

BUYERS IN THE BABY MARKET: TOWARD A TRANSPARENT CONSUMERISM

June Carbone & Jody Lyneé Madeira *

Abstract: This Article assesses the forces on the horizon remaking the fertility industry, including greater consolidation in the health care industry, the prospects for expanding (or contracting) insurance coverage, the likely sources of funding for future innovation in the industry, and the impact of globalization and fertility tourism. It concludes that concentration in the American market, in contrast with other medical services, may not necessarily raise prices, and price differentiation may proceed more from fertility tourism than from competition within a single geographic region. The largest challenge may be linking those who would fund innovation, whether innovation that produces new high cost products or innovations making fertility services more accessible and affordable, with the constantly shifting market niches of a globalized era.

INTRODUCTION	71
I. BABY MARKETS: THE BUSINESS OF FERTILITY.....	75
II. REMAKING BABY-MAKING	79
A. The Changing Health Care Landscape.....	80
B. Expanding Insurance Coverage.....	86
C. The Future of Innovation.....	93
D. Globalization, Brokers, and Network Creation	100
CONCLUSION	106

INTRODUCTION

Health care today, taken as a whole, is often characterized by the increasing consolidation of health care providers, opaque payment systems in which neither doctors nor patients understand the full price of medical procedures, and increasing distance between doctors and patients.

Yet, certain segments of the health care industry such as cosmetic

* June Carbone, Robina Chair in Law, Science, and Technology and Associate Dean for Research and Planning, University of Minnesota Law School. Jody Lyneé Madeira, Professor of Law and Louis F. Niezer Faculty Fellow, University of Indiana Maurer School of Law. We would like to thank Katerina Lee, Shiveta Vaid, and Tracy Shoberg for their research support and Jack Kirkwood for his courtesy and support in including us in this symposium.

surgery, many dental and mental health services, and most of assisted reproduction, have until recently defied the trends. They did so in large part because insurance and government subsidies cover a much smaller portion of these procedures. Instead, these services have usually occurred in the context of relatively small or solo practices, or university centers where patients pay for the services they receive with much less (if any) subsidization or third party involvement, and deal directly with individual professionals in the process. As a result, market forces influence supply and demand much more directly than in other parts of the health care industry, and the health care provider-patient relationship is a more commercially driven seller-buyer one.

These forces—particularly the absence of wide scale insurance or government subsidization—have shaped assisted reproduction technologies (ART) from their inception. Almost every aspect of ART has been controversial, from the initial use of artificial insemination with donor sperm (AID), to use of fertility drugs that increase the frequency of multiple births, to in vitro fertilization (IVF), which permits conception outside of the human body. The Catholic Church, for instance, identifies human dignity with conception by a married couple within a woman's body, and it therefore opposes IVF—and government subsidization of IVF—altogether.¹ Others have expressed concern about the health effects of fertility drugs, the hormones used in IVF, the increased incidence of multiples, and other ART practices.² The combination of religious objections to the procedures, and concern that government inquiries would result in restrictive measures, have blocked inclusion of ART in national health legislation and funding for research that would contribute to better understandings of the long term health risks involved with these procedures.³ Instead, relatively little regulatory oversight exists and only a small number of states mandate any form of

1. Congregation for the Doctrine of the Faith, *Instruction on Respect for Human Life in Its Origin and on the Dignity of Procreation: Replies to Certain Questions of the Day*, VATICAN (Feb. 22, 1987), http://www.vatican.va/roman_curia/congregations/cfaith/documents/rc_con_cfaith_doc_19870222_respect-for-human-life_en.html [https://perma.cc/N73Y-YPS9].

2. See, e.g., Michele Goodwin, *A View from the Cradle: Tort Law and the Private Regulation of Assisted Reproduction*, 59 EMORY L.J. 1039, 1058–61 (2010) (discussing potential complications from ART).

3. See June Carbone & Naomi Cahn, *Embryo Fundamentalism*, 18 WM. & MARY BILL RTS. J. 1015 (2010). The tacit compromise underlying the development of assisted reproduction has been that “no laws are passed that even tangentially sanction embryo destruction and no laws are passed that intrude on the profitability of fertility treatments.” *Id.* at 1015; see also 1032–36. In addition, “[l]egislative and regulatory oversight of assisted reproduction has been characterized by moral posturing and regulatory gridlock.” *Id.* at 1032.

insurance coverage.⁴

For most of its existence, therefore, ART practices have taken place in the context of a different consumer and ethical infrastructure than other health care services. This means that even where fertility clinics experience many of the same forces as the rest of the medical profession, the implications may not be the same. For example, ART practitioners, like other medical clinics, face pressures to innovate. This innovation increases returns to scale and take place in the context of global competition. In the fertility context, consolidation, at least initially, may offer more rather than less price competition and competition across jurisdictional lines offers not just opportunities to leverage price differences but to jurisdiction shop for different regulatory environments. Competition for providers across state and national lines may therefore give consumers a wider array of choices.

At the same time, the competition for fertility services involves selection for particular services as much as, if not more, than selection for price. The global market for fertility services includes wealthy and sophisticated patients who may scour the world for a place willing to provide surrogacy services for older or non-traditional couples. It also includes those who would like to employ new techniques to select a child of a desired sex, to avoid the transmission of hereditary diseases, or to conceive a “savior sibling” capable of providing a bone marrow transplant to a family member whose life depends on finding a compatible donor.⁵ Increased competition and “fertility tourism” may thus expand the availability of services not just by making them more affordable, but also by making it easier to evade ethical restrictions that limit the availability of controversial services.⁶

4. *Insurance Coverage in Your State*, RESOLVE, http://www.resolve.org/family-building-options/insurance_coverage/state-coverage.html [<https://perma.cc/3TYH-CQNE>] (last visited Feb. 23, 2016) (noting that only fifteen states currently offer this coverage).

5. See, e.g., *Gender Selection*, FERTILITY INSTS., http://www.fertility-docs.com/programs-and-services/gender-selection/select-the-gender-of-your-baby-using-pgd.php?utm_expid=859852-9.IPJ9NYcHRJcPZh9q8VY-vg.0&utm_referrer=https%3A%2F%2Fwww.google.com%2F [<https://perma.cc/F8LU-5H46>] (last visited Feb. 5, 2016) (providing sex selection as an advertised service). For a discussion of “savior siblings,” see MALCOLM K. SMITH, *SAVIOUR SIBLINGS AND THE REGULATION OF ASSISTED REPRODUCTIVE TECHNOLOGY: HARM, ETHICS AND LAW 1–2* (2015) (defining the term and arguing for the use of “saviour children” rather than “saviour sibling” since the children chosen for such reasons are not necessarily limited to siblings); Susan M. Wolf et al., *Using Preimplantation Genetic Diagnosis to Create a Stem Cell Donor: Issues, Guidelines & Limits*, 31 J.L. MED. & ETHICS 327, 330–36, 336 n.5 (2003) (discussing the bioethics issues in “savior sibling” cases); I. Glenn Cohen, *Intentional Diminishment, the Non-Identity Problem, and Legal Liability*, 60 HASTINGS L.J. 347, 364 (2008) (discussing possible feelings of guilt by savior siblings who refuse to consent to use of their tissue).

6. See *Choosing a Medical Tourism Agency to Plan Your Fertility Treatment Abroad*, FERTILITY

Faced with these clinic practices, infertile individuals become “consumers” as well as patients. Patients may enjoy a choice of clinics on the east and west coasts of the United States, as well as abroad.⁷ They can, and often do, ask exactly what fertility procedures will cost, and can consider different potential fertility packages in deciding on a course of action. Still, a larger percentage of the public may pursue less expensive options in Mexico than those who will price shop within their home markets in the United States, much less negotiate with individual providers. Some argue that any form of price consideration reduces one of life’s most fundamental experiences—the creation of a human life—to a dollars-and-cents commercial transaction.⁸ Others express concern that for-profit clinics press the limits of ethical behavior in their desire to recruit more patients.⁹ Yet others hold up fertility clinics as a model of informed choice: the infertile at least enjoy a choice of clinics, with transparent prices, that allow the patients to select their preferred course of treatment.¹⁰ Discovering the true cost of cancer surgery is, in contrast, a much more difficult process.¹¹

This Article will assess the forces on the horizon remaking the fertility industry. In Part I, the Article discusses the differences between health care generally and ART services and the forces that produce these differences. In Part II, the Article identifies looming events remaking the nature of fertility services. These forces include the impact on ART services of greater consolidation in the health care industry, the prospects for expanding (or contracting) insurance coverage, the likely sources of funding for future innovation in the industry, and the impact of globalization and fertility tourism. The Article conducts this inquiry

TREATMENT ABROAD, <http://fertility.treatmentabroad.com/agencies/choosing-a-medical-tourism-agency> [https://perma.cc/CE8Y-93H3] (last visited Feb. 5, 2016).

7. See *infra* notes 54–55 (describing clinic efforts to increase geographic reach within the United States); *infra* notes 153–70 and accompanying text (describing growth of fertility tourism across international lines); DEBORA L. SPAR, *THE BABY BUSINESS: HOW MONEY, SCIENCE, AND POLITICS DRIVE THE COMMERCE OF CONCEPTION* 54 tbl.2-1 (2006) (describing location of largest clinics, which tend to be concentrated in the East Coast, and major U.S. cities).

8. ANTHONY OAKLEY DYSON, *THE ETHICS OF IVF* 35 (1995) (stating that “IVF involves the commodification, commercialization and exploitation of persons and processes”).

9. See, e.g., Goodwin, *supra* note 2, at 1056 (suggesting that “aggressive fertility claims distort reproductive realities and misinform patients; ART’s failure rate is estimated to be 70%”).

10. See Jody Lyneé Madeira, *Conceiving of Products and the Products of Conception: Reflections on Commodification, Consumption, ART, and Abortion*, 43 J.L. MED. & ETHICS 294, 299–300 (2015) (summarizing the debate).

11. See, e.g., STEVEN BRILL, *AMERICA’S BITTER PILL: MONEY, POLITICS, BACKROOM DEALS, AND THE FIGHT TO FIX OUR BROKEN HEALTHCARE SYSTEM* (2015) (documenting opaque billing practices in health care).

by examining the changing business model of the industry and recounting interviews with providers about the potential consequences of that change.

In Part III, the Article concludes that future developments will likely remake the industry in fundamental ways. The United States, long a pioneer in fertility clinics, has taken a largely free market approach to innovation that stands in contrast with the development of other medical advances, which are far more likely to be the product of either substantial public funding or extensive government oversight. Innovation in the future is increasingly likely to occur either through private funding or abroad. In either event, the relationship between providers, patients, and regulatory authorities is likely to be more attenuated. Accordingly, the Article concludes that concentration in the American market, in contrast with other medical services, may not necessarily raise prices, and price differentiation may proceed more from fertility tourism than from competition within a single geographic region. The largest challenge may be linking those who would fund innovation, whether innovation that produces new high cost products or innovations making fertility services more accessible and affordable, with constantly shifting market niches of a globalized era.

I. BABY MARKETS: THE BUSINESS OF FERTILITY

Health care, of course, has long been a business. In some eras, it has been a service that could be separated into for-profit and not-for-profit sectors.¹² That changed with the development of third-party payment systems.¹³ In 1940, ten percent of Americans had health insurance.¹⁴ By 1957, that number increased to seventy-two percent, prompted primarily by the growth in employer-provided health insurance.¹⁵ The expansion of Medicare and Medicaid extended health care coverage to the elderly and the poor, who did not have or could not get other health care benefits.¹⁶ By 2013, the percentage of the American public not covered by any health insurance had dropped to fourteen percent.¹⁷ As a result,

12. See Terry L. Corbett, *Healthcare Corporate Structure and the ACA: A Need for Mission Primacy Through a New Organizational Paradigm?*, 12 IND. HEALTH L. REV. 103, 110 (2015) (discussing how non-profit hospitals once gave doctors greater freedom from market pressures).

13. *Id.* at 121.

14. Eleanor D. Kinney, *For Profit Enterprise in Health Care: Can It Contribute to Health Reform?*, 36 AM. J.L. & MED. 405, 409 (2010).

