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Steven Goldberg

Georgetown University Law Center, goldberg@law.georgetown.edu

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TECHNOLOGY UNBOUND: WILL FUNDED LIBERTARIANISM DOMINATE THE FUTURE?

Steven Goldberg*

On May 2, 2006, a liberal and a conservative on the U.S. Court of Appeals for the District of Columbia Circuit joined forces and held that terminally ill patients have a constitutional right to use certain medicines that have not received Food and Drug Administration (FDA) approval.¹ The panel decision in the *Abigail Alliance* case may or may not survive further review,² but the important point has already been established. The FDA has expressed sympathy with the plaintiffs' desire for increased access to non-approved drugs.³ The increasing reduction of FDA oversight in recent decades⁴ has taken another dramatic step.

Access to pharmaceuticals does not stand alone. In vitro fertilization (IVF) is a modern medical procedure that raises a variety of ethical and consumer protection issues.⁵ Yet in the United States, it takes place in an unregulated environment reminiscent of the Wild West. State and federal regulators have almost no role, leaving the field to modest and non-binding self-regulation.⁶

* Professor of Law, Georgetown University Law Center.

1. *Abigail Alliance for Better Access To Developmental Drugs v. von Eschenbach*, 445 F.3d 470 (D.C. Cir. 2006). Judge Rogers, who wrote the opinion, is generally regarded as liberal, while Chief Judge Ginsburg, who joined the opinion, is usually viewed as conservative. See, e.g., Chris Mooney, *Circuit Breaker*, THE AMERICAN PROSPECT, Mar. 1, 2003, <http://www.prospect.org/print/V14/3/mooney-c.html>.

2. See Christopher Bowe, *Ruling on Right to Medicine Gets to the Heart of American Culture*, FIN. TIMES (USA Edition), May 17, 2006, at 4. On November 21, 2006, the panel in *Abigail Alliance* denied a petition for rehearing, *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 2006 U. S. App. LEXIS 28834 (D.C. Cir. Nov. 21, 2006), and the D. C. Circuit granted a petition for rehearing en banc, *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 2006 U.S. App. LEXIS 28974 (D.C. Cir. Nov. 21, 2006).

3. Bowe, *supra* note 2 at 4.

4. See, e.g., Marshall H. Chin, *An American Dilemma: The Patient's Role in Choice of Medications: Direct-to-Consumer Advertising and Patient Decision Aids*, 5 YALE J. HEALTH POL'Y L. & ETHICS 771 (2005).

5. See, e.g., Lyria Bennett Moses, *Understanding Legal Response to Technological Change: The Example of In Vitro Fertilization*, 6 MINN. J. L. SCI. & TECH. 505 (2005).

6. See, e.g., Alexander N. Hecht, *The Wild Wild West: Inadequate Regulation of*

Just one year before the *Abigail Alliance* decision, President Bush decried the creation of “spare embryos,” a central consequence of IVF,⁷ yet his words have led to no restrictions on the widespread availability of this procedure.

These developments do not represent a victory for those who would let the market decide what drugs and medical procedures should be produced and consumed. The plaintiffs in *Abigail Alliance* have joined forces with groups lobbying for increased federal spending on medical research.⁸ The IVF community has a similar record of pushing for government-funded research on enhancing fertility.⁹ These groups support what might be called funded libertarianism: the government should use taxpayers’ money to support research, but the products and procedures that result should be available on a caveat emptor basis. The maturation of the Internet provides a rough but helpful analogy. Developed initially with substantial government funding, the Internet now operates in a largely unregulated fashion, despite calls for government action against pornography and other social ills.¹⁰

This new pressure for unfettered access to drugs and medical procedures turns the received wisdom about government regulation of new technology on its head. It has long been noted that novel technologies receive far more regulatory scrutiny than old-fashioned ones.¹¹ As Cass Sunstein observed in 1997, “people are especially hostile to new risks.”¹² Coal mining may be particularly hazardous for workers and emissions from coal plants may substantially endanger the public, but coal mining, an old industry, will never be subject to the level of regulatory oversight that governs the newer nuclear power industry.¹³ Yet proponents of access to new pharmaceuticals and to IVF actually seek less regulation than is typical for older drugs and procedures.

