8 HOUS. J. HEALTH L. & POL'Y 195-205

ISSN 1534-7907

FOREWORD

Jennifer L. Rosato, J.D.*

In some ways, medical decision making for children and adolescents reflects the broad and well-recognized issues that arise in any legal context involving children. Those issues include: What should be the scope of parental authority over their children? What autonomy (if any) should children have to make their own decisions? To what extent should the state (through its legislators or judges) be permitted to interfere with parental decision making?

Although these issues are constantly debated, they are far from being resolved. In general, parents possess the right to care for, maintain custody of, and exercise control over their children and are presumed to know what is best for them.[1] The right to parent is assured through both common and constitutional law, as well as federal and state statutes.[2] The state has a limited ability to interfere with parents' decisions—usually when the child has been subjected to harm by the parent (e.g., abuse or neglect).[3] Most recently, the

* Senior Associate Dean for Student Affairs and Professor of Law, Drexel University Earle Mack School of Law.

1 Troxel v. Granville, 530 U.S. 57 (2000) (acknowledging the presumption that fit parents act in the best interests of their children).

2 *See* Kimberly M. Mutcherson, *No Way to Treat a Woman: Creating an Appropriate Standard for Resolving Medical Treatment Disputes Involving HIV-Positive Children*, 25 HARV. WOMEN'S L.J. 221, 246-55 (2002) (analyzing cases in which the state sought to interfere with the relationship between a child with a life-threatening disease and the parent).

3 *See, e.g.*, Clare Huntington, *Rights Myopia in Child Welfare*, 53 UCLA L. REV. 637, 638 (2006) (noting that state intervention to protect a child's right to be free from abuse and neglect may be essential in some cases, but comes at a high cost to the child in welfare cases); *see Troxel*, 530 U.S. at 68 (noting that as long as the parent is fit, "there will normally be no reason for the State to inject itself into the private realm of the family").

limits of state interference were illustrated dramatically when the state of Texas removed 450 children from the Yearning for Zion ranch. The state suspected widespread harm to the children based on the sect's polygamous practices; however, the state supreme court later forced the state to return those children because it failed to show individual harm to the particular children removed.[4]

Children do possess a right to autonomy, but it can be seen as a junior version of the right that is often trumped by the rights of the parents or the interests of the state.[5] For example, children possess free speech and reproductive rights, but the state may interfere more readily with these rights than with the corresponding constitutional rights of adults.[6] Adolescents are permitted to exercise the right, but only in limited circumstances.[7] These circumstances are based on conduct or subject (e.g., driving), status (e.g., married or emancipated), and maturity.[8] In the end, the state of the law relating to children remains unpredictable and the result of an individual case or conflict depends on the resolution of competing rights in a particular context.[9]

The resolution of these conflicts in the context of medical decision making is rendered even more difficult by constantly evolving medical innovations that the law is ill-prepared to address. The technologies addressed by the articles in this volume include the growth attenuation of a severely disabled child, which prevents a child from achieving puberty;[10] preimplantation genetic diagnosis (PGD), which permits potential parents to choose to implant embryos

---

4 In re Steed, No. 03-08-00235-CV, 2008 WL 2132014 (Tex. App.—Austin, May 21, 2008) (per curiam); *see also* Dan Frosch, *Court to Hear Challenge on Sect Children*, N.Y. TIMES, April 25, 2008, at A18.

5 *See* Kimberly M. Mutcherson, *Whose Body is it Anyway? An Updated Model of Healthcare Decision-Making Rights for Adolescents*, 14 CORNELL J.L. & PUB. POL'Y 251, 259-60 (2005).

6 *See, e.g.*, Hazelwood School District v. Kuhlmeier, 484 U.S. 260 (1988); *Carey v. Population Services International*, 431 U.S. 678, 693 (1977).

7 Larry Cunningham, *A Question of Capacity: Towards a Comprehensive and Consistent Vision of Children and Their Status Under Law*, 10 U.C. DAVIS J. JUV. L. & POL'Y 275, 334-35 (2006).

8 Jennifer Rosato, *Let's Get Real: Quilting a Principled Approach to Adolescent Empowerment in Health Care Decision-Making*, 51 DEPAUL L. REV. 769, 776-77 (2002).

9 *Id.* at 795.