15. *Id.*

16. *Id.* at 409, 411–12.

17. JESSICA C. SMITH & CARLA MEDALIA, U.S. CENSUS BUREAU, HEALTH INSURANCE

even medical providers with a mandate to cover underserved populations do not provide services without charge. Instead, they receive substantial revenues from third-party payers.¹⁸ Further, with third-party payers such as private insurance companies or state-run Medicare and Medicaid programs, the doctor may not necessarily be aware of the true cost of the treatment or the relationship between those costs and what patients pay directly.¹⁹

The development of fertility treatments, in contrast, has taken place in relatively smaller clinics that rely to a much greater degree on customers who pay out-of-pocket.²⁰ The portion of the population most likely to be concerned about fertility issues is also the least likely to have health insurance; those between the ages of eighteen and thirty-five—the peak childbearing years—are less likely than younger or older people to have health care coverage.²¹ Only fifteen states mandate any fertility coverage, and their mandates are neither comprehensive nor uniform.²²

COVERAGE IN THE UNITED STATES: 2013, at 4 fig.4 (2014), <https://www.census.gov/content/dam/Census/library/publications/2014/demo/p60-250.pdf> [<https://perma.cc/G4X7-WPG9>].

18. See, e.g., Erin C. Fuse Brown, *Irrational Hospital Pricing*, 14 Hous. J. Health L. & Pol'y 11, 37 (2014) (explaining charity care hospital billing practices).

19. *Id.* at 16, 35 n.127 (noting that hospital prices remain almost completely opaque, variable even with the same hospital and unintelligible and involve both physician and hospital components).

20. See Judith F. Daar, *Accessing Reproductive Technologies: Invisible Barriers, Indelible Harms*, 23 BERKELEY J. GENDER L. & JUST. 18, 37 (2008) (observing that insurance mandates have relatively little effect on fertility treatment usage because those with insurance coverage are the patients most likely to be able to afford fertility treatments on their own); Marianne Bitler & Lucie Schmidt, *Health Disparities and Infertility: Impacts of State-Level Insurance Mandates*, 85 FERTILITY & STERILITY 858, 864 (2006). *But see* SPAR, *supra* note 7, at 33 (observing that there are still barriers to entry, given the lengthy training necessary to be able to do IVF, and returns to scale).

21. SMITH & MEDALIA, *supra* note 17, at 6 fig.4. Racial disparities are also substantial, with the highest utilization among older, educated Caucasian women with income greater than 300 percent above the poverty level. Low-income women with under twelve years of education were the least likely to access infertility services. See Eve C. Feinberg et al., *Comparison of Assisted Reproductive Technology Utilization and Outcomes Between Caucasian and African American Patients in an Equal-Access-to-Care Setting*, 85 FERTILITY & STERILITY 888, 889 (2006). Yet, lower income and minority women experience higher rates of involuntary infertility. Daar, *supra* note 20, at 39 (“Hispanic women, non-Hispanic black women, and other women of color are significantly more likely to be infertile than white women.”); see Kimberly M. Mutcherson, *Transformative Reproduction*, 16 J. GENDER RACE & JUST. 187, 222 (2013) (“[A] disproportionate number of infertile women in this country are Black.”).

22. Seema Mohapatra, *Fertility Preservation for Medical Reasons and Reproductive Justice*, 30 HARV. J. RACIAL & ETHNIC JUST. 193, 206 (2014); see also Tara Siegel Bernard, *Insurance Coverage for Fertility Treatments Varies Widely*, N.Y. TIMES (July 25, 2014), <http://www.nytimes.com/2014/07/26/your-money/health-insurance/insurance-coverage-for-fertility-treatments-varies-widely.html> [<https://perma.cc/Q72F-QLRL>] (noting that of the states that mandate coverage, only eight—Arkansas, Connecticut, Hawaii, Illinois, Maryland, Massachusetts, New Jersey and Rhode Island—require some level of coverage for IVF).

In the states that do not mandate coverage, insurance companies typically do not cover such treatments, thus utilization of fertility services falls.²³ Public programs such as Medicaid similarly treat fertility issues as elective and uncovered, and private charities do not place much emphasis on access to services such as IVF.²⁴ Deborah Spar estimates that only a little more than one-third of the infertile seek fertility treatments.²⁵

As a result, fertility treatments, much like cosmetic surgery or dentistry, traditionally took place in fragmented practices dependent on out-of-pocket patient payments.²⁶ This is changing, however, as clinics consolidate to take advantage of economies of scale. These clinics treat patients who are socioeconomically advantaged²⁷ and, with fewer third-party imposed requirements, they may be quite profitable.²⁸ Still, they depend on the patients' ability and willingness to pay.

The United States provides relatively little regulation of fertility treatments.²⁹ Federally mandated reporting requirements, which include

23. See Melinda B. Henne & M. Kate Bundorf, *Insurance Mandates and Trends in Infertility Treatments*, 89 FERTILITY & STERILITY 66 (2008) (noting that comprehensive insurance mandates are associated with greater utilization of ART and lower rates of births per cycle and multiple births per ART birth); John A. Robertson, *Commerce and Regulation in the Assisted Reproduction Industry*, 85 TEX. L. REV. 665, 674 (2007) (reviewing SPAR, *supra* note 7, and discussing the limited availability of insurance coverage for assisted reproduction).

24. Mohapatra, *supra* note 22, at 223.

25. SPAR, *supra* note 7, at 32.

26. See, e.g., Kimberly D. Krawiec, *Altruism and Intermediation in the Market for Babies*, 66 WASH. & LEE L. REV. 203, 213–14 (2009) (“[P]rofits are undeniably a—if not *the*—motivating factor in the industry as well. Although many fertility centers are affiliated with nonprofit hospitals or academic institutions, the fertility center itself is often a professionally managed, for-profit, private corporation.” (emphasis in original)); HARRIS WILLIAMS & CO., FERTILITY MARKET OVERVIEW (2015) [hereinafter FERTILITY MARKET OVERVIEW], http://www.harriswilliams.com/sites/default/files/content/fertility_industry_overview_-_2015.05.19_v10.pdf [<https://perma.cc/WA9W-2FGN>] (commenting on highly fragmented nature of the U.S. market).

27. Patients with higher incomes tend not just to be better able to pay for fertility treatments on their own; they are also more likely to have health insurance, and to have insurance that covers fertility treatments. On health insurance coverage, see SMITH & MEDALIA, *supra* note 17, at 9 tbl.4.

28. See, e.g., Debora Spar & Anna M. Harrington, *Building a Better Baby Business*, 10 MINN. J.L. SCL. & TECH. 41, 49 (2009) (“ART has become a big business in the United States precisely because it costs so much.”). Spar and Harrington estimate the cost per live birth (using a fifty-one percent success rate) at between \$29,411 and \$49,020. *Id.* at 50.

29. Judith Daar emphasizes that this perception of American practices comes from the lack of a “top-down” system in the United States, but that the notion that American fertility clinics are the wild west of medicine is an “urban myth.” Judith Daar, *Federalizing Embryo Transfers: Taming the Wild West of Reproductive Medicine?*, 23 COLUM. J. GENDER & L. 257, 257, 266 (2012). She emphasizes instead that American reproductive practice, like all others areas of medicine, “is subject to quality control through a variety of mechanisms, most notably licensure of physicians by state-based medical boards, application of practice standards established by professional societies, and

reports of success rates, constitute the most direct regulation.³⁰ Perhaps as importantly, the lack of federal research support also influences industry practices.³¹ Even when there is no direct public oversight of medical practices, federal grants often prompt medical innovations through research funds typically conditioned on agreement to observe ethical practices prescribed by professional groups or committees.³² Congress, however, has restricted research on embryos since the 1970s, starting almost immediately after the legalization of abortion. These efforts culminated in the “Dickey Amendment,” which has been attached to every Health and Human Services appropriations bill since 1996.³³ The amendment forbids federal funding for “research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death.”³⁴ Fertility clinics therefore rely either on private research funding, with relatively few restrictions compared to federal grants,³⁵ or their patients’ willingness to undergo certain untested IVF

private tort litigation.” *Id.* at 262. These physician-based regulatory systems, however, tend to be voluntary rather than mandatory, suggesting professional guidelines without necessarily prohibiting alternative practices. In addition, enforcement, if it occurs at all, typically occurs after harm has occurred. In the case of “Ootomom” Nadya Suleman, for example, her doctor violated professional guidelines in implanting a large number of embryos, and ultimately lost his medical license because of it. *Id.* at 313–14. Yet, no regulation controls the acceptable number of embryos that can be implanted at one time, and the after-the-fact-actions taken against the doctor involved almost certainly reflect the publicity the case generated, and the utterly irresponsible nature of the doctor’s actions. *Id.* at 314 (noting that the doctor’s appeal was rejected because of the “serious breach of the standard of care”).

30. *Id.* at 267–68 (discussing comprehensive reporting requirements); *see also* Fertility Clinic Success Rate and Certification Act, 42 U.S.C. § 263(a)(1)–(7) (2012). Federal regulations also cover laboratory testing. *See* Clinical Laboratory Improvement Act of 1988, 42 U.S.C. § 263(a); 21 C.F.R. §§ 1271.55, 1271.80 (2016) (implementing regulations).

31. *See* Carbone & Cahn, *supra* note 3, at 1052. In contrast, the federal government had once funded the vast majority of biomedical research. *See* June Carbone, *Toward a More Communitarian Future? Fukuyama as the Fundamentalist Secular Humanist*, 101 MICH. L. REV. 1906, 1923 (2003).

32. *See* Note, *Guiding Regulatory Reform in Reproduction and Genetics*, 120 HARV. L. REV. 574, 579 (2006).

33. Carbone & Cahn, *supra* note 3, at 1033–34.

34. Balanced Budget Downpayment Act, Pub. L. No. 104-99, § 128, 110 Stat. 26, 128 (1996). The 2005 version of the amendment provided:

None of the funds made available in this Act may be used for . . . research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

Department of Health and Human Services Appropriations Act, 2006, Pub. L. No. 109-149, § 509, 119 Stat. 2833, 2880 (2005).

35. Note, *supra* note 32, at 586–87 (observing that IVF clinics had little difficulty attracting private research funds, and in this context, “caution was not a foremost concern, and few external forces existed to slow the work of the clinic”).

procedures such as using genetic material from three individuals without clinical trials beforehand.³⁶

Despite the lack of public research support, the combination of private support, lack of restrictions, and paying patients has allowed the United States to develop a large, profitable fertility industry—one whose potential impact is likely to grow.³⁷

II. REMAKING BABY-MAKING

Newsweek ran a piece a number of years ago, before the end of the cold war, that recited a little ditty attempting to explain differences in national political cultures. It went something like this: in the United States, everything is allowed unless it is specifically prohibited; in East Germany, everything is prohibited unless it is specifically allowed; in the Soviet Union, everything is prohibited especially if it is allowed; and in Italy, everything is allowed especially if it is prohibited. While casual and perhaps too cute, this ditty nonetheless captures some fundamental approaches to governance. The NBAC [President Clinton's National Bioethics Advisory Commission] took this advice to heart.³⁸

A decade and a half ago, Alto Charo's ditty summarized the state of the fertility business. National cultures—public and private—determined the approaches to fertility treatments, and in the United States, public bodies mostly looked the other way, allowing private entities to oversee the development of the industry largely on their own. To be sure, the occasional front page news story, from Baby M³⁹ to Octomom,⁴⁰ focused the spotlight on fertility practices and led to narrowly focused reforms,

36. See Carbone, *supra* note 31, at 1920–21 (attributing lack of animal testing to lack of research funding); *infra* Section II.C (describing the cytoplasmic research that occurred at St. Barnabas in 1996). The Food and Drug Administration, however, has since asserted jurisdiction over such procedures, with the result that such direct testing on patients has become more likely to take place abroad. See *infra* note 104 and accompanying text.

37. See generally SPAR, *supra* note 7 (arguing that it is necessary to acknowledge the commercial implications of fertility treatment and its market dynamics).