We will look first at the *Abigail Alliance* litigation and what it can tell us about drug regulation and deregulation. We will then turn to the remarkable status of IVF procedures, which have eluded regulation despite (or perhaps because of) obvious links to disputes over the legal status of the embryo. We will then look at the future of funded libertarianism. Although the matter is not free from doubt, it seems unlikely that this approach can serve as a new template for technological progress.

Assisted Reproductive Technology, 1 HOUS. J. HEALTH L. & POL’Y 227 (2001).

7. William Neikirk & Mark Silva, *Stem Cell Bill OKd: Measure Goes to Senate as President Reaffirms Veto Promise*, CHI. TRIB., May 25, 2005, at 1.

8. See *infra* Part I.

9. See *infra* Part II.

10. See, e.g., Susan P. Crawford, *Shortness of Vision: Regulatory Ambition in the Digital Age*, 74 FORDHAM L. REV. 695, 704-09 (2005).

11. See Peter Huber, *The Old-New Division in Risk Regulation*, 69 VA. L. REV. 1025 (1983).

12. Cass R. Sunstein, *Which Risks First?*, 1997 U. CHI. LEGAL F. 101, 130 (1997).

13. See, e.g., Huber, *supra* note 11, at 1031.

I. ABIGAIL ALLIANCE AND DRUG DEREGULATION

Under the federal Food, Drug, and Cosmetic Act,¹⁴ a new drug cannot be marketed until the FDA determines it is safe and effective. The FDA makes this determination by subjecting investigational new drugs (INDs) to three phases of testing.¹⁵ In order to understand the holding of the *Abigail Alliance* court, it is necessary to describe these phases.

Phase I testing, which takes about one year, involves administering the drug to a small number of human subjects to determine if it is dangerous.¹⁶ The subjects are often healthy, although Phase I can also involve ill patients. According to the FDA, drugs that make it through Phase I are “sufficiently safe for substantial human testing,” but they have not yet been shown to be safe and effective enough to be commercially sold.¹⁷

If an IND survives Phase I, it moves to Phase II, where it is subjected to a large controlled clinical study involving hundreds of human subjects who have the disease for which the drug is designed. The participants are randomly divided into two groups, one receiving the drug and the other a placebo. Neither the subjects nor those administering the drugs know which group a patient is in. Phase II provides evidence on the effectiveness of the IND as well as additional evidence on its safety. If a drug makes it through Phase II, it moves on to Phase III, which is an expanded controlled study that might involve thousands of human subjects. Those INDs that successfully complete Phase III are eligible to be marketed commercially.

This FDA process can take years. An individual who might benefit from a drug under study might not be chosen for the clinical trials and, in any event, might receive a placebo in those trials. The FDA has the authority to grant “compassionate use” exemptions for patients who are not receiving a drug under study, but it typically does so only when a drug has at least entered Phase II and there is some evidence of the drug’s effectiveness.

The Abigail Alliance for Better Access to Developmental Drugs (Abigail Alliance) is a lobbying group that was founded by Frank Burroughs after his twenty-one-year-old daughter Abigail died in 2001 of cancer.¹⁸ Abigail was unable to obtain promising drugs that were working their way through the FDA process while she was dying.¹⁹

14. 21 U.S.C. § 301 (1997).

15. *Abigail Alliance*, 445 F.3d 470, 473 (D.C. Cir. 2006).

16. The description of FDA procedures in the following three paragraphs is drawn from *Abigail Alliance*, 445 F. 3d at 473-74, and from Gail H. Javitt, *Drugs and Vaccines for the Common Defense: Refining FDA Regulation to Promote the Availability of Products to Counter Biological Attack*, 19 J. CONTEMP. HEALTH L. & POL’Y 37, 52-59, 97-107 (2002).

17. *Abigail Alliance*, 445 F.3d at 473.

18. *Fighting for a Miracle*, CBS NEWS, Nov. 13, 2005, <http://www.cbsnews.com/stories/2005/11/13/sunday/main1041404.shtml>.