10 Alice R. Ouellette, *Growth Attenuation, Parental Choice, and the Rights of Disabled Children: Lessons from the Ashley X Case*, 8 HOUS. J. HEALTH L. & POL'Y 207 (2008).

that possess desirable genetic traits;[11] and new drugs prescribed for children, whether based on FDA approval or off-label use.[12] Other technological advances raising similar ethical and legal concerns include separation of conjoined twins;[13] sexual surgery on babies born with male and female sexual organs;[14] and gene therapy.[15]

There are a number of reasons why the law relating to children's medical decision making is undeveloped, unsettled, and seemingly incoherent. Technology usually develops far ahead of consideration of its ethical and legal consequences.[16] And even if consideration of these consequences could be made in advance, consensus would be difficult to attain because doing so requires us to address core ethical issues, such as when life begins[17] or who is a parent[18]—issues in

---

11 Susannah Baruch, *Preimplantation Genetic Diagnosis and Parental Preferences: Beyond Deadly Disease*, 8 HOUS. J. HEALTH L. & POL'Y 245 (2008).

12 Ralph F. Hall and Tracy A. Braun, *Leaving No Child Behind? Abigail Alliance, Pediatric Products and Off-label Use*, 8 HOUS. J. HEALTH L. & POL'Y 271 (2008).

13 *See* Robin Jane Effron, *Dependence, Identity, and Abortion Politics*, 1 N.Y.U.J.L. & LIBERTY 1108, 1113 (2005) (discussing the factual back ground and ethics issues involved in a controversial British case involving the separation of conjoined twins); *British Doctors Begin Surgery to Separate Conjoined Twins*, N.Y. TIMES, November 7, 2000, at A14.

14 Kate Haas, *Who Will Make Room for the Intersexed?*, 30 AM. J.L. & MED 41, 57-60 (2004) (discussing when, and to what extent, the government may interfere with a parent's decision to perform surgery on intersexed children).

15 *See* Food and Drug Administration, FDA Talk Paper, FDA Places Temporary Halt on Gene Therapy Trials Using Retroviral Vectors in Blood Stem Cells (Jan. 14, 2003), *available at* http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01190.html; Eithan Galun, *Gene Therapy Has Vast Potential Despite Setbacks; Push On With Human Trials*, L.A. TIMES, February 18, 2003, at 13; Anthony Deutsch, *Gene Therapy Allows Boy to Leave his Bubble*, PITT. POST-GAZETTE, September 5, 2002, at A3.

16 *See generally* Raymond R. Coletta, *Biotechnology and the Creation of Ethics*, 32 MCGEORGE L. REV. 89.

17 PRESIDENT'S COUNCIL ON BIOETHICS, REPRODUCTION & RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES (2004), *available at* http://www.bioethics.gov/reports/reproductionandresponsibility/fulldoc.html (acknowledging the debate on whether human embryos, from the time of fertilization, are entitled to "full moral status" or if they deserve less than that); *see also* Davis v. Davis, 842 S.W.2d 588 (Tenn. 1992) (analyzing status of embryo for purposes of embryo disposition dispute between divorcing couple).

18 *See, e.g.*, In re Marriage of Buzzanca, 72 Cal. Rptr. 2d 280, 61 Cal. App. 1410 (4th Dist. 1998) (holding husband of artificially inseminated wife must provide child support as the child's lawful father, even though wife promised to assume all responsibility for child's care); K.M. v. E.G., 117 P.3d 673, 37 Cal. 130 (2005) (holding woman who donated her eggs to her lesbian partner for in vitro fertilization is a lawful parent due to her genetic relationship with the child).

which reasonable people can and do disagree. We also develop these technologies in the shadow of a history of abuse of technology, particularly in instances involving vulnerable populations.[19]

Legal oversight ranges from limited regulation, to constitutional protection, to extensive regulation targeted to protect children. One end of the continuum—limited regulation—is exemplified by assisted reproductive technology (ART).[20] With few exceptions, intended parents ultimately make the decisions as to which technologies they will use, whether IVF (in vitro fertilization), ICSI (intra cytoplasmic sperm injection), PGD, multiple embryo implantation, or egg freezing. The parents' decisions are guided by the expertise and ethics of their physicians.[21]

In ART, some legal oversight takes place after the initial medico-ethical decisions are made by the parents. Traditional doctrines in family and tort law are used to resolve the disputes that inevitably arise. For example, family law resolves custody and support disputes among possible parents, including egg and sperm donors, surrogates, and intended parents.[22] In tort law, the intended parents may attempt to sue providers for alleged harm based on their negligent conduct in diagnosis or treatment.[23] Other "new frontiers"—such as the separation of conjoined twins—are unregulated, as these innovations are often considered therapies rather than clinical trials, which would require additional protections for children as human research subjects.