38. R. Alta Charo, *Cloning: Ethics and Public Policy*, 27 HOFSTRA L. REV. 503, 508 (1999).

39. See *In re Baby M.*, 537 A.2d 1227 (N.J. 1988) (invalidating surrogate parenting arrangements for violating state law, enacted long before the practice of surrogacy was known in the state, prohibiting the payment of money in connection with adoption).

40. See, e.g., Naomi R. Cahn & Jennifer M. Collins, *Eight Is Enough*, 103 NW. U. L. REV. COLLOQUY 501, 501 (2009) (critiquing IVF practices that led to the birth of octuplets and proposing limits on the number of embryos to be implanted at any one time).

but no comprehensive oversight of the industry emerged.⁴¹ Nonetheless, new factors may prompt reconsideration; this Part examines these factors in turn. Section II.A considers the changing nature of health care more generally as new technologies and regulations bring increasing returns to scale. Section II.B then examines how increased demand for fertility services and the growing evidence that links reproductive efforts and children's health to adult genetic predispositions is increasing the demand for insurance coverage. Section II.C considers the cumulative effect of narrowly focused regulations on the climate for innovation, as the combination of federal limits and state restrictions affect developments on the horizon. Finally, Section II.D. addresses how the globalization of the supply of fertility services and customer demand make the relevant markets for fertility services increasingly international in scope.

A. *The Changing Health Care Landscape*

Consolidation increasingly characterizes the health care landscape, with individual physicians selling practices to larger entities,⁴² hospital associations becoming larger, and insurance companies merging.⁴³ These trends began in the 1990s,⁴⁴ accelerated with a shift in Medicare reimbursement formulas,⁴⁵ and increased further after adoption of the Affordable Care Act (ACA) in 2009.⁴⁶ Some of the reasons for these

41. Indeed, as Charo notes, some bodies such as the NBAC, which were set up to consider oversight, did not enact reforms. Charo, *supra* note 38. In Georgia, which took up legislation designed to curb fertility practices, the only result was state authorization of embryo adoption procedures, but not limitations on the fertility industry. Cahn & Collins, *supra* note 40, at 508; *see also* Carbone & Cahn, *supra* note 3, at 1041–43 (recounting Georgia's efforts to place limits on embryo implantation after 100,000 people contacted the state legislature opposing the measure).

42. *See* Lucia DiVenere, *The Affordable Care Act and the Drive for Electronic Health Records: Are Small Practices Being Squeezed?*, 25 PRAC. MGMT. 36, 36 (2013), http://www.jfponline.com/fileadmin/qhi/obg/pdfs/0713_PDFs/0713_OBG_DiVenere.pdf [<https://perma.cc/RQX2-2GLR>] (“In 2000, 57% of all physicians were in independent practice; by the end of 2013, only 36% of physicians are projected to remain independent.”).

43. *See, e.g.*, Thomas F. Cotter, *Patents, Antitrust, and the High Cost of Health Care*, ANTITRUST SOURCE, Apr. 2014, at 1, 5 (“[T]he market for health care related services has become remarkably more concentrated over the past two decades.”); Brandon Gould, *How the Countervailing Power of Insurers Can Resolve the Tradeoff Between Market Power and Health Care Integration in Accountable Care Organizations*, 22 GEO. MASON L. REV. 159, 178 (2014).

44. Cotter, *supra* note 43, at 5.

45. Gould, *supra* note 43, at 167 (noting the origination of some of the pressures for consolidation with creation of accountable care organizations, first implemented as part of Medicare reimbursement reforms).

46. *See* 5 *Forces Driving Hospital Consolidation*, STRATASAN (July 10, 2013), <http://stratasan.com/5-forces-driving-hospital-consolidation/> [<https://perma.cc/7BTA-ZNEA>]

trends will have little if any impact on reproductive care. For example, the change in Medicare reimbursement formulas to emphasize outcome-oriented health care is likely to have little effect on fertility services.⁴⁷

Nonetheless, other industry trends may affect fertility clinics as well. First, even if everything else were to stay the same, one of the factors driving consolidation is the increased costs associated with the switch to electronic records. Industry observers note that “the healthcare sector’s reliance on increasingly sophisticated electronic medical records and other health information technologies to reduce costs and enhance quality, safety, and efficiency are foundational to healthcare reform.”⁴⁸ Yet, moving from a paper-based to an electronic system is expensive. The average cost of an electronic medical records system is \$50,000 per physician,⁴⁹ and implementing such a system requires training, maintenance, and compliance with various privacy laws and regulatory requirements that generate additional costs.⁵⁰ The need to acquire and maintain these systems creates returns to scale that encourage larger practices or cost-sharing administrative groups. In itself, the switch to electronic records may be a problem of transition; over time, it may interact with other changes to encourage consolidation of a fragmented industry.

Fertility clinics face further pressures to consolidate because of the returns to scale within the industry. Deborah Spar reports that smaller, private clinics have faced increased pressure to join networks such as IntegraMed, which provides member clinics with “management advice, pharmaceutical products, and in house-financing.”⁵¹ These networks may be better able to negotiate with drug companies for volume discounts,⁵² they can ease the problems associated with financing new equipment and lab maintenance in a rapidly changing field, and they offer advantages in

(showing an increase in mergers post-2009).

47. Gould, *supra* note 43, at 178 (“Reliance on Medicare data may also be inappropriate for services infrequently provided to Medicare beneficiaries, such as pediatric and obstetric care.”).

48. Brian Kerby, *The Top Five Drivers of Healthcare Consolidation in 2015*, CROW HORWATH (Apr. 21, 2015), <http://www.crowehorwath.com/insights/healthcare-connection/top-five-drivers-hc-consolidation-2015.aspx> [<https://perma.cc/AS5K-CEQE>].

49. Paul R. Brezina et al., *How Obamacare Will Impact Reproductive Health*, 31 SEMINARS REPROD. MED. 189, 194 (2013).

50. *Id.*

51. SPAR, *supra* note 7, at 51.

52. An industry analyst reports that the U.S. fertility services market of about \$3 to \$4 billion consists of \$1.7 to \$2.5 billion in fertility services and approximately \$1.5 billion for fertility medications. See FERTILITY MARKET OVERVIEW, *supra* note 26, at 1.

advertising and new patient acquisition.⁵³ As a result, fertility clinics, like the rest of the health care field, are experiencing increasing consolidation.⁵⁴ The result does not just increase clinic size; it also expands clinic geographic reach.⁵⁵

Interviews with fertility industry professionals underscore the accuracy of Spar's assertions, though the doctors' impressions (and business knowledge and savvy) vary considerably. One physician remarked:

[W]hen you talk to physicians in our field . . . there's a strong sense that consolidation is occurring, and the forces that are driving us . . . [are] to be able to have electronic medical records, being able to have the embryology resources and technology, and all the other back office, IT and marketing and all the types of things you need today to . . . compete. It's hard to do as a solo practice.⁵⁶

An executive with a for-profit fertility clinic management corporation stressed the importance of "efficiencies of scale": "[g]roup purchasing is a big one. The cost of equipment. If that's done through group purchasing arrangement[s], they can get really good discounts through a larger organization. . . . Or also, the financial advantages if they want to expand—it's very expensive to build out a practice."⁵⁷ Finally, consolidation may improve research, which may be particularly important for university centers: in a large group, "[b]ecause the EMR [Electronic Medical Records] is linked to all these practices, they have a massive database. So they can actually provide fantastic data for any form of research that's being done within the organization. So they get recognition—academic recognition—as much as clinical recognition."⁵⁸

Doctors also perceive that consolidation may be a response to tough

53. SPAR, *supra* note 7, at 51 (describing a doctor who joined his practice to IntegraMed reporting that it allowed him to keep his practice open "52 weeks a year, fully staffed all the time, offering even the most exotic reproductive technologies").

54. FERTILITY MARKET OVERVIEW, *supra* note 26, at 9 (noting that small industry players want to broaden their access to patients and that referral networks and platform providers like Integra seek affiliation with additional practices to spur growth, realize synergies, and increase geographic presence).

55. *Id.*

56. Telephone Interview by Jody Lyneé Madeira with Anonymous Physician Two (Aug. 15, 2015) (on file with author) [hereinafter Interview with Physician Two].

57. Telephone Interview by Jody Lyneé Madeira with Anonymous Fertility Clinic Management Corporation Executive (Aug. 29, 2015) (on file with author) [hereinafter Interview with Management Corporation Executive].

58. *Id.*

market conditions. An executive in a for-profit fertility clinic management corporation described these changing dynamics: “I think it’s very difficult for a single physician, or even [a] two physician practice, to survive because of the changing demographic. A lot of the population is getting older. . . . It’s very difficult for them in the current [climate], especially with insurance issues.”⁵⁹ An official with a fertility-related nonprofit explained the logic behind consolidation:

[Y]ou have a lot of people who can’t access it, so the field isn’t growing. And so you’ve got . . . to figure out how you’re gonna keep sustaining. So a lot of times, that’s consolidation. That’s [saying], “Look the guy across the street is struggling too, or maybe not so much struggling, but we’re all sort of status quo; maybe if we join forces, we’ll be more efficient, we’ll capture more of the . . . patient population, and we’ll be in a position to continue as an entity, to grow and improve.”⁶⁰

There is much speculation that the ACA, in particular, will prompt further consolidation.⁶¹ As an executive at a for-profit fertility pharmaceutical corporation stated:

[I]t’s kind of analogous on some level to what we’ve seen in the hospitals in the [1980s] where . . . the small regional hospitals were kind of consolidating to form . . . bigger, more geographically dispersed conglomerates. . . . [Everyone’s going to] speculate that okay, we have the Affordable Care Act looming in 2016, most states won’t be able to afford to include fertility in their essential health benefits package. And that’s gonna . . . repeal, or lessen the effects of these mandates and . . . the whole market’s going to drop back from a heavily managed market to probably more of a cash market, which will shrink the market significantly. . . . These practices are realizing that to be competitive in this space, and potentially be competitive in the next five to ten years . . . that they’re going to have to figure out how to do this more effectively, cost-effectively. And consolidation seems to be the approach. . . . A lot of the practices that are doing this are already the largest

59. *Id.*

60. Telephone Interview by Jody Lyneé Madeira with Anonymous Non-Profit Official (Aug. 28, 2015) (on file with author) [hereinafter Interview with Non-Profit Official].

61. The ACA requires the U.S. Department of Health and Human Services (HHS) to establish a minimum level of health benefits that must be offered by certain health plans that are participating in the individual and small group health insurance markets. HHS could choose to include fertility care as a benefit within the maternity care category, but it has not yet made a decision on the issue. *See Daar, supra* note 29, at 322.

practices in their region. And . . . now they're just moving out and gobbling up their local competition, . . . realizing they just can't compete with the economies of scale working against them.⁶²

The trend toward consolidation in the fertility industry may be unique in some respects. This physician felt that consolidation patterns in fertility medicine were different than in other fields of medical practice:

I don't think we feel the pressures as much as in other fields. . . . I know there are hospitals gobbling up practices, particularly primary care-type practices, [and that] hasn't touched us yet. . . . [M]ost IVF centers don't want to be restricted, . . . and beholden to a hospital system, so the few that are still in them . . . often look at ways of getting out of there.⁶³

A top official in a nonprofit fertility organization noted that, not only is there a trend toward consolidation, but practices in one state are beginning to expand outside their current regions and other clinics in the same region may merge:

I think what we've seen . . . in the last couple of years are larger clinics—so they might be top ten or top fifteen in the U.S. in terms of number of IVF cycles—that are expanding outside their original states, into other states. So you see this with clinics such as Shady Grove Fertility going to Pennsylvania. You'll see clinics like Boston IVF opening offices in New York, like Albany, and . . . Colorado Center for Reproductive Medicine, or CCRM, . . . opening an office in Houston, Texas. . . . [T]he other thing is . . . clinics in the same marketplaces that are either merging [or] consolidating. . . . [Y]ou saw the announcement that RMA of New Jersey, which is one of the largest clinics in the country, is forming a “partnership” with . . . Shady Grove Fertility.⁶⁴

Some may have concerns that consolidation could negatively impact patients' care experience. One physician opined, “customer experience is a number one issue and they don't want to feel like cattle or like [a] number, like they usually feel when they're in these big centers where they have . . . three, four thousand cycles a year.”⁶⁵ Another physician

62. Telephone Interview by Jody Lyneé Madeira with Anonymous Pharmaceutical Corporation Executive (Sept. 11, 2015) (on file with author) [hereinafter Interview with Pharmaceutical Corporation Executive].