19. *Id.*

On June 11, 2003, the Abigail Alliance and the Washington Legal Foundation petitioned the FDA to allow terminally ill patients to have access to drugs that had made it through Phase I of the FDA process.²⁰ After the petition was denied, they brought suit.²¹ The District Court dismissed their case, but the District of Columbia Circuit reversed.²²

Written by Judge Judith Rogers, a Clinton appointee associated with the court's liberal wing, and joined by Chief Judge Douglas Ginsburg, a conservative Reagan appointee, *Abigail Alliance* found that terminally ill patients have a substantive due process right to use "potentially life-saving new drugs that the FDA has yet to approve for commercial marketing but that the FDA has determined, after Phase I clinical human trials, are safe enough for further testing on a substantial number of human beings."²³ By carefully defining their claim in this fashion, the plaintiffs persuaded the court that they had satisfied the Supreme Court's requirement that the Due Process Clause not be used to "multiply rights without principled boundaries."²⁴

Moreover, by limiting their claim to drugs that have made it through Phase I, the plaintiffs avoided the question of whether individuals have a right to unsafe medications, and thus avoided a precedent from 1980 upholding the FDA's refusal to approve the use of Laetrile for cancer.²⁵ As Judge Rogers said, Laetrile might have been "a poison," while Phase I approval assures that drugs have passed somewhat of a threshold.²⁶

The panel's substantive due process analysis found that terminally ill patients had a fundamental right to use potentially life-saving drugs by applying the Supreme Court's *Glucksberg*²⁷ approach.²⁸ Under this test, the court asks whether the asserted fundamental right is "objectively, 'deeply rooted in this Nation's history and tradition'" and whether it is "implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if [it] were sacrificed."²⁹

On the historical point, the court, citing cases beginning in 1609, argued that control over one's body has been traditionally protected at common law for centuries.³⁰ Government regulation, on the other hand, began in 1906, and only

20. *Abigail Alliance*, 445 F.3d at 473.

21. *Id.* at 473-74.

22. *Id.* at 474, 486.

23. *Id.* at 477.

24. *Id.*

25. *Id.* at 485-86.

26. *Id.* at 486.

27. *Washington v. Glucksberg*, 521 U.S. 702 (1997).

28. *Abigail Alliance*, 445 F.3d at 475-77.

29. *Id.* at 476-77 (quoting *Glucksberg*, 521 U.S. at 721).

30. *Id.* at 480-83.

in 1962 did Congress require that drugs be effective as well as safe.³¹

This approach, of course, turns entirely on the level of generality employed on judicial review. It was in the twentieth century that the public became aware of the dangers of modern pharmaceuticals,³² and so it is not surprising that regulation began then.

Under the court's approach, it will be difficult to find a tradition of government regulation for any new technology. In this sense, the court was echoing the approach used by the Supreme Court when it struck down the Communications Decency Act (CDA)³³ which was designed to regulate offensive communications on the Internet: "Neither before nor after the enactment of the CDA have the vast democratic fora of the Internet been subject to the type of government supervision and regulation that has attended the broadcast industry."³⁴ Given the newness of the "vast democratic fora of the Internet" when Congress passed the CDA in 1996,³⁵ the lack of previous regulation is hardly surprising.

Turning to whether the liberty interest in taking a life saving drug is "implicit in the concept of ordered liberty," the court relied on the Supreme Court's *Cruzan*³⁶ decision, which found a substantive due process right to refuse treatment.³⁷ "The logical corollary" of *Cruzan*, the court reasoned, "is that an individual must also be free to decide for herself whether to assume any known or unknown risks of taking a medication that might prolong her life."³⁸

Having found a fundamental right protected by the Due Process Clause, the court remanded the case to the district court to give the government an opportunity to argue that its regulatory regime is "narrowly tailored to serve a compelling governmental interest."³⁹ This is always a difficult burden for the government to meet.⁴⁰ One possible approach would be to argue that making drugs available after Phase I would make it impossible to recruit patients for the controlled studies that take place under Phases II and III. Who would want to run the risk of being given a placebo when they can obtain the experimental

31. *Id.* at 481-83.

32. *Id.* at 482.

33. 47 U.S.C. § 223 (1996), *portions invalidated by Reno v. ACLU*, 521 U.S. 844 (1997).

34. *Reno v. ACLU*, 521 U.S. 844, 868 (1997).

35. *Id.* at 844, 849, 868-69.

36. *Cruzan v. Dir. Mo. Dep't of Health*, 497 U.S. 261 (1990).

37. *Abigail Alliance*, 445 F.3d at 484.

38. *Id.* For a related argument that the government cannot refuse access to safe and effective medicines derived from therapeutic cloning, see Steven Goldberg, *Cloning Matters: How Lawrence v. Texas Protects Therapeutic Research*, 4 YALE J. HEALTH POL'Y L. & ETHICS 305 (2004).