In contrast to ART, the area of children as human research subjects is extensively regulated. At the federal level, children are explicitly identified as a vulnerable population and regulated in ways that are intended to give children access to clinical trials while at the

---

19 Leonard Glantz, *Research with Children*, 24 AM. J.L. & MED. 213 (1998) (outlining abuses against children as research subjects); *see also* Ouellette, *supra* note 10.

20 *See generally* Judith Daar, REPRODUCTIVE TECHNOLOGIES AND THE LAW 684-93 (LexisNexis Matthew Bender 2006).

21 Jennifer Rosato, *The Children of ART (Assisted Reproductive Technology): Should the Law Protect Them From Harm?*, 2004 UTAH L. REV. 57 (2004).

22 A recent dispute involved resolution of parental rights between an intended father and gestational surrogate, litigated extensively in two state courts. *See* J.F. v. D.B., 897 A.2d 1261 (Pa. Super. 2006) (finding the gestational carrier did not have standing to seek custody of triplets against the wishes of the sperm donor father).

23 *See generally* Rosato, *supra* note 21.

same time protecting them from harm.[24] When it comes to approval of drugs for use in children, federal law provides incentives for manufacturers to develop certain drugs,[25] and penalizes those who do not include children in drug development.[26] The combination of "carrots and sticks" is significantly increasing the number of drugs approved for children's use.[27]

In a few areas, children's medical decision making has been guided by principles of constitutional law. Reproductive decision making is the primary area that has been constitutionalized at the federal level.[28] Notably, it is also the area of medical decision making in which children possess the most autonomy. For example, when minors seek an abortion, they are not required to obtain parental consent or permission if a judicial bypass process exists that permits pregnant minor girls to demonstrate that they are mature enough to make the abortion decision or that an abortion is in their best interests.[29]

Although developments in brain science seem to suggest that adolescents may mature later than originally thought,[30] there may be other public policy reasons to defer to the child's decision in this area as well as others.

As most areas of children's health care lack legal oversight except in the most extreme circumstances, the limits of permissive conduct

---

24 45 C.F.R. §§ 46.401-46.409 (2008).

25 Best Pharmaceuticals for Children Act of 2007 (BPCA), 21 U.S.C. § 355a.

26 Pediatric Research Equity Act of 2007 (PREA), 21 U.S.C. § 355c.

27 *See* Hall and Braun, *supra* note 12, at 305-06; *see also* "Drug Research and Children," at http://www.fda.gov/fdac/special/testtubetopatient/children.html (pointing to "carrot and stick" approach of FDA).

28 *See* Rosato, *supra* note 8, at 772-73.

29 *See* Teresa Stanton Collett, *Seeking Solomon's Wisdom: Judicial Bypass of Judicial Involvement in a Minor's Abortion Decision*, 52 BAYLOR L. REV. 513, 515 (2000) (detailing the precedent cases, judicial process and federal statutes governing judicial bypass proceedings across the country); Bellotti v. Baird, 443 U.S. 622 (1979) (plurality opinion) (concluding that states may impose parental consent requirements on minors seeking abortions, as long as a mechanism is provided for an alternate decision maker to approve the procedure).

30 *See* Roper v. Simmons, 543 U.S. 551, (2005) (citing scientific literature in decision determining that subjecting juveniles to the death penalty is unconstitutional); Jay D. Aronson, *Brain Imaging, Culpability and the Juvenile Death Penalty*, 13 PSYCHOL. PUB. POL'Y & L. 115 (May 2007) (focusing on brain imaging to show an adolescent's brain is not as developed as that of a mature adult).

(by parents, health care providers, or the state), are sometimes determined by ethics, not law. For example, ethical guidelines exist for specialists practicing ART,[31] and hospital bioethics committees are consulted to provide ethical guidance to practitioners in their institutions.[32] Although ethical guidelines may be preferable for practitioners as they permit the most discretion, they may not be sufficient to protect children. Particular structural concerns include insufficient enforcement mechanisms and a lack of transparency.[33] This lack of trust in this process is exacerbated because the providers—who possess a vested interest in the practices at issue—are deciding whether an ethical breach has been caused by one of their colleagues.