63. Interview with Physician Two, *supra* note 56.

64. Interview with Non-Profit Official, *supra* note 60.

65. Telephone Interview by Jody Lyneé Madeira with Anonymous Physician One (Aug. 13,

stressed, “I wouldn’t want to imply that the choice is between a small, wonderful practice, or a big, . . . unfeeling conglomerate.”⁶⁶ That physician did believe, however, that larger practices could focus more intensely on creating a personalized patient experience:

I think we’re very big. . . . Every patient at our practice has one physician and one nurse and a home office[,] and I think we’ve worked really hard to avoid that perception, or that experience. . . . And we give patient surveys quarterly, and we [give] our staff a bonus for patient satisfaction. All these things are critical to us. So I think a smart, big consolidated group will recognize how critical patient care and patient experience is, and will probably do better. . . . I think that big practices have the ability to look at the data, and the desire to[,] and the resources to ensure best practices, . . . high quality technology, and the embryology lab in particular, so I think there’s an advantage.⁶⁷

Interestingly, this physician also objected to the use of “conglomerate” versus “consolidation”: “[conglomerate] has such negative implications. . . . [I]t implies impersonal, profit-driven, without any thought for quality of patient care.”⁶⁸ The official in a fertility-related nonprofit agreed: “however they set up their teams, [the large practices have] been able to do it in such a way that patients still feel an incredible connection to that practice.”⁶⁹

Finally, consolidation can promote best practices. According to Physician One, “we physicians, . . . we’re not good collaborators, . . . especially the [baby] boom generation.”⁷⁰ If this is true, consolidation helps to break down barriers to collaboration:

IntegraMed, for instance, has an annual conference in which [best practices] are shared . . . and they’re looking at outcomes and . . . encouraging practices to share best practices, and when you’re part of the network, you’re much more transparent with each other, without the posturing that you would have with a typical large ASRM meeting.⁷¹

The official in a fertility-related nonprofit organization stressed that consolidation enables the latest technologies to spread from practice to

2015) (on file with author) [hereinafter Interview with Physician One].

66. Interview with Physician Two, *supra* note 56.

67. *Id.*

68. *Id.*

69. Interview with Non-Profit Official, *supra* note 60.

70. Interview with Physician One, *supra* note 65.

71. Interview with Physician Two, *supra* note 56.

practice:

RMA of New Jersey . . . they've really developed this chromosomal screening . . . that technology is [now being used] in many practices, so it's sort of like leveling the playing field . . . [T]hat's a technology that is still proprietary to RMA of New Jersey, but they're . . . partnering with other clinics to offer that.⁷²

The official also noted that larger firms tended to “have more ability to offer financing programs” and that biotech firms developing new technologies were “going to the large practices to do their testing, and the larger practices seem to be more open to being early adopters.”⁷³

While these doctors differ in their attribution of cause and effect, and they differ significantly in their knowledge of and ability to assess business trends, they tend to agree that consolidation is an increasing characteristic of the fertility industry, and that the consolidation trend is likely to continue. Deborah Spar concludes that the most successful clinics “are either very high volume or very high tech,” and the need to compete in such an arena is squeezing the profit margins of the “smaller, less sophisticated, less commercial” clinics, increasing the pressure to merge.⁷⁴ Doctors’ sense that continuing market pressure produces greater consolidation is almost certainly accurate.

B. *Expanding Insurance Coverage*

A potentially sweeping effect on the structure of the fertility market is the possibility of greater insurance coverage. Spar describes insurance coverage as a double-edged sword for the fertility industry:

On the one hand, when insurers cover infertility as a medical illness, they nearly guarantee a greater demand for fertility treatments: people who previously couldn't afford treatment suddenly enter the market, and people who bought minimal services now buy more. Thus, political demands in this industry can easily translate into expanded commercial demand. On the other hand, though, insurance coverage comes at a cost, forcing providers to charge only what the insurers will pay. Accordingly, insurance—and even the *threat* of insurance—acts to cap prices in the industry and put an even greater premium on

72. Interview with Non-Profit Official, *supra* note 60.

73. *Id.*

74. SPAR, *supra* note 7, at 58.

volume.⁷⁵

Spar's analysis follows from the relative lack of price competition for IVF, which creates greater incentives for clinics to try to enter the upper end of the market rather than to expand volume through lower prices.⁷⁶ Ironically, while fertility clinic pricing is more transparent than pricing in forms of medicine covered by third-party payers, clinic prices tend to be relatively uniform across clinics, and customers tend not to comparison shop on the basis of price, at least within a given regional market.⁷⁷ Insurance companies, in contrast, are repeat players with more information and greater market power, giving them greater ability than consumers to negotiate lower prices.⁷⁸

Doctors believe that the fact that most patients pay all or most of their IVF treatment costs already has made IVF more cost-effective than other forms of medical care that are subsidized by insurance. Physician Two observed the following:

[W]hen a high percentage of patients pay out-of-pocket, you have to really focus on being transparent and competitive about pricing. And that, I think, is good for patients in this field. I think that fertility treatment is expensive, but actually if you compare it to "What is my IVF cycle cost versus an arthroscopy of the knee?" I think IVF is much more technically challenging and cost-effective and complex, and the time spent by people is much greater, but yet the arthroscopy probably gets twice as much, because of hospitals and surgery centers and the equipment manufacturers and everything else. . . . [F]ertility treatment's price rises ha[ve] been less than medicine by a long, long way because of the transparency and the fact that patients are self-paying.⁷⁹

Yet, as Spar indicates, while the lack of third-party payment has restricted the size of the market, it has increased emphasis on high profit procedures rather than lower cost, higher volume approaches.⁸⁰ Expanded insurance coverage would change this dynamic, and could thus have a major impact on future industry development. So, however, could cutbacks in existing insurance coverage, which would have the

75. *Id.* at 34 (emphasis in original).

76. *Id.* at 65.

77. *Id.* at 59 (listing prices).

78. *Id.* at 58.

79. Interview with Physician Two, *supra* note 56.

80. Spar describes clinics as competing to serve wealthy clients, with relatively high value, high profit services, rather than expanding volume. SPAR, *supra* note 7, at 34.

most effect in places like Massachusetts that now mandate broader insurance coverage.⁸¹

Recent interviews with reproductive industry professionals suggest that the ACA provides no incentives for retaining insurance mandates compelling fertility services coverage, and speak to the dramatic changes in store should those mandates terminate in 2016. As one physician remarked:

[T]here has to be a basic package, a basic basket of services that are offered. . . . So IVF would not be in a basic basket of services. So that may be the basis by which the state would then say, “Well hang on, if the basic medical package doesn’t include IVF, then it shouldn’t be a state mandate for IVF” I think the field . . . is anxious about . . . what the implications will be. . . . Nobody really knows what it means. . . . There’s a big school of thought that the mandates will disappear . . . I know we didn’t sign an expensive lease on a new space because we were worried⁸²

Insurance coverage need not extend to every aspect of IVF or other fertility treatments to have an effect. Current fertility-related medical coverage has three components: (1) diagnosis and treatment of underlying disorders that contribute to infertility such as endometriosis and surgery to correct it; (2) procedures designed to produce a pregnancy such as in IVF; and (3) medical care for pregnant women, and care of the resulting children.⁸³ Insurance routinely covers costs associated with the first and third, but not treatments such as IVF aimed at fertility per se.⁸⁴ In addition, some prospective patients who would like access to IVF may have no known disorders,⁸⁵ and with increasing numbers of same-sex couples having children with third-party participants, some of the demand for assisted reproduction does not involve medical infertility at

81. See MASS. GEN. LAWS ANN. ch. 175, §§ 1–227 (West, Westlaw through 2015 1st Annual Sess.); 211 MASS. CODE REGS. 37 (2016).

82. Interview with Physician Two, *supra* note 56.

83. See, e.g., Michael H. Shapiro, *What Should Insurance Insure in the PPACA Age? On Paying for Other People’s Reproductive Decisions and Ambitions*, 33 WHITTIER L. REV. 27, 29 (2011) (noting that health care insurance is certainly expected to cover medical disorders and pregnancy-related illnesses and expenses).

84. Insurers have argued that, while improper function of reproductive organs may be an illness, infertility is not. See Noah Baron & Jennifer Bazzell, *Assisted Reproductive Technologies*, 15 GEO. J. GENDER & L. 57, 78 (2014).

85. FERTILITY MARKET OVERVIEW, *supra* note 26, at 2, put the percentage of “unexplained” infertility at twelve percent.

all.⁸⁶

Industry professionals are well aware of the problems resulting from a lack of insurance coverage for infertility; as one physician stated, “from [one] hundred patients that require in vitro fertilization as a treatment . . . only ten to twenty are getting it in the States.”⁸⁷ Another physician was frustrated by the lack of insurance for fertility issues as opposed to other procedures:

My 84-year-old mother who is pretty healthy . . . just had a femoral artery dilated and angioplasty. And she’s on Medicare, and . . . she really probably did not need this procedure. . . . [I]t drives me crazy that Medicare will probably spend \$30,000 or \$40,000 on what she’s just been through, she didn’t really need, and yet I’ve had a 30-year-old woman with tubal factor infertility who could easily have two children but she can’t afford the \$10,000 for the IVF cycle.⁸⁸

Thus, the scope of insurance may be changing, though in which direction is not yet clear. As knowledge about infertility increases, more medical causes may become apparent, and treatment of the underlying issues may be integrated with fertility care. For example, obesity increases the incidence of infertility and fertility-related obesity interventions can range from nutritional coaching to hormonal or other drug interventions to IVF.⁸⁹ Greater integration of the two, such as requiring a weight-loss regimen before attempting IVF, may blur the distinctions between fertility and non-fertility medical procedures.⁹⁰

The most intriguing development along these lines involves the effect of increased genomic information as more couples become aware of hereditary conditions that could seriously impair the health of their offspring and could be eliminated through use of IVF and genetic screening.⁹¹ The result could increase the demand for IVF and increase

86. Scholars refer to this as “structural infertility” and explain that it “occurs when an individual or couple desires to reproduce but must do so through means other than sexual intercourse because of the social structure in which they self-identify. Single individuals and same-sex couples provide examples of structural infertility.” Daar, *supra* note 20, at 24.

87. Interview with Physician One, *supra* note 65.

88. Interview with Physician Two, *supra* note 56.

89. See Renato Pasquali et al., *Obesity and Infertility*, 14 CURRENT OPINION ENDOCRINOLOGY DIABETES & OBESITY 482, 482–84 (2007) (describing the complex role of obesity in infertility and pregnancy outcomes).

90. See FERTILITY MARKET OVERVIEW, *supra* note 26, at 6 (describing potential responses to obesity in intended parents).

91. See David Sable, *The Seven Trends that Define the Future of IVF*, FORBES (Feb. 28, 2015, 4:53 PM), <http://www.forbes.com/sites/davidsable/2015/02/28/the-seven-trends-that-define-the-future-of-ivf/>.

the pressure for insurance coverage of both the genetic screening and the availability of IVF for those facing a significant possibility of passing on disabling traits.⁹²

Even without government mandates, health insurers, who will bear the costs for children with medical complications or special needs, have shown some inclination to expand coverage to include procedures that reduce overall costs. These procedures may extend to genetic screening as the ability to identify genetic risks increases, and may include at least some rounds of IVF as studies show that insurance coverage contributes to patient willingness to implant one embryo at a time, reducing the risks (and costs) associated with multiples.⁹³

The biggest unknown in this process, however, is how politics will affect the ART industry. On the one hand, interest in offering insurance coverage for fertility services is increasing as more couples delay childbirth and face potential difficulties having children.⁹⁴ This may increase pressure on legislators to mandate coverage and on employers to include IVF coverage options.⁹⁵ On the other hand, if insurance costs were to rise generally, employers might find IVF coverage a relatively easy benefit to drop. Moreover, both factors may occur simultaneously, with coverage (and coverage mandates) increasing more rapidly in large urban areas and better educated tech centers where the age of first birth is rising more rapidly, and coverage remaining limited in other parts of the country.⁹⁶

At present, insurance coverage for fertility services appears to be rising gradually. A 2013 study indicated that sixty-five percent of

92. Judith Daar observes that the Affordable Care Act gives HHS the authority “to specify which services and benefits are to be included within a benefit category as an essential health benefit. Fertility care, for example, could be included as a benefit within the maternity care category.” Daar, *supra* note 29, at 322.