39. *Abigail Alliance*, 445 F.3d at 486.

40. On the difficulty of meeting it here, see *id.* at 499-500 (Griffith, J., dissenting).

drug in question on their own?⁴¹ Without the later phases, the government would lack the evidence on efficacy and the additional information on safety that the current approach provides. But the *Abigail Alliance* court might well conclude that this desire for further information does not overcome a terminally ill patient's right to potentially life saving treatment.

The substantive due process right found in *Abigail Alliance* may not survive. As the dissent points out, the Supreme Court may well believe that the legislature, rather than the courts, is the appropriate place to balance the conflicting values involved in drug regulation.⁴² Reversal of *Abigail Alliance* by the en banc District of Columbia Circuit or by the Supreme Court is quite possible.

But the broader point—the remarkable attractiveness of reduced regulation of powerful pharmaceuticals—will remain, regardless of further litigation. The seemingly odd coalition of Judge Rogers and Chief Judge Ginsburg is part of a bigger picture. Spurred in part by the AIDS epidemic, faster access to new drugs has been an increasingly popular position for decades.⁴³ The FDA's "compassionate use" policy was codified by Congress in 1997,⁴⁴ and there have been continuing calls on Capitol Hill for further deregulation.⁴⁵ The classic scientific value of the double-blind studies in Phases II and III is increasingly seen as an inadequate basis for refusing consumer access to drugs.⁴⁶

But this is not a libertarian movement. Despite the considerable private expenditures on research and development by drug companies, there is strong support by those who would loosen FDA requirements for using taxpayers' money for government-supported basic research in this area. The Abigail Alliance does not believe in leaving the emergence of pharmaceuticals to the private market. It has joined forces with the Sarcoma Foundation of America, which advocates "increased government funding" of cancer research, and with Research America, which calls for "strong, increased investment" by agencies such as the National Institutes of Health and the National Science Foundation.⁴⁷

41. In the past, patients have enrolled in multiple studies to reduce the odds they are receiving placebos. Lois K. Perrin, Note, *The Catch-22 for Persons With AIDS: To Have or Not to Have Easy Access to Experimental Therapies and Early Approval for New Drugs*, 69 S. CAL. L. REV. 105, 126 (1995).

42. *Abigail Alliance*, 445 F.3d at 491-99 (Griffith, J., dissenting).

43. See Chin, *supra* note 4; Javitt, *supra* note 16.

44. 21 U.S.C. § 360bbb (2006), amended by National Institutes Health Reform Act of 2006, Pub. L. No. 109-482, 120 Stat. 3675 (2007).

45. See, e.g., Steven R. Salbu, *Regulation of Drug Treatments for HIV and AIDS: A Contractarian Model of Access*, 11 YALE J. ON REG. 401, 418 (1994).

46. *Id. passim*.

47. The Abigail Alliance says on their web page that they are "working together" with the Sarcoma Foundation and that they "join forces" with Research America. Abigail Alliance Homepage, <http://abigail-alliance.org/> (last visited June 19, 2006). The Abigail Alliance page provides links to the web pages of these organizations from which the quotes

This is what might be called funded libertarianism. And, as the case of IVF shows, it does not stand alone.

II. ASSISTED REPRODUCTION AND PRIVATE CHOICES

Assisted reproductive technologies have revolutionized procreation in recent decades. The most widely used technology is in vitro fertilization, which is used to overcome several types of infertility.⁴⁸

In its most common form, IVF involves removing eggs from a woman's ovaries, fertilizing them with sperm, and then transferring one or more of the fertilized eggs into the woman's uterus in the hope of starting a pregnancy.⁴⁹ The procedure is quite modern. The first "test-tube baby," Louise Brown, was born in the United Kingdom in 1978, while the first such birth in the United States took place in 1981.⁵⁰ To date, well over 200,000 IVF babies have been born in the United States.⁵¹

There has been sharp controversy about IVF from the beginning.⁵² Much of it stems from the fact that multiple eggs are fertilized in the laboratory. It is then common to insert several fertilized eggs into the uterus to raise the odds of a successful pregnancy.⁵³ As a result, the instance of twins, triplets, and other multiple births increases with IVF and there may be health hazards as a result to the babies, as well as to their mothers.⁵⁴

But the largest controversies come because more eggs are typically fertilized than are introduced into the uterus. These "spare embryos" are often frozen, and after a period of time they are sometimes discarded by the laboratories with the consent of the egg and sperm donors.⁵⁵ To many Americans, a "spare embryo" is a human life.⁵⁶ As a result, discarding an

in the text are taken. See Sarcoma Foundation of America Homepage, <http://www.curesarcoma.org/> (last visited June 19, 2006); Research!America Homepage, <http://www.researchamerica.org/about/> (last visited June 19, 2006).