It is time to consider a more comprehensive, coherent development of the law regarding medical decision making for children and adolescents. The following goals should be considered priorities:

- to anticipate the legal and ethical issues as technologies are being developed and create bodies to provide guidance to providers and decision makers;
- to create more coherent doctrines and pass laws in areas in where consensus is possible, such as protection of children and other vulnerable populations;
- to ensure a decision making process with a neutral third party (e.g., judge) when parents possess a conflict of interest that may interfere with their ability to protect their children's best interests;
- to train judges and lawyers in science and ethics, since knowledge of both is needed to resolve these issues;
- to develop accountability mechanisms (such as IRBs) for medical practitioners, not just researchers; and
- to provide greater decision making authority to older adolescents, particularly relating to decisions that affect

---

31 The American Society for Reproductive Medicine (ASRM) promulgates ethical guidelines on a number of issues in ART. *See generally* American Society for Reproductive Medicine, http://www.asrm.org (last visited Oct. 12, 2008).

32 *See, e.g., In the matter of* AB, 768 N.Y.S.2d 256 (S.Ct. N.Y. 2003) (refusal of life-sustaining treatment for child).

33 *See* Rosato, *supra* note 21, at 57.

their future.

The articles in this issue of the Houston Journal of Health Law and Policy bring us closer to meeting these goals. They contribute to the literature by identifying the problems with existing practices and thoughtfully considering how those problems should be resolved, with an awareness of the strong competing interests involved.

In "Preimplantation Genetic Diagnosis and Parental Preferences: Beyond Deadly Disease,"[34] Susannah Baruch considers the limits of parental preference in creating their future children. PGD now allows parents to choose embryos that possess certain genetic traits, not only to prevent childhood diseases but also for other purposes such as determining gender and predisposition to late-onset diseases. Baruch describes the results of a recent survey of PGD providers, which provides initial insight into what kinds of choices parents are currently making. The author recognizes that there is currently a lack of societal consensus as to which choices should be permitted; consequently, she recommends additional regulatory oversight as to safety and efficacy issues, leaving the ethical issues to voluntary professional societies and patient advocacy groups.[35]

This approach seems to be the right one at present. I agree with Baruch that additional regulatory oversight seems unwarranted at this time, considering the parents' privacy rights that would be implicated if uses were limited, the lack of proof (so far) that these uses harm children, and the lack of consensus on what limits should be imposed. I also agree that a more proactive approach needs to be taken through other means—additional data needs to be collected, the ethical issues need to be discussed at the national level, and guidance needs to be given to providers through their professional organizations. It is important that the guidance that develops is clear as well as enforceable. Otherwise, we will remain where we are now, left with the parents' unfettered choices and no tools to limit them.

In "Leaving No Child Behind: Abigail Alliance, Pediatric Products and Off-label Use,"[36] Ralph F. Hall and Tracy A. Braun examine the fundamental challenge of balancing the need to protect

---

34 Baruch, *supra* note 11.

35 *Id.*

36 *See* Hall and Braun, *supra* note 12.

children against harm with the desire of giving them access to needed therapies. The authors themselves identify the core question as: "Do we have an appropriate system in place for providing safe and efficacious pediatric therapies?"[37] After reviewing the article, my sense is that the authors would answer that question with cautious optimism. Specifically, Hall and Braun consider all the ways that pediatric therapies are developed, including FDA testing and approval, off-label use, and "enhanced" off-label use (essentially off-label use with dissemination of information regarding safety and efficacy to the medical community). The authors foresee an increase in children's access and, in particular, anticipate even more off-label use of medical products in the future.

Through their comprehensive analysis, the authors further some of the goals that I have articulated above: dealing with ethical issues as they are presented; developing accountability mechanisms for medical practitioners (through providing additional information); and creating a coherent doctrine relating to regulating pediatric therapies.

Specifically, Hall and Braun consider developing coherence in the applicable constitutional doctrine. They posit that if adults possess a Constitutional right to access to unapproved drugs without governmental interference,[38] then children should also possess such a right. The authors base their conclusion on recognition of a child's right when it concerns medical therapy, and that the child's need is the same as an adult. Although I agree that the child's right may be recognized for these reasons, it still may be a "junior" version of the right warranting less deference to the parent or the child, and perhaps requiring more protection and process. Since the most recent court opinion denied this right to adults, the applicability to children does not need to be addressed yet. But Hall and Braun are asking the right questions, to ensure that a coherent doctrine is finally developed improving access (which children need) while minimizing the risk of harm.