93. *See id.* at 315–19, 323 (noting that patients in the U.S. and abroad who have access to some form of insurance coverage for IVF deliver fewer multiples).

94. Bernard, *supra* note 22.

95. *See* Daar, *supra* note 29, at 321 (describing support for increased insurance coverage).

96. In addition, the pressure for employers to extend coverage may vary considerably. *See* Matt McCue, *OvaScience CEO Talks Apple, Facebook and the \$9 Billion Fertility Market*, FORTUNE (Oct. 16, 2014, 11:54 AM), <http://fortune.com/2014/10/16/fertility/> [<https://perma.cc/7H7G-62FJ>] (“There is a trend in companies covering more fertility-related costs for employees; however, in the U.S. it varies greatly by employer and state.”). For a discussion of the role of religious objections to IVF in the failure to extend insurance coverage, *see* generally Carbone & Cahn, *supra* note 3. Where anti-abortion restrictions, such as personhood amendments, are seen as restricting IVF, however, those restrictions have lost at the polls, even in states such as Mississippi. *See* Jonathan F. Will, *Beyond Abortion: Why the Personhood Movement Implicates Reproductive Choice*, 39 AM. J.L. & MED. 573, 585 (2013).

businesses with more than 500 employees will pay for an initial evaluation by a fertility specialist, though only twenty-seven percent cover IVF (up from twenty-three percent in 2012). Forty-one percent of large employers cover drug therapies associated with infertility treatments.⁹⁷

And what about IVF costs for patients paying out-of-pocket—will average prices for an IVF cycle trend upward or downward, or stay the same? The long-term stability of the average cost of an IVF cycle might actually mean that costs have *decreased* over time, however expensive it may seem in today’s dollars. As Physician One emphasized, “they have decreased a lot, when you look at twenty, thirty years ago, yes, it was fifteen, twenty thousand dollars; it was much more difficult. And now it has remained the same, so in actual dollars, it’s much cheaper.”⁹⁸ This physician stressed that the bulk of profits from fertility treatment go into the pockets of other parties, including pharmaceutical providers, and that fertility providers—and physicians in general—are not as well-off as most would believe:

[W]hile the cost of being a physician is going up, the average physician comes out with \$250,000 of debt. . . . A lot of people have this thing on their mind, that physicians are super-rich, and . . . the average physician earns eighty-five, a hundred thousand bucks. . . . Three elements are making the money here[:] . . . the hospitals, the pharmaceutical [industry], and the medical devices. . . . The doctors have been used as a scapegoat in the health care system debate because the doctors, as I told you, we’re not good collaborators, so it’s a weaker link.⁹⁹

In the future, some fertility professionals believe that prices for IVF will remain fairly stable. “[I]t’ll either have to stay the same or decrease. I don’t think that people can carry an increase in the cost,” opined the executive in a fertility management organization:

[I]f you look at third-parties, where patients are spending twenty, thirty thousand for a single cycle . . . I don’t think that patients can afford more than that. And I do think that there’re going to be more financial programs that come into effect, that

97. Bernard, *supra* note 22.

98. Interview with Physician One, *supra* note 65; see also *The Costs of Infertility Treatment*, RESOLVE, <http://www.resolve.org/family-building-options/making-treatment-affordable/the-costs-of-infertility-treatment.html> [[https:// perma.cc/F7RV-CR64](https://perma.cc/F7RV-CR64)] (last visited Feb. 17, 2016) (supporting Physician One’s assertions).

99. *Id.*

help patients actually pay for it.¹⁰⁰

If the market will not bear an increase in IVF cost, this leaves the question of who will pay for innovations, and how. The executive in a fertility-related nonprofit remarked:

Here's the problem with all these great new things that are gonna come down the pipe. They're gonna add cost. . . . [If] you're gonna add on some of these things that could potentially bring a standard old IVF cycle, with a few of these things to . . . now be . . . twenty to twenty-five thousand? I just don't see it. So I think there's gonna have to be some sort of cost reduction at somewhere along the line.¹⁰¹

The executive at a for-profit fertility pharmaceutical corporation, however, asserted that prices must drop:

Everybody wants to "grow the market." They all want a bigger piece of the pie. But the pie is only getting smaller. And the consolidation is helping with some of that, in keeping the volumes up inside the practices, and moving forward—but eventually, you can't consolidate any more. You just have to become better at what you're doing. And something has to happen to the price of IVF for these practices to continue to grow. . . . And this industry, these issues, these practices, are extremely profitable. And they've done that over the years because of the ability to set that price of managed care, where they have a pretty good reimbursement going. The cash market is just not gonna bear the price points that these physicians have put on their services. . . . [L]ook at Dr. [Name] in upstate New York, whose model has always been . . . "Cheap IVF." . . . Dr. [Name] is . . . basing his practice model on "Hey, rich people can afford a \$4,500 dollar cycle. Poor people can't afford a \$15,000 dollar cycle. And as long as I'm doing a good job, I don't see the best success rates in the country, but as long as I'm on par with the national average, and I offer IVF at 4,500 dollars, those richer couples are still going to come to me, because why pay \$13,000 dollars for a procedure you can have done successfully for \$4,500? They're smart consumers. But if I don't put my price there, I lose all of that middle-income couples [population]."¹⁰²

Greater insurance coverage would almost certainly increase the

100. Interview with Management Corporation Executive, *supra* note 57.

101. Interview with Non-Profit Official, *supra* note 60.

102. Interview with Pharmaceutical Corporation Executive, *supra* note 62.

supply of those seeking IVF, and it is likely to encourage further industry consolidation. The question is whether it would also spur the search for lower cost, higher volume services or whether increased demand would further segment the industry, encouraging new procedures with higher profit margins as well.

C. *The Future of Innovation*

The future of reproductive medicine innovation has two dimensions: (1) where will innovation occur, and (2) how will these innovations be implemented? Increasingly, innovations are coming not from fertility clinics but from entrepreneurial biotech startups such as OvaScience, and may be just as likely to be developed and tested outside the United States as inside national boundaries. Moreover, implementation of the innovations on the horizon may overlap with consolidation. Entrepreneurial companies may take advantage of consolidating clinics to market their innovations first to larger fertility clinics, which have greater patient volume as well as the financial and technological resources to purchase and implement these innovations.

Innovation, which has traditionally occurred through university research centers or individual physician initiatives, may increasingly occur abroad or in more entrepreneurial start-ups that leverage jurisdictional differences. What may propel research abroad is the breakdown in the implicit American reproductive research bargain: almost no federal funding and almost no limit on privately funded research.¹⁰³ Unlike other countries, American researchers do not require advance approval before they begin preliminary research into assisted reproduction.¹⁰⁴ And unlike pharmaceutical companies, fertility clinics have not needed advance regulatory approval before trying new techniques such as IVF.¹⁰⁵ This hands-off approach to reproductive innovations ended, however, when the Food and Drug Administration (FDA) asserted jurisdiction over cytoplasm transfers and cloning in the

103. See Kerry Lynn Macintosh, *Brave New Eugenics: Regulating Assisted Reproductive Technologies in the Name of Better Babies*, 2010 U. ILL. J.L. TECH. & POL'Y 257, 271 (noting that the FDA claimed it had jurisdiction over "human cells used in therapy involving the transfer of genetic material by means other than the union of gamete nuclei").

104. Charo, *supra* note 38, at 507.

105. See Mohammad Reza Sadeghi, *How Should We Deal with the Barrage of New Infertility Treatments and Innovative Technologies?*, 13 J. REPROD. & INFERTILITY 181, 181–82 (2012) (describing rapid rate of innovation and lack of clinical trials and testing for new fertility technologies).

late 1990s.¹⁰⁶

In 1996, the St. Barnabas Medical Center in New Jersey experimented with an effort to “rejuvenate” aging eggs by adding cytoplasm obtained from the eggs of younger women donors.¹⁰⁷ The doctors, who had limited research funds, simply tried the technique on their patients.¹⁰⁸ The result produced thirty children worldwide, born using gametic material from three parents.¹⁰⁹ Two out of eighteen fetuses developed Turner’s Syndrome, a chromosomal abnormality, and researchers speculated that it could have come from the technique or from the patient’s age.¹¹⁰ These children, however, did not inherit the donor DNA, but at least two other children in the group did.¹¹¹ Ethicists objected to the prospect of germline genetic engineering—that is, the creation of children using DNA from a third party who would pass on the donor DNA to their own children¹¹²—and the FDA, alarmed at the use of an untested technique of uncertain safety, asserted jurisdiction.¹¹³ The result effectively shut down this type of research in the United States, at least on humans.¹¹⁴

106. For a discussion of the FDA’s jurisdiction in such matters, see Richard A. Merrill & Bryan J. Rose, *FDA Regulation of Human Cloning: Usurpation or Stewardship?*, 15 HARV. J.L. & TECH. 85, 102 (2001).

107. See Jody Lyneé Madeira, *Conceivable Changes: Effectuating Infertile Couples’ Emotional Ties to Frozen Embryos Through New Disposition Options*, 79 UMKC L. REV. 315, 316 (2010).

108. Carbone, *supra* note 31, at 1920.

109. The process used a fertilized egg from the intended parents with nuclear DNA from the intended mother and father, and added cytoplasm from a donor egg that would ordinarily contain the donor’s mitochondrial DNA. Jason A. Barritt et al., *Epigenetic and Experimental Modifications in Early Mammalian Development: Part II, Cytoplasmic Transfer in Assisted Reproduction*, 7 HUM. REPROD. UPDATE 428, 428 (2001).

110. See Macintosh, *supra* note 103, at 272 (reviewing the safety debate).

111. Barritt et al., *supra* note 109, at 429–30. The cytoplasm was intended to strengthen the function of, rather than replace, the cytoplasm of the egg from the intended mother, and the child would not necessarily express the donor’s DNA. *Id.* at 433. This process can be used with minimal or no transfer of mitochondrial DNA from the donor. See Jacques Cohen et al., *Birth of Infant After Transfer of Enucleate Donor Oocyte Cytoplasm into Recipient Eggs*, 350 LANCET 186, 187 (1997).

112. See John A. Robertson, *Oocyte Cytoplasm Transfers and the Ethics of Germ-Line Intervention*, 26 J.L. MED. & ETHICS 211, 211–13 (1998) (describing the various techniques). Researchers did find mitochondrial DNA from the donor in two of the children born using the St. Barnabus procedure, but not the others. See Kim Tingley, *The Brave New World of Three-Parent I.V.F.*, N.Y. TIMES (June 27, 2014), <http://www.nytimes.com/2014/06/29/magazine/the-brave-new-world-of-three-parent-ivf.html> [<https://perma.cc/BCV3-RPV5>].

113. See Judith Daar, *Multi-Party Parenting in Genetics and Law: A View from Succession*, 49 FAM. L.Q. 71, 74 (2015) (observing that after the FDA said in 2001 that any further use of cytoplasmic injection would require an Investigational New Drug application, the practice ceased throughout the United States).

114. It has, however, been done in the United States in monkeys. See David Cyranoski, *DNA-Swap Technology Almost Ready for Fertility Clinic*, NATURE (Oct. 24, 2012),

The farthest reaching developments have occurred abroad. In February 2015, Parliament authorized the United Kingdom regulatory body that oversees assisted reproduction to license clinics that wished to use three-party IVF to eliminate the risk of mitochondrial disease.¹¹⁵ The authorization is more restrictive than the St. Barnabas procedures used in the 1990s in that it is designed to deal only with mitochondrial disease, not the problems associated with aging eggs.¹¹⁶ Nonetheless, it allows the research to proceed to human trials that will produce children.