48. Note, *Assessing the Viability of a Substantive Due Process Right to In Vitro Fertilization*, 118 HARV. L. REV. 2792, 2793 (2005).

49. Mary Ann Davis Moriarty, Note and Comment, *Addressing In Vitro Fertilization and the Problem of Multiple Gestations*, 18 ST. LOUIS U. PUB. L. REV. 503, 504-05 (1999).

50. *Id.* at 505.

51. Joshua Kleinfeld, *Tort Law and In Vitro Fertilization: The Need for Legal Recognition of "Procreative Injury"*, 115 YALE L.J. 237, 238 n.11 (2005).

52. See, e.g., Stephen Smith, *Twenty Years of Test-tube Babies: A Revolutionary Birth* (Minnesota Public Radio Broadcast Apr. July 23, 1998), available at http://news.minnesota.publicradio.org/features/199711/20_smiths_fertility/part7/section1.shtml.

53. Moriarty, *supra* note 49, at 507.

54. *Id.*

55. MICHAEL H. SHAPIRO & ROY G. SPECE, CASES, MATERIALS AND PROBLEMS ON BIOETHICS AND LAW 625-41 (2d ed. 2003).

56. Barbara Gregoratos, Note, *Tempest in the Laboratory: Medical Research on Spare*

embryo is utterly unacceptable. If you doubt that this point of view is important, consider the titanic controversy over stem cell research. Whether the government should fund or even allow such research on “spare embryos” has divided legislatures and the public for years.⁵⁷ It was a proposal for federal support of stem cell research that led to President Bush’s May 2005 statement that there should be no “spare embryos” and that excess embryos resulting from IVF should be adopted.⁵⁸ His proposal has had no impact on the availability of IVF.

One would think that since many Americans want to forbid stem cell research on embryos, there would be enormous state and federal restrictions on simply discarding the very same embryos. But that would be wrong. The hundreds of medical centers offering IVF across the United States operate in what many commentators have called a “Wild West” environment of non-regulation.⁵⁹ While a federal statute requires that such centers disclose certain information about the success rate of their procedures in bringing about pregnancies,⁶⁰ there is virtually no government regulation at any level relating to the risks associated with multiple births or to the disposition of spare embryos.⁶¹ Industry groups provide limited self-regulation, but many centers are not even members of such groups.⁶²

To some extent, IVF benefits from the all-or-nothing approach many people take to the question of embryonic life. Many opponents of IVF would entirely forbid the procedure,⁶³ and they do not have the political power to bring about that result. Yet there is nothing about IVF that makes regulation short of prohibition impossible. In the United Kingdom, for example, IVF is a lawful, but closely regulated, procedure.⁶⁴

The key to the American situation is that IVF proponents want to make their own decisions about reproduction free from government interference. They want to weigh the risks and benefits of multiple pregnancies and they

Embryos from In Vitro Fertilization, 37 HASTINGS L.J. 977, 983-84 (1986).

57. See, e.g., LORI B. ANDREWS ET AL., GENETICS: ETHICS, LAW AND POLICY 165-82 (2d ed. 2006).

58. Neikirk & Silva, *supra* note 7.

59. See Hecht, *supra* note 6; Michael J. Malinowski, *Choosing the Genetic Makeup of Children: Our Eugenics Past–Present, and Future?*, 36 CONN. L. REV. 125, 179 (2003) (quoting *Making Babies* (PBS television broadcast June 1, 1999)).

60. Congress has enacted the Fertility Clinic Success Rate and Certification Act of 1992. 42 U.S.C. § 263a-1 (1992). See Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation*, 55 FLA. L. REV. 603, 614-15 (2003).

61. See Hecht, *supra* note 6.

62. See Noah, *supra* note 60, at 606 n.9.

63. See, e.g., John B. Shea, *The Moral Status of In Vitro Fertilization (IVF)*, CATHOLIC INSIGHT, Jan.-Feb., 2003, available at http://catholicinsight.com/online/church/vatican/article_475.shtml.

64. Moses, *supra* note 5, at 545-49.

want to determine the fate of the embryos they create without state regulation.

This is obviously tied to the pro-choice position on abortion. But not everyone who utilizes IVF supports *Roe v. Wade*.⁶⁵ People seeking to have a baby may be pro-life in more ways than one.⁶⁶ Our understanding of the unregulated state of the American IVF industry is enhanced by looking at the effort in recent decades to reduce FDA regulation of life-saving drugs. In both cases we see a desire for unmediated access to new technology or, in other words, for a kind of libertarian approach to the fruits of modern science.

And in both cases it is funded libertarianism that is desired. The infertility lobby, which strongly supports IVF, does not want to leave to the marketplace the production of new techniques to enhance reproduction any more than the Abigail Alliance wants to keep the government out of drug research.

Consider RESOLVE, The National Infertility Association (RESOLVE), a major lobbying group founded in 1974. RESOLVE “supports the rights of individuals experiencing infertility . . . to elect their family building method(s)” and “to be free from interference in making the very personal decision about the uses of their own body tissues, including reproductive tissues and fertilized reproductive tissues.”⁶⁷ Indeed, RESOLVE believes “the current regulatory environment for assisted reproduction . . . works phenomenally well.”⁶⁸ On the other hand, RESOLVE supports increased funding for infertility research by the National Institutes of Health, the National Institute of Child Health and Human Development, and the Centers for Disease Control.⁶⁹

Because there is no meaningful regulation of IVF, there is no case like *Abigail Alliance* challenging such regulation. But if the government were ever to sharply restrict access to IVF, it is easy to imagine the contours of a challenge that might be brought.

First, just as the court in *Abigail Alliance* was able to describe drug regulation as relatively new, opponents of restrictions on IVF would be free to argue that those restrictions are novel. These opponents would note that for decades after the 1978 birth of Louise Brown the government left IVF alone. Of course this argument depends arbitrarily on the frame of reference, but in a legal culture that views the Internet as historically unregulated, those opposing IVF restrictions would have a plausible argument.

As for showing that they are defending an interest “implicit in the concept

65. *Roe v. Wade*, 410 U.S. 113 (1973).

66. Janet L. Dolgin, *Surrounding Embryos: Biology, Ideology, and Politics*, 16 HEALTH MATRIX 27, 36-38 (2006).

67. Letter from Bonnie Gilbert, Acting Executive Dir., RESOLVE to O. Carter Snead, General Counsel, The President’s Council on Bioethics (on file with author), available at http://www.resolve.org/site/PageServer?pagename=ta_pap_regart.

68. *Id.*

69. Player Profile: The Infertility Lobby, <http://www.stanford.edu/class/siw198q/websites/reprotech/New%20Ways%20of%20Makin%20Babies/resolve.htm> (last visited June 2, 2006).

of ordered liberty,” IVF supporters would cite the line of cases from *Skinner v. Oklahoma*⁷⁰ to *Griswold*⁷¹ and *Roe*⁷², which establish a right to make personal decisions about reproduction free from government control. Here again, while it is far from clear that the courts would extend this controversial line of cases in a new direction, the argument, which draws on support for bringing about new life and which has been endorsed by several commentators, is far from frivolous.⁷³ It is plausible that any material government restriction on IVF would have to meet the demanding “compelling state interest” test.⁷⁴

As with drug regulation, the important point about IVF is not how restrictions would fare in court, but how our broader social attitudes find expression. Couples want the freedom to make their own decisions, combined with substantial government funding for research, to enhance the choices available to them.

III. THE FUTURE OF FUNDED LIBERTARIANISM

Are the movements to secure access to drugs that have only been through Phase I testing and to utilize IVF free of regulation harbingers of things to come? At a minimum, they do not stand alone. After decades of strict FDA regulation and physician oversight, patients are pushing for an increased role in deciding what new pharmaceuticals to take, as the growth of direct-to-consumer advertising for prescription drugs makes clear.⁷⁵ And after decades in which the law was deeply suspicious of new methods of reproduction, a lack of regulation is becoming the norm for a variety of assisted reproductive technologies. It is hard to believe that not long ago courts found that sperm donation constituted adultery,⁷⁶ while today surrogacy, pre-implantation genetic diagnosis, and a host of other developments have reshaped human reproduction.⁷⁷

These developments are particularly striking because they involve reduced regulation for new risks. In 1983, Peter Huber began his influential article *The Old-New Division in Risk Regulation*: “Federal systems of risk regulation

70. *Skinner v. Oklahoma ex rel. Williamson*, 316 U.S. 535, 541 (1942) (“The right to procreate is a basic right of man, so fundamental to the existence of the human race that the government should not interfere.”).

71. *Griswold v. Connecticut*, 381 U.S. 479 (1965).

72. *Roe v. Wade*, 410 U.S. 113 (1973).

73. John A. Robertson, *Procreative Liberty in the Era of Genomics*, 29 AM. J.L. & MED. 439, 453 (2003); Note, *supra* note 48, at 2813.

74. Moriarty, *supra* note 49, at 516.

75. See Chin, *supra* note 4.

76. Note, *Human Cloning and Substantive Due Process*, 111 HARV. L. REV. 2348, 2360 (1998).

77. SHAPIRO & SPECE, *supra* note 55, at 621-631.

subtly but systematically distinguish the devils we know from the ominous unknown.”⁷⁸ Surveying a host of regulatory environments, he found that new products and technologies were subjected to more regulation than those that had been around for a long time: “Old risks are those to which society has been widely exposed before Congress or an agency finds federal regulation necessary New risks loom on the horizon, threatening to undermine the perceived safety of the status quo.”⁷⁹

Cass Sunstein’s impressive 1997 analysis of risk regulation supported Huber’s insight, noting that “people are especially hostile to new risks. Old risks tend to be taken for granted.”⁸⁰ Sunstein identified a general “status quo bias” under which we “impose special barriers to new risks.”⁸¹

This tendency to regulate the new more stringently than the old has been a particular feature of food and drug regulation, making the *Abigail Alliance* movement particularly remarkable. Huber’s article described at length how the FDA failed in its efforts to regulate saccharin, a well-established sugar substitute which posed a cancer risk, while it successfully restricted access to newer products that were no more dangerous.⁸² In a detailed discussion of FDA regulation of additives that might cause cancer, Richard Merrill found that government policies “favor old additives and disfavor new ones.”⁸³ The argument that consumer choices, old and new, are “voluntary” and should be unregulated has never carried the day.⁸⁴

Under the circumstances, it is appropriate to ask whether the new push for funded libertarianism represents the beginning of a trend. We can dispose of one part of this question quite easily. The “funded” part of funded libertarianism represents an extension of established policy and is certain to endure. In supporting federally funded research on drugs and fertility, the groups we are discussing are safely in the mainstream.

In theory, government funding of basic research does not fit easily with unfettered consumer choice. Funded libertarianism is a paradoxical concept, since for libertarians, mandatory taxation for science is deeply problematic. In *End Government Science Funding*, a paper published by the Cato Institute, Terence Kealey argues that “companies fund pure science very generously,” while government funding of science “is largely unproductive,” and he concludes that “[s]cientists may love government money, and politicians may

78. Huber, *supra* note 11, at 1025.

79. *Id.* at 1026.

80. Sunstein, *supra* note 12, at 130.

81. *Id.* at 120-121.

82. Huber, *supra* note 11, at 1045-49.

83. Richard A. Merrill, *FDA’s Implementation of the Delaney Clause: Repudiation of Congressional Choice or Reasoned Adaptation to Scientific Progress?*, 5 YALE J. ON REG. 1, 76 n.367 (1988).

84. Sunstein, *supra* note 12, at 125-28.

love the power its expenditure confers upon them, but society is impoverished by the transaction.”⁸⁵

That may be the theory, but the reality is that the federal government has long funded basic research, such funding enjoys broad bipartisan support, and it is not going to end any time soon.⁸⁶ Either because of weaknesses in his theoretical argument,⁸⁷ or because of political realities, Kealey’s point of view is not about to prevail.

The real question is whether relatively unregulated access to new products and procedures is going to gradually replace large areas of current government control. Only time will tell whether we are seeing the beginning of a new era in which consumers increasingly make their own risk calculations. But I must confess that I am doubtful. Indeed, I believe the Abigail Alliance and IVF movements will not lead to a lasting reduction of regulation, even in their