Amy McGuire and Courtenay Bruce focus on confidentiality in "Keeping Children Secrets: Confidentiality in the Physician-Patient

---

37 *Id.*

38 *Id.* (Abigail Alliance claimed a right of access to post-Phase 1 drugs for mentally competent adults facing a terminal illness who were under a physician's care).

Relationship."[39] The authors recognize that confidentiality of patient information is essential to the preservation of the doctor-patient relationship and ensuring effective treatment for minors. They carefully examine federal and state laws, as well as ethics, to determine when doctors can and should reveal information to the minor patient's parents. The authors are guided by what they articulate as the primary obligation—the patient—and that "as a fiduciary of the patient [the provider] must seek to protect and promote the patient's health-related interests."[40]

McGuire and Bruce's nuanced analysis of the confidentiality issue evidences the need for a more comprehensive and coherent approach. States differ not only in the areas in which minors can make health care decisions (e.g., substance abuse, sexually transmitted diseases), but also when doctors possess the discretion to reveal information to the parent(s). Specifically, where the law is unclear, doctors have discretion to allow parental access to the minor's health information and ethics can fill the void. But in this area, according to the authors, there does not appear to be clear "ethical consensus."[41]

In the end, McGuire and Bruce highlight the challenges of the existing confidentiality doctrine: determining the appropriate balance of policies, and providing clear guidance to doctors and patients based on sound ethical judgment. Confidentiality is essential to ensure that minors trust their providers, seek medical care when needed, and talk to the providers truthfully. Only then will they receive the most effective care.

I would underscore that maintaining confidentiality is crucial to respecting adolescents' developing autonomy and their need to participate in important decisions. Those decisions may include whether to refuse life-sustaining treatment or to obtain information about predisposition to genetic diseases.

In "Growth Attenuation, Parental Choice, and the Rights of Disabled Children: Lessons from the Ashley X Case,"[42] Professor

---

[39] Amy L. McGuire and Courtenay R. Bruce, *Keeping Children's Secrets: Confidentiality in the Physician-Patient Relationship*, 8 HOUS. J. HEALTH L. & POL'Y 315 (2008).

[40] *Id*. at 333.

[41] *Id*.

[42] Ouellette, *supra* note 10.

Alicia R. Ouellette challenges the limits of unfettered parental choice. The Ashley X case involved a six-year-old whose growth was attenuated through a hysterectomy, mastectomy, and hormonal treatments. Ouellette concludes that deference to her parent's decision to allow these medical procedures insufficiently protected Ashley's interests, even though the hospital ethics committee recommended that the procedures be performed.

Ouellette raises three particular concerns with letting parents make decisions in this context: the significant risks posed by these procedures (which were major medical interventions); the conflict of interest these parents possessed (as the procedures were intended to ease the burdens of care, not to treat Ashley for a particular medical problem); and the potential for abuse of these kinds of procedures (which include sterilization). The author focuses on three procedural reforms that will ensure that the child's interests are adequately protected, including a third-party decision maker, an advocate who represents the child's interests, and criteria for the decision maker to follow.

Ouellette is rightfully concerned about deferring to the parents' decision when they have a conflict of interest. Although the doctors in this case had ethical obligations, it does not appear they were enough to ensure that Ashley's parents were provided with a balanced view of the procedures' risks and benefits.[43] And the ethics committee recommendation, even if appropriate, was not binding.[44]

Ouellette's proposal for third-party oversight is one that should be considered outside the growth attenuation context. To apply this approach to other contexts would bring more coherence to the medical decision making doctrine, as well as make practitioners more accountable when conducting procedures that are, in reality, more experimentation than clinical practice. Such oversight should be considered for similar areas of "parental conflict," including certain high-risk procedures in ART (e.g., implantation of multiple embryos), and separation of conjoined twins. This may be an area of consensus ripe for regulation.

In contexts that pose a significant risk of serious harm to the

---

43 *Id.*

44 *Id.* at 213.

child or future child, an outside decision maker is needed—such as a judge or an administrative body unrelated to the provider. Internal processes should not resolve the issues even if they appear neutral. In addition, the outside decision maker should be adequately trained in the legal, ethical, and medical aspects of these cases.

These articles each provide a valuable perspective related to the past, present, and future of children's decision making. As to the past, the articles comprehend the tensions existing law has created. As to the present, the articles provide insightful analysis and propose solutions to vexing legal and ethical problems facing parents and providers at the cutting edge of bioethics. Finally, as to the future, the articles articulate approaches and provide observations that will be helpful to resolving difficult dilemmas in the future, and bring us closer to realizing the goals set forth above.