In the United States, the FDA has started discussion of whether the procedure should be allowed here.¹¹⁷ Before Parliament acted, the United Kingdom required animal testing and human experimentation on embryos up until the fourteen-day stage.¹¹⁸ The FDA would similarly require clinical trials before authorizing the procedure, and the funding for such measures would presumably have to come from private sources.¹¹⁹ The lack of such private funding sources is what shut down developments when the FDA asserted jurisdiction over the St. Barnabas procedures, and it is unclear whether that funding now exists.¹²⁰

<http://www.nature.com/doi/10.1038/nature.2012.11651> [<https://perma.cc/RE3B-PMYH>]. This research continues in the lab, without use of public funds. See Tingley, *supra* note 112.

115. James Gallagher, *UK Approves Three-Person Babies*, BBC NEWS (Feb. 24, 2015), <http://www.bbc.com/news/health-31594856> [<https://perma.cc/YN9Y-JXMW>].

116. See Tingley, *supra* note 112.

117. See Dina Fine Maron, *Making Babies with 3 Genetic Parents Gets FDA Hearing*, SCI. AM. (Feb. 25, 2014), <http://www.scientificamerican.com/article/making-babies-with-3-genetic-parents-gets-fda-hearing/> [<https://perma.cc/AT8U-SLUB>]. As this Article was going to press, the U.S. Institute of Medicine issued a report recommending that clinical investigations be authorized, but limited to the creation of boys, who could not transmit the donor genes to offspring. The report suggested guidelines for such investigations, including a requirement that the investigators secure funding for long-term monitoring of children born through use of the procedure. NAT'L ACADS. OF SCI., ENG'G & MED., *MITOCHONDRIAL REPLACEMENT TECHNIQUES: ETHICAL, SOCIAL, AND POLICY CONSIDERATIONS* (2016) [hereinafter *MITOCHONDRIAL REPLACEMENT TECHNIQUES*], <http://iom.nationalacademies.org/reports/2016/Mitochondrial-Replacement-Techniques> [<https://perma.cc/GB78-QJXP>]. Nonetheless, a provision in the Consolidated Appropriation Act of 2016 may bar the procedure even if the FDA approves it. Joel Achenbach, *Ethicists Approve '3 Parent' Embryos to Stop Diseases, but Congressional Ban Remains*, WASH. POST (Feb. 3, 2016), <https://www.washingtonpost.com/news/speaking-of-science/wp/2016/02/03/to-prevent-disease-ethicists-approve-creation-of-embryos-with-three-genetic-parents/> [<https://perma.cc/W2UX-6MDP>].

118. See Gallagher, *supra* note 115.

119. See J. Ravindra Fernando, *Three's Company: A Constitutional Analysis of Prohibiting Access to Three-Parent In Vitro Fertilization*, 29 NOTRE DAME J.L. ETHICS & PUB. POL'Y 523, 527 (2015) (describing FDA approval process that includes searching review of the method's safety and efficacy as well as satisfactory completion of human trials).

120. See Tingley, *supra* note 112 (discussing funding available for stem cell research). "While the creation of human embryos for research is not prohibited under federal law in the United States (although some states are more restrictive), neither FDA nor any other agency of the U.S. Department of Health and Human Services can financially support such research where embryos are

In the meantime, other research is moving abroad, hoping to establish that medical procedures work in other jurisdictions before attempting to use them in the United States. The owners of biotech start-up OvaScience have expressed their frustration with U.S. procedures. They observe that there have not been any significant improvements in IVF in more than two decades.¹²¹ The most pressing issues involve egg quality, such as aging eggs that fail to produce pregnancies or women who for a variety of reasons fail to produce mature eggs capable of reproducing. New experimentation builds on the earlier procedures; some scientists would like to refine the process of cell “rejuvenation,” perhaps adding some of the intended mother’s own, healthy mitochondria to her eggs.¹²² Other experimenters propose taking a woman’s immature eggs and allowing them to develop outside her body, or using a woman’s stem cells to create entirely new eggs.¹²³ Extracting stem cells—or immature eggs—from a patient might be cheaper and less intrusive than extracting mature ova, and it would extend women’s reproductive lives. Scientists expect egg production to be the new frontier for assisted reproduction.¹²⁴

In 2013, OvaScience proposed to commercialize a new treatment it called “Augment” that would boost egg quality by using a woman’s own mitochondria.¹²⁵ When it announced plans to do so, the FDA asserted that rather than treat the process as a medical procedure, subject to light regulation, it would subject the treatment to its more rigorous standards for drug development.¹²⁶ The company’s share price tanked as a result,

destroyed, discarded, or subjected to risks with no prospect of medical benefit for the embryo.” George Dvorsky, *US Experts Say Three-Parent Babies Are Okay—Just No Girls*, GIZMODO (Feb. 3, 2016, 6:11 PM), <http://gizmodo.com/us-experts-say-three-parent-babies-are-okay-just-no-girls-1756947506> [https://perma.cc/64Z5-DGRG] (quoting MITOCHONDRIAL REPLACEMENT TECHNIQUES, *supra* note 117, at 24).

121. Don Seiffert, *OvaScience Advances Fertility Treatments Quickly Outside the U.S.*, BOS. BUS. J., <http://www.bizjournals.com/boston/blog/bioflash/2014/09/ovascience-advances-fertility-treatments-quickly.html?s=print> [https://perma.cc/F9UB-ZU2J] (last updated Sept. 2, 2014, 3:05 PM).

122. See Jonathan L. Tilly & David A. Sinclair, *Germline Energetics, Aging, and Female Infertility*, 17 CELL METABOLISM 838, 838–50 (2013) (describing rejuvenation of eggs).

123. See Dori C. Woods & Jonathan L. Tilly, *The Next (Re)Generation of Ovarian Biology and Fertility in Women: Is Current Science Tomorrow’s Practice?*, 98 FERTILITY & STERILITY 3, 6–7 (2012) (describing the potential for taking egg stem cells and using them to develop new mature eggs).

124. Anita Slomski, *Hard to Conceive*, PROTO (Nov. 5, 2014), <http://protomag.com/articles/ivf-hard-to-conceive> [https://perma.cc/5HLZ-W3US].

125. *AumentSM Treatment*, OVASCIENCE, <http://www.ovascience.com/treatments/augment> [https://perma.cc/KB2B-KM9E] (last visited Feb. 23, 2016).

126. Seiffert, *supra* note 121.

but it dealt with the setback by moving commercialization abroad.¹²⁷ Today, Augment is still not available in the United States, but in May 2015, OvaScience announced the birth of the first child born through use of the procedure in Toronto, Canada.¹²⁸ It believes that the global market is large enough that it makes more sense to test the effectiveness of its products through human use and testing abroad. OvaScience's chief scientific officer observed, "People get hung up on, it's a U.S. thing versus outside (the U.S.), I think of it as, where are the patients?"¹²⁹ And he concluded that, on a global basis, ninety percent of the IVF treatments occur abroad.¹³⁰

OvaScience represents a major change in the source of innovation in assisted reproduction. The company thinks of itself as an entrepreneurial firm, intent on changing the way innovation in fertility treatments occurs.¹³¹ It seeks to disrupt, not exploit, existing markets.¹³² It has attracted venture capital investors,¹³³ and it is a publically traded corporation.¹³⁴ Both groups—private equity investors and shareholders—tend to focus on short term results. If the company is successful, it may be acquired by a larger operation; if its early products founder, it may soon be out of business. In this context, the company approaches regulations as obstacles to circumvent.

The FDA, which comprehensively regulates drugs, has typically taken a different approach to medical procedures and human tissue, and thus

127. Alison Motluk, *IVF Booster Offered in Canada But Not in US*, CTR. FOR GENETICS & SOC'Y (Jan. 14, 2015), <http://www.geneticsandsociety.org/article.php?id=8304> [https://perma.cc/F3M6-72RP]; *OvaScience's Fertility Technology in Limbo After FDA Demands IND Filing*, EP VANTAGE (Sept. 12, 2013), <http://www.epvantage.com/Universal/View.aspx?type=Story&id=455479&isEPVantage=yes> [https://perma.cc/K8HC-KWRM].

128. *First Baby Born with OvaScience's Augment Fertility Treatment*, OVASCIENCE INC. INV. REL. (May 7, 2015), <http://ir.ovascience.com/mobile.view?c=251343&v=203&d=1&id=2045382> [https://perma.cc/4VXC-6XMW].

129. Seiffert, *supra* note 121.

130. *Id.*

131. *Id.*; see also *OvaScience Chief Executive Officer Selected Entrepreneur of the Year 2013 Finalist for New England by Ernst & Young*, OVASCIENCE (June 3, 2013), <http://www.ovascience.com/news/article/ovascience-chief-executive-officer-selected-entrepreneur-of-the-year-2013-f> [https://perma.cc/Y8JU-5SJ3] (highlighting the successes of its executives as entrepreneurs).

132. Seiffert, *supra* note 121.

133. *OvaScience*, CRUNCHBASE, <https://www.crunchbase.com/organization/ovascience> [https://perma.cc/XX4L-5GHL] (last visited Feb. 5, 2016).

134. Don Seiffert, *Clinical Data May Not Win over OvaScience Skeptics—but Revenue Will*, BOS. BUS. J. (June 17, 2015, 12:11 PM), <http://www.bizjournals.com/boston/blog/bioflash/2015/06/clinical-data-may-not-win-over-ovascience.html> [https://perma.cc/Q2W8-WHPL].

has had relatively limited involvement in IVF.¹³⁵ It nonetheless intended its assertion of jurisdiction over human cloning and the St. Barnabas cytoplasm procedure to have an *in terrorem* effect;¹³⁶ that is, the mere suggestion that the FDA would require review before the procedure could be done shut down such experimentation in the United States.¹³⁷

This has taken place in large part because of the lack of funding for testing that would satisfy the FDA's safety and efficacy concerns. Such testing in the pharmaceutical arena is enormously expensive, and it has tended to focus private efforts on the development of "blockbuster" drugs, with large payoffs for the developers.¹³⁸ The market for assisted reproduction is not only more limited; the lack of insurance coverage makes it harder to realize the types of profits that fuel pharmaceutical research.

OvaScience dealt with the FDA assertion of jurisdiction by moving abroad and for the moment, the company and the agency are at loggerheads.¹³⁹ OvaScience hopes that, by demonstrating success abroad, it will persuade the FDA to relent.¹⁴⁰ The FDA, which has successfully shut down this type of research in the past,¹⁴¹ risks becoming irrelevant if the effect of its efforts are to push reproductive research abroad. But when OvaScience announced the birth of a baby born through use of Augment in Toronto, Canada, *its share prices fell* because industry analysts expressed concern about the lack of appropriate testing.¹⁴² An analysis of the company's prospects, however, indicated that while the clinical data is not yet winning over skeptics, "revenue will."¹⁴³ The company's business model effectively requires that it position itself to succeed in the global market if it wishes to

135. The FDA's assertion of authority is itself controversial. See Macintosh, *supra* note 103, 273–74; Merrill & Rose, *supra* note 106.

136. Merrill & Rose, *supra* note 106, at 100 ("The predictable *in terrorem* effect of these statements was almost certainly intended . . .").

137. Macintosh, *supra* note 103, at 270.

138. See generally June Carbone, *Ethics, Patents and the Sustainability of the Biotech Business Model*, 17 INT'L REV. L. COMPUTERS & TECH. 203 (2003) (describing business model of drug development).

139. Taryn Hillin, *Why an Incredible New Method to Extend Fertility Is off Limits in the U.S.*, FUSION (Aug. 4, 2015, 5:54 AM), <http://fusion.net/story/164309/new-fertility-treatment-ovascience-augment-ivf-eggs/> [<https://perma.cc/2YMY-S2C5>].

140. See Seiffert, *supra* note 121.

141. Daar, *supra* note 113, at 74 (discussing the FDA's shut down of the earlier experimentation with cytoplasmic transfers).

142. Seiffert, *supra* note 134.

143. *Id.*

establish itself in the United States.¹⁴⁴ In the meantime, however, OvaScience's share price has been incredibly volatile, ranging from a high of \$55.69 per share to a low of \$7.90 per share over a fifty-two week period.¹⁴⁵

Once innovations are ready for the market, companies such as OvaScience will take advantage of larger clinic networks, produced through consolidation, to distribute innovations. As a result, larger clinics will be able to offer their patients higher-end services at more competitive prices. According to a top fertility nonprofit official, "people who are paying out-of-pocket . . . are requiring and requesting a higher-quality end result."¹⁴⁶ This official sees innovations occurring not in the sense of a "big breakthrough on the medical side" but in "the devices, the testing."¹⁴⁷ But because larger firms "tend to be more willing to be test sites . . . or they're early adopters, . . . widespread use on some of these things is gonna take a long time."¹⁴⁸

In the early stages, the latest scientific advances will cost more, require better trained, more sophisticated staff and carry higher profit margins on the performance of what is likely to be, at least initially, a small number of procedures. Yet, these new procedures will offer some prospective parents their only chance of having a genetically related child. The high-end market may, accordingly, remain lucrative.¹⁴⁹

144. Indeed, in an effort to reassure its investors, OvaScience emphasizes its international reach, with new agreements to distribute Augment in Spain, Latin America, Japan, and the U.K. Its press releases underscore the size of its partners, highlighting its relationship with IVI Valencia, "a leading IVF clinic in Spain that is part of the IVI Group of 38 clinics spanning nine countries, which is the largest IVF clinic network in the world" and the largest group of clinics in Japan. Press Release, *OvaScience Reports Second Quarter 2015 Financial Results* (Aug. 10, 2015), <http://ir.ovascience.com/phoenix.zhtml?c=251343&p=irol-newsArticle&ID=2078484> [https://perma.cc/CNN8-8LMY].

145. See *Ovascience Inc. Analyst Price Target Update*, AM. TRADE J. (Oct. 16, 2015), <http://www.americantradejournal.com/ovascience-inc-analyst-price-target-update/6127536/> [https://perma.cc/P6K9-4BV2].

146. Interview with Non-Profit Official, *supra* note 60.

147. *Id.*

148. *Id.*

149. SPAR, *supra* note 7, at 65 (observing there is still considerable room at the top end of the market). With greater fertility tourism, this will be true whether or not the procedure is permitted in a given jurisdiction. If the procedure proves safe and popular abroad, pressure will build to introduce it into the United States. If not, American clinics may feel greater pressure to have foreign offices in jurisdictions that allow the procedure. In either case, larger, more flexible, and multi-jurisdictional clinics will be in a better position to leverage regulatory differences for their own benefit.

D. Globalization, Brokers, and Network Creation

These forces—globalization, increasing economies to scale, and the potential to leverage jurisdictional differences—may ultimately come together to remake assisted reproduction. For providers, economies of scale are prompting the type of consolidation going on across the medical profession; larger entities in turn may try to serve a larger clientele though the right mix of higher volume, lower cost services, and high-end developments for those who can afford them.

At the same time, consumers are becoming more sophisticated in their search for more affordable—or more custom-tailored—products.¹⁵⁰ Increasingly, they are recognizing jurisdictional differences in medical care pricing, quality, and service availability.¹⁵¹ Medical tourism, defined as “the travel of patients from the ‘home country’ to the ‘destination country’ for medical treatment,” is a rapidly growing multi-billion-dollar industry involving thousands of patients from the United States alone.¹⁵² The Centers for Disease Control and Prevention (CDC) estimates that 750,000 U.S. residents travel abroad for health care each year.¹⁵³ In total, the 2014 worldwide market for medical tourism was estimated to be between \$38.5 billion and \$55 billion.¹⁵⁴

American patients travel abroad for health care for the same reasons that companies locate some of their activities overseas: prices may be more affordable and restrictions may be less onerous.¹⁵⁵ And rather than try to stem the travel abroad, American medical providers have sometimes sought to take advantage of the opportunities for their own benefit. For example, Johns Hopkins Medical International entered into a joint venture with Panama City’s Hospital Punta Pacifica, which gave the Panamanian facility “the advantages of an internationally recognized brand and access to the expertise of U.S. medical practitioners regarding

150. Indeed, preliminary research in 2010 indicates that patients are using the internet to seek out care abroad, typically after having sought treatment in their home country. See Eric Blyth, *Fertility Patients’ Experiences of Cross-Border Reproductive Care*, 94 FERTILITY & STERILITY e11, e14 (2010).

151. *Id.* at e12–e13 (indicating that patients are motivated both by factors such as cost and waiting time and by availability of services such as oocyte donation).

152. I. Glenn Cohen, *Circumvention Tourism*, 97 CORNELL L. REV. 1309, 1311 (2012).

153. *Medical Tourism*, CTR. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/features/medicaltourism/> [<https://perma.cc/9LZU-WYWT>] (last visited Feb. 5, 2016).

154. Joseph L. Muzaurieta, *Surgeries and Safaris: Creating Effective Legislation Through a Comparative Look at the Policy Implications, Benefits, and Risks of Medical Tourism for the American Patient*, 29 TEMP. INT’L & COMP. L.J. 115, 116 (2015).

155. *Id.* at 117.

best practices and patient safety.”¹⁵⁶ In addition, some insurance plans are considering (or in a few cases have already implemented) programs that would incentivize or mandate their insured patients to use medical tourism.¹⁵⁷ There have also been proposals to allow Medicare and Medicaid beneficiaries to use their benefits abroad, given the potential cost savings involved for government programs.¹⁵⁸

On a smaller scale, patients have also engaged in “fertility tourism” for similar reasons: to take advantage of lower prices abroad and/or to circumvent restrictions.¹⁵⁹ International surrogacy, particularly in India, has perhaps attracted the most attention—and criticism.¹⁶⁰ The price difference between services stateside and overseas creates enormous incentives to move surrogacy abroad. In India, for example, a surrogate who successfully gives birth typically makes between \$5000 and \$6000, “an amount that exceeds a typical salary for several years of ordinary labor in India.”¹⁶¹ The clinic, in turn, charges American medical tourists \$15,000 to \$20,000 for the entire process, which constitutes “between a third and a fifth of what clients would pay for a similar service in the United States.”¹⁶² It also generates more than \$500 million per year in revenues for India, constituting a respectable part of that country’s overall economic growth.¹⁶³

Moreover, since many countries ban surrogacy, or limit it to married,

156. U.S. INT’L TRADE COMM’N, CARIBBEAN REGION: REVIEW OF ECONOMIC GROWTH AND DEVELOPMENT, at xix (2008).

157. I. Glenn Cohen, *Protecting Patients with Passports: Medical Tourism and the Patient-Protective Argument*, 95 IOWA L. REV. 1467, 1473 (2010).

158. See generally DEAN BAKER & HYE JIN RHO, CTR. FOR ECON. & POL’Y RES., FREE TRADE IN HEALTH CARE: THE GAINS FROM GLOBALIZED MEDICARE AND MEDICAID (2009) (outlining a plan for globalizing Medicare and Medicaid programs); Jennifer Conley, *Medicare and Medical Tourism: Saving Medicare with a Global Approach to Coverage*, 21 ELDER L.J. 183, 218 (2013) (“Medical tourism is a viable way for Medicare to rein in out-of-control health care spending and costs.”).

159. See, e.g., Blyth, *supra* note 150, at e11; Cohen, *supra* note 152, at 1323 (observing that reproductive restrictions have prompted significant amounts of medical tourism).

160. See, e.g., Lisa C. Ikemoto, *Reproductive Tourism: Equality Concerns in the Global Market for Fertility Services*, 27 LAW & INEQ. 277, 282 (2009) (“The most troubling aspects of reproductive tourism arise from the use of third parties who furnish gametes and from surrogates who gestate babies for others. In fact, the strongest critics of these practices use the term ‘trafficking’ rather than ‘tourism.’”).

161. Cohen, *supra* note 152, at 1324–25; see also Pamela Laufer-Ukeles, *Mothering for Money: Regulating Commercial Intimacy*, 88 IND. L.J. 1223, 1272 (2013) (“Indian surrogates, in contrast to [American surrogates], demonstrate a very low level of education and economic earning power.”).

162. Cohen, *supra* note 152, at 1325.

163. Michele Goodwin, *Reproducing Hierarchy in Commercial Intimacy*, 88 IND. L.J. 1289, 1292 (2013) (noting that \$500 million a year of that revenue stays in India).

heterosexual couples,¹⁶⁴ some couples find that they can have genetically related children only by going abroad.¹⁶⁵ Many couples whose home countries provide no access to surrogacy come to the United States.¹⁶⁶ Stuart Bell, the chief executive of Growing Generations, a Los Angeles surrogacy agency, reported that four years ago, “only about 20 percent of its clients came from overseas, but now international clients are more than half.”¹⁶⁷ Other agencies report similar trends.¹⁶⁸

Practices such as surrogacy and egg donation are controversial because of the risk of exploitation of the women involved and/or because of ethical objections to the practice wherever it occurs.¹⁶⁹ This kind of travel—to evade restrictions in the home country—has been termed “circumvention tourism.”¹⁷⁰ The expansion of fertility tourism, however, also involves factors common to globalization generally: efforts to leverage differences in price,¹⁷¹ to receive care from high quality, experienced and successful specialists,¹⁷² to access newly developed or niche treatments not widely available,¹⁷³ or to find a cultural milieu more supportive than that in the home country.¹⁷⁴ Cutbacks in insurance

164. See Cohen, *supra* note 152, at 1323. China, France, Germany, Italy, Japan, Pakistan, Portugal, Saudi Arabia, Spain, and Turkey ban all forms of surrogacy while other countries and some U.S. states prohibit only commercial surrogacy. Joseph Chamie & Barry Mirkin, *Surrogacy: Human Right or Reproductive Exploitation?*, YALE GLOBAL ONLINE (Oct. 28, 2014), <http://yaleglobal.yale.edu/content/surrogacy-human-right-or-reproductive-exploitation> [<https://perma.cc/26W7-N4ND>].

165. See Debora Spar, *Reproductive Tourism and the Regulatory Map*, 352 NEW ENG. J. MED. 531, 531 (2005).

166. Tamar Lewin, *Coming to U.S. for Baby, and Womb to Carry It: Foreign Couples Heading to America for Surrogate Pregnancies*, N.Y. TIMES (July 5, 2014), <http://www.nytimes.com/2014/07/06/us/foreign-couples-heading-to-america-for-surrogate-pregnancies.html> [<https://perma.cc/7X8P-5JWT>].

167. *Id.*; see also Blyth, *supra* note 150, at e11.

168. Lewin, *supra* note 166; see also Blyth, *supra* note 150, at e14 (reporting increase in internet searches for surrogacy agencies).

169. Ikemoto, *supra* note 160, at 130.

170. Cohen, *supra* note 152, at 1311–12.

171. Lack of insurance coverage tends to increase the willingness to go abroad. See Ikemoto, *supra* note 160, at 298.

172. For example, “success rates” were a factor for some patients. See Blyth, *supra* note 150, at e13. Kimberly Mutcherson observes further that the “reputation that the United States has earned as a nation with wide accessibility to high-quality fertility care, for those who can afford the equally high price tag that accompanies such care” attracts patients here. See Kimberly M. Mutcherson, *Welcome to the Wild West: Protecting Access to Cross Border Fertility Care in the United States*, 22 CORNELL J.L. & PUB. POL’Y 349, 364 (2012).

173. See, e.g., *supra* Section II.C (discussing Augment, which is only available outside of the United States).

174. See Ikemoto, *supra* note 160, at 286–87 (noting existence of clinics and destinations that

coverage or the adoption of more restrictive regulations may spur increased interest in reproductive travel.¹⁷⁵ For example, when Italy adopted Europe's most restrictive laws, some Italian doctors simply moved their clinics across the border to Switzerland and the international clientele in Spain grew substantially.¹⁷⁶ Today, cross-border fertility travel in Europe is robust,¹⁷⁷ and most observers expect it to continue to grow.¹⁷⁸

What remains to be seen is whether the globalization of ART will also reduce prices. The Low-Cost IVF Foundation, a Swiss non-profit, is seeking to develop fertility treatments that could assist women in the developing world. It is currently working with Zambia's health ministry to set up an IVF program in Africa that would use clomiphene citrate (Clomid), a drug that provides a modest boost to ovulation and costs just \$12 per attempt, instead of standard injectable gonadotropin drugs used in the United States that cost thousands per cycle.¹⁷⁹ Though Clomid might not be as effective as injectable gonadotropins, for some women its lower price may mean the difference between access to some treatment and no treatment at all. Belgian researchers have experimented with cheaper equipment that produced results comparable to those from pricier, standard labs.¹⁸⁰ And American doctors are attempting to streamline the egg collection process, hoping to cut IVF costs in half for most patients.¹⁸¹ As with Augment, biotech start-ups have begun to

emphasize their support for same-sex couples).

175. *The Guardian* commented at the height of the recession:

As the NHS cuts back on free treatment for the childless, lumping IVF with tattoo removal as an act of kindness rather than treatment for a disease, the competitive prices of private clinics overseas compared with their UK rivals will look ever more tempting. This weekend a number of them will be touting for business at the Fertility Show, now in its second year, at London's Olympia.

Sarah Boseley, *Fertility Becomes Big Business as NHS Cuts Back on Treatment*, *GUARDIAN* (Nov. 5, 2010), <http://www.theguardian.com/society/2010/nov/06/fertility-treatment-foreign-clinics> [<https://perma.cc/7D8V-SCZV>].

176. Richard F. Storow, *Quests for Conception: Fertility Tourists, Globalization and Feminist Legal Theory*, 57 *HASTINGS L.J.* 295, 325 n.134 (2005) (citing Tamsin Smith, *Fertility Laws Frustrate Italians*, *BBC NEWS* (Aug. 9, 2004), <http://news.bbc.co.uk/2/hi/europe/3548242.stm> [<https://perma.cc/94DF-4L2U>]).

177. See Storow, *supra* note 176, at 296–97.

178. Mutcherson, *supra* note 172, at 355.

179. *Maybe Babies*, *ECONOMIST* (July 19, 2014), <http://www.economist.com/news/international/21607881-vitro-fertilisation-once-seen-miraculous-now-mainstream-rich-countries-soon> [<https://perma.cc/Q9U9-KS7B>].

180. *Id.*

181. *Great Expectations*, *ECONOMIST* (Oct. 25, 2014), <http://www.economist.com/news/science-and-technology/21627560-new-procedure-may-halve-cost-vitro-fertilisation-great-expectations> [<https://perma.cc/JY93-4WTQ>]. Indeed, the efforts of the Low Cost Foundation also focus on egg

create innovative procedures that have already been approved for use abroad, though not in the United States.¹⁸²

These developments suggest that ART will increasingly be seen as a global phenomenon. Innovations may come from around the world, and new developments may target diverse patient groups with varying needs and abilities to pay. Yet, these developments are still in their infancy, driven by innovative individual researchers and accessed by enterprising patient-consumers who seek out the treatments. And the services that grow the quickest are those with funding that is most readily available from better-off patients.¹⁸³ Observers wonder whether fertility tourism, like medical tourism in general, will benefit from increased numbers of international brokers who can attest to quality, determine safety, and advise patients, or whether patients will become prey to less scrupulous operators, precisely because of the lack of the third parties such as insurance companies and government regulators.¹⁸⁴ Today, the emerging market for brokers tends to focus on the supply of sperm, eggs, embryos, and surrogates, although that may change with the availability of three parent IVF in the UK or sex selection procedures in the United States.¹⁸⁵ Indeed, even within the United States, separate agencies that do not necessarily provide fertility treatments themselves often recruit sperm and egg donors and surrogates.¹⁸⁶

collection. Its methods involve fewer drugs, less artificial stimulation of the woman's ovaries, which both reduced costs and the physical and emotional damage to women from egg collection. While the initial results may be lower success rates, the researchers are optimistic that over the long term, the results may become comparable. *See Boseley, supra* note 175.

182. *Great Expectations, supra* note 181.

183. The Low Cost Foundation, for example, though it is partnering with an African Health Minister and has support from the World Health Organization, has struggled for funds. *The Guardian*, after interviewing Foundation researchers, observed, “[t]he only money for now is in the cash registers of the burgeoning commercial clinics around the globe – and it’s coming from patients who may have sold or mortgaged all they have in the world for the chance of a baby.” *Boseley, supra* note 175.

184. A U.K. expert on cross-border reproductive services, for example, advises that Spain is “very good,” and the Czech Republic has labs that are inspected in accordance with high standards. But she recommends against going to the Ukraine or to Greece, where the regulatory body has not gotten off the ground because of a lack of funding. *Id.*

185. Ikemoto, *supra* note 160, at 287 (emphasizing that reproductive services take place in a context broader than the doctor-patient relationship); *see also id.* at 291–92 (describing role of brokers in facilitating international services).

186. KARA W. SWANSON, *BANKING ON THE BODY: THE MARKET IN BLOOD, MILK, AND SPERM IN MODERN AMERICA* 199 (2014) (observing that most sperm banks and egg donor agencies are for-profit enterprises, selling over the internet, and focused more on recruiting patients than serving doctors). *See generally* RENE ALMELING, *SEX CELLS: THE MEDICAL MARKET FOR EGGS AND SPERM* (2011) (providing a comprehensive account of the recruitment of egg and sperm donors).

Nonetheless, connections established across all parts of the fertility business may ultimately contribute to a more globalized industry. First, individual clinics increasingly see the internet as a source of patients, and websites are designed to appeal to international patient audiences and to those seeking services, such as sex selection, that are not universally available.¹⁸⁷ These appeals in turn contribute to word-of-mouth information—and to satisfied customers who help recruit others.¹⁸⁸ They may also contribute to niche markets for certain procedures, such as sex selection, which is widely available in the United States or mitochondrial transfer in the U.K.¹⁸⁹ Second, as clinics become larger, they may establish multi-jurisdictional partnerships or affiliations. Lisa Ikemoto, for example, describes a relationship between an American clinic and a Romanian lab, which recruited egg donors in Romania, had the eggs fertilized in Bucharest and shipped back to the United States, allowing the patient to realize savings both in the price of the eggs and the medical procedures done abroad.¹⁹⁰ She also mentions a Danish clinic with centers in two Danish cities, Lithuania, and several African countries.¹⁹¹ The Fertility Institutes' homepage lists offices in New York and Los Angeles, a presence in the United States, Mexico, and India, and a network of over 240 associated U.S. and international fertility centers.¹⁹² Third, increasing numbers of brokers, whether third-party internet sites, travel agencies, or fertility specialists offer to provide information or arrange trips involving clinics abroad.¹⁹³ Such brokers have fueled the growth of international surrogacy and egg donation, and

187. Ikemoto, *supra* note 160, at 285–89; Blyth, *supra* note 150, at e13–14.

188. *See* Blyth, *supra* note 150, at e14 (discussing the importance of internet information in prompting cross-border care).

189. Meredith Leigh Birdsall, *An Exploration of "The 'Wild West' of Reproductive Technology": Ethical and Feminist Perspectives on Sex-Selection Practices in the United States*, 17 WM. & MARY J. WOMEN & L. 223, 226 (2010) (describing that more and more couples from other countries are coming to the United States for sex-selection procedures that they are denied at home); *see also supra* notes 115–20 and accompanying text (describing FDA responses to U.K. authorization of three parent IVF to address mitochondrial disease).

190. Ikemoto, *supra* note 160, at 290.

191. *Id.*

192. FERTILITY INSTS., <http://www.fertility-docs.com/about-us/clinics-and-staff.php> [<https://perma.cc/F8LU-5H46>] (last visited Feb. 5, 2016); *International Programs*, FERTILITY INSTS., <http://www.fertility-docs.com/programs-and-services/international-programs.php> [<https://perma.cc/K6PL-5MF7>] (last visited Feb. 9, 2016); *see also* PAC. FERTILITY CTR., <http://www.pacificfertilitycenter.com/the-center/infertility-center> [<https://perma.cc/Y9BT-Z5M7>] (last visited Feb. 5, 2016); *International Patients*, PAC. FERTILITY CTR., <http://www.pacificfertilitycenter.com/treatment-care/international-patients> [<https://perma.cc/TA6V-Z3A6>] (last visited Feb. 5, 2016) (describing itself as having an independent affiliate in Japan).

193. Ikemoto, *supra* note 160, at 291–92.

they could help fuel reproductive tourism more generally.¹⁹⁴

CONCLUSION

Larger entities, better-established networks, more global clientele, or greater use of brokers may offer greater flexibility. Fertility clinics may need to become more nimble in adopting new technologies, acquiring the ability to custom tailor services to meet client demand, and functioning in markets that may simultaneously reward less expensive approaches that can generate greater volume and high-end products for those who can pay for them. David Sable observes that:

I have seen countless business plans over the past couple of years describing various combinations of IVF centers in different parts of the country merging, gaining economies of scale, trying to maintain pricing power and protecting quality branding. This trend . . . will accelerate as the market expands and consumer decisions are made less by individual patients and more by a combination of large insurers assembling networks and Uber/Open Table/Zoc Doc aggregators efficiently helping patients find an appropriate clinic. As has occurred in many areas of medicine, business will move to big purchaser (insurer/payor/patient purchasing service) buying from big provider (hospital/mega clinic[]).¹⁹⁵

These developments suggest a market that will be even more segmented in the future. It may involve clinics that scan the globe for new developments that can be implemented in sophisticated, high profit-margin offices while referring more cost-conscious patients abroad. At the same time, innovation may come from a mix of government-sponsored and privately-initiated research. Ironically, government-supported research may be most critical to the low cost procedures with the potential to expand care while private investment stakes out the lower volume, but higher profit-margin innovations. And the innovations may come from across the globe. For example, in September 2015, the French announced that they had produced human sperm in a lab for the

194. *Id.*; see also Nicole Grather & Adam May, *Going Global for a Family: Why International Surrogacy Is Booming*, AL JAZEERA AM. (May 12, 2014, 7:30 PM), <http://america.aljazeera.com/watch/shows/america-tonight/articles/2014/5/12/going-global-forfamilywhyinternationalsurrogacyisbooming.html> [<https://perma.cc/2LUY-U39H>] (describing the role of brokers in the growth of fertility tourism); Jennifer Rimm, *Booming Baby Business: Regulating Commercial Surrogacy in India*, 30 U. PA. J. INT'L L. 1429, 1456–59 (2009) (describing the positive and negative roles of agencies in commercial surrogacy).

195. Sable, *supra* note 91.

first time, and a French biotech start-up sought a patent for the process jointly with French National Center for Scientific Research.¹⁹⁶

These changes should ultimately remake not just the availability of fertility treatments, but the nature of the doctor-patient relationship. Administrators will need to be both medical professionals and business men and women. Their patients will also need to be consumers, able to shop the most appropriate and affordable treatments. States interested in securing the safety of their citizens will need to be aware of international as well as national developments. At the center of these developments will be information flows—how should we conceive of what doctors need to know and to tell patients versus what the patients can be expected (for better and worse) to find out on their own? With an international race to invest, profit, evade regulatory restrictions, and realize the future, the doctor-patient relationship will require ever more sophisticated ways to determine safety and preserve the capacity for meaningful choice. The physicians' remarks quoted above illustrate that they are already conscious of the shifts that the fertility industry is currently experiencing and will continue to experience in the future. But such awareness merely complicates the picture. For example, will they communicate the risks and benefits of developments such as fertility tourism or technological innovations unavailable at their own clinics to patients? Is such information material to the project of informed consent, wherein physicians must inform patients about a treatment procedure's risks, benefits, side effects, and alternatives? And how are these ethical responsibilities affected by the fact that certain treatment options may not be offered at a patient's home clinic, or indeed, within the borders of the United States? The future of fertility treatments will increasingly take place within a global marketplace; yet, no global infrastructure exists for determining the safety or the ethical permissibility of the developments on the horizon.

196. Jonathan O'Callaghan, *First Lab-Grown Human Sperm Technique Revealed by Scientists*, IFL SCI. (Sept. 21, 2015), <http://www.iflscience.com/health-and-medicine/human-sperm-created-lab-first-time-scientists-claim> [<https://perma.cc/KCD4-NSMK>].