of development and self-identity. The physical disorders of sexual development are rare, and can make identification of male or female difficult.

Physical Disorders of Sexual Development

Examples include:

1. Male pseudo-hermaphrodite (the underdone male)
2. Female pseudo-hermaphrodite (the virilized female)
3. Mixed Gonadal Dysgenesis
4. True hermaphrodite
5. XX maleness
6. Cloacal defect

Male Pseudo-Hermaphrodite

These are genetic male infants who have a deficient response to androgens in utero. This deficient response can come from underproduction of androgens or from defects in androgen receptors.

Underproduction of androgens in utero comes from either of two different enzyme deficiencies: 17-hydroxylase deficiency or 22-desmolase deficiency. The adrenal and the gonad are lacking in the ability to convert androgen precursors to more effective forms of these hormones and so the expected virilization of the androgen-sensitive anlage does not occur completely.

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Defects in androgen receptors result in an inability of the genetically male fetus to respond to the masculinizing effects of testosterone. The testicle still produces Anti-Mullerian hormone which regresses the uterus, fallopian tubes and the upper third of the vagina, but the lack of active stimulation of testosterone and its important metabolite, di-hydro-testosterone causes the external genital structures to remain in a female configuration. In the case of complete androgen insensitivity there is never any change in tissue response and the patient is reared as a female. In the case of partial androgen insensitivity, virilization may occur with the onset of puberty, and the patient may choose to be reared subsequently as a male.

Female Pseudo-Hermaphrodite

Patients with these disorders are genetically female, but have different degrees of virilzation due to excess androgen exposure in utero.

Diagnoses here include congenital adrenal hyperplasia due to 21-hydroxylase deficiency which causes the female fetus to virilize the external genital structures to varying degrees depending on the degree of enzyme deficiency. Another possible diagnosis is transient production of androgens by the mother which cross the placenta and partially virilize the female structures prenatally.

In contrast to the pseudo-hermaphrodite male and female, there are genetic disorders that lead to ambiguity or disorders of sexual development. These include mixed gonadal dysgenesis, true hermaphroditism, and XX maleness.

Mixed Gonadal Dysgenesis

Also known as X0/XY mosaicism, mixed gonadal dysgenesis is a mosaicism of the sex chromosomes (45,XO/46,XY mosaicism). Mixed gonadal dysgenesis is a rare disorder of sex development in humans. Depending on the gonadal chromosomal complement, the phenotype can be either that of a male or of female with a Turner syndrome (45 XO).

True Hermaphroditism

True hermaphroditism is defined as the simultaneous presence of both ovarian and testicular tissue within the same individual. The most common peripheral karyotype was 46, XX but other karyotypes such as 47, XXY and mosaicism 46, XX/46, XY or 46, XX/47, XXY can be found. The birth phenotype is generally female but with ambiguous genitalia. The ovarian tissue is frequently functional, but the testicular tissue is rarely functional. This presents the appearance of some degree of virilization of the genital anlage with development of breast tissue once puberty occurs.

XX Maleness

The phenotype of XX males is masculine, albeit with smaller penis and testes. The genotype is 46 XX, with some additional genetic material on one arm of the X chromosome. XX males usually have normal male genitalia, small azoospermic testes, and hypergonadotropic hypogonadism.

Other Reasons for Ambiguous Genitalia

Multifactorial etiologies of ambiguous genitalia include congenital Cloacal defects (which are multifactorial), wherein the genital structures are missing or malformed due to disruption of the normal migration of the anlage for the bladder and/or the rectum. These malformations are not the result of hormonal signaling. There are rare cases of iatrogenic mutilation such as failed circumcision.

The above summarize the physical reasons for ambiguities in sexual morphology. But these physical disorders are distinct from the psychological disorder known as "Gender Identity Disorder."

Gender Identity Disorder (GID)

Gender Identity Disorder is a term coined by Dr. Kenneth Zucker. Zucker is a clinical psychologist who established a landmark clinic in Toronto where he treated over 500 children and adolescents with gender discordance. His dedication to the patients and their families was centered on the plan to realign the gender identity with the biologic sex whenever possible. He authored the definitive chapter on Gender Identity Disorders in the most respected textbook on *Child and Adolescent Psychology*. His works are widely published and he is considered world-wide as an authority on the subject. Gender Identity Disorder was classified as a DSM-IV diagnosis, and against Dr. Zucker's protestations, it was re-classified as Gender Dysphoria to eliminate the concept of gender discordance as pathologic and to instead classify the suffering from lack of acceptance as the pathologic disorder. Zucker's clinic was recently shut down by pressure from LGBT activists.

The definition of GID is that the patient believes that they are born into the body of the wrong sex. Thus GID presents often when parents or the primary care provider note behaviors stereotypic of the opposite sex, for example boys playing with dolls, or boys who fantasy play in roles of female heroes and villains. In girls, parents may note girls who wear short hair and prefer boy's clothing, and who mimic "tough guy" play.

Parents, relatives and peers frequently provide abundant negative feedback. There is often a background of significant psychopathology in one or both parents. There are numerous co-morbidities which occur from young childhood onward due to the parental and societal disapproval, and there is often significant family disruption.

The natural history of childhood GID is spontaneous resolution. 80-98% of GID resolves when the patient reaches adolescence and experiences the effects of their innate pubertal hormones. Some will persist with same sex attraction. Adaptation can be mentally healthy but it can also be a mental health nightmare. Some live a heterosexual lifestyle or bisexual lifestyle with or without psychological morbidity.

The Role of Psychotherapy

Competent therapists can evaluate the family and the patient and unearth any primary pathology. Subsequent therapy should present the known facts and all options.

There is clearly an opportunity to "recruit" the gender change option in the pre-adolescent if the therapist has such an agenda.

Use of Gender Identity Disorder as an Opportunity for Recruitment to Alternative Lifestyles

The transgender community has a worldwide organization, WPATH, which promulgates the idea that humans are born transgender and that these transgendered people have civil rights as a class of individuals. WPATH holds conferences internationally, nationally and regionally to promote its ideology. WPATH maintains a bibliography for use by its members to help provide testimony for legal battles. It developed "standards of care" for transgender medical treatment. It provides "expert opinion" for the mainstream medical societies which are so focused on political correctness that they accept these opinions without any credible scientific scrutiny. These networking efforts then encourage the professional societies to write policy guidelines which are sent to Educators, government agencies, and to physicians. Their dogma is that gender must be taught to children as a spectrum, not as male or female and that this education should begin in kindergarten, if not pre-school. They promote early cross-dressing, and are the major behind-the scenes pushers of anti-bullying campaigns. People who question the validity of innate transgenderism are labeled as racists, and the transgendered are coddled as victims.

In response to the Endocrine Society's creation of Guidelines for treatment of transgendered persons published in 2009 with input only from WPATH sympathizers, and with purposeful exclusion of anyone likely to disagree, there has been an exponential increase in the number to so-called "Centers of Excellence for Transgender Care" in this country. Before 2009, there were essentially two centers in the U.S. and now there are nearly fifty. Most of these entities are sponsored by medical universities who are also busy simultaneously creating curricula to teach the WPATH dogma.

Let us examine the 2009 Guidelines from the Endocrine Society. Because of the specific lack of dissenting individuals, there is little science to back up the 22 recommendations. Only three of the recommended guidelines are considered to be based on a moderate degree of valid evidence. Those three statements outlined the necessary concerns raised by suppression of puberty, the use of cross-gender hormones and the concern about long-term psychological outcomes. The remaining 19 recommendations where nearly evenly split between no basis in science and very little basis in science. To summarize the suggested recommendations:

1. Look for any psychologic issues and treat with supportive care.
2. Support the child and patient in their wished-for gender role.
3. Suppress puberty once it has started and then offer cross-gender hormone therapy.
4. At the age of consent, offer surgical alterations if that is desired by the patient.
5. Watch out for complications associated with blocking puberty and using cross-gender hormones.

Unlike the above recommendations, for disorders of sexual differentiation (DSD), there are thoughtful, well-crafted, scientifically valid guidelines which were developed and carefully revised recently. These guidelines serve as a compass for those rare cases where gender assignment is not clear. This is in clear contrast to the guidelines published by WPATH and subsequently by the Endocrine Society which are not applicable in any way to the DSD population.

What We Should Have Learned From the Past

Johns Hopkins became a world-wide referral center for patients with DSD because of the clinical and bench research performed there in the 1960's-1980's. There was a wealth of patients with genital development disorders and a desire to improve the plight of infants undergoing surgery with a move toward GYN and away from Urology with a goal of providing better sexual functional anatomy. In parallel with the surgical intervention was the assessment of psychological aspects under the auspices of John Money, PhD. He was the head of the Psycho-hormonal Group, a division of the Department of Psychiatry at Johns Hopkins. His methodology was to have a theory and then to apply that theory to actual patients with no boundaries or controls and see what happened. His medical references were essentially conversations with fellows in the pediatric endocrine program and publications by his colleagues Alfred Kinsey and Harry Benjamin. The transcriptions of his interviews with children contained information that pointed to a complete lack of scientific method and to outright indoctrination of the patients. In one instance, a six-year-old boy with precocious puberty was asked how often he masturbated, and when the child didn't understand the concept, it was explained to him in great detail. At the next patient encounter, the boy freely admitted to masturbating multiple times daily. Money had decided that all amputees viewed the stumps of their remaining limb parts as a phallus with which to masturbate, and presented a conference about this to the endocrine fellows. When his theory was questioned on the basis of known orthopedic clinical experience from traumatic war injury, he decided to change the subject. Money began to run into trouble with outcomes of his clinical advice. The most well-known of his travesties was the case of the boy whose penis was burnt off accidentally with a bovie knife during an attempt to cauterize a bleeding point from circumcision. This boy was surgically changed in infancy to appear as a girl and was raised as such until early puberty when he was told of his medical history when he persisted in his feelings of being a boy. He decided to live as a male but subsequently committed suicide as an adult. Money ran the adult trans-sexual program at Hopkins. The pediatric endocrine fellows had the experience of caring for these patients, watching them first cross-dress, then receive cross-sex hormones, and then undergo surgical revision. Enter Dr. Paul McHugh, a new Psychiatrist-in-Chief. Dr. McHugh reviewed the final outcome of the patients. All suffered from depression and maladjustment. Many acted as caricatures of their new gender. Because of the failures that began to materialize from Money's ideology, the Psycho-hormonal group was abolished and Money was forced into retirement.

A Better Approach

The young child with GID, and the child's family, should be evaluated extensively by a competent therapist without an agenda to recruit to a transgender lifestyle. The child should be reared as his or her biologic sex. The pubertal adolescent should be re-evaluated for gender identity once endogenous sex hormones have had opportunity for manifestation in that individual with the strong likelihood of return to consensus with biologic sex. If such is not the case, the consenting adult patient (age 18 or older) should have the opportunity to interface with adults who have been treated medically and/or surgically but who have subsequently returned to their biological sexual identity. Only under these circumstances can there be a truly informed consent.

We are in the process of requiring the medical community and the rest of society to adapt the whole environment around a new and burgeoning class of children, adolescents and adults with a mental disorder.

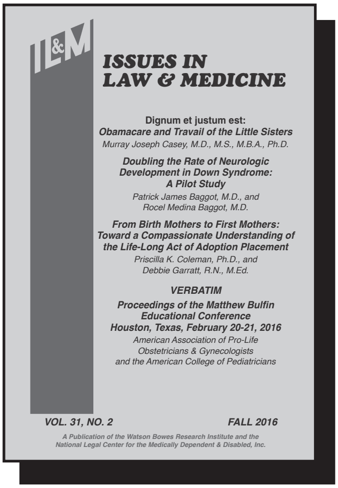
Dr. Paul McHugh aptly stated that treating a patient with gender identity disorder with hormones and surgery is akin to treating a patient with anorexia nervosa with diet and liposuction.

Novi Libri

Novi Libri

Watt, Helen. *The Ethics of Pregnancy, Abortion and Childbirth: Exploring Moral Choices in Childbearing*. New York: Routledge, 2016.

The Ethics of Pregnancy, Abortion and Childbirth addresses the unique moral questions raised by pregnancy and its intimate bodily nature. From assisted reproduction to abortion and “vital conflict” resolution to more everyday concerns of the pregnant woman, the book argues for pregnancy as a close human relationship with the woman as guardian or custodian. If the status of the fetus is conclusive for at least some moral questions raised by pregnancy, so too are facts about its bodily relationship with, and presence in, the woman who supports it. The pregnant woman is not a mere “neighbor” or helpful stranger to the fetus but is rather already in a real familial relationship bringing real familial rights and obligations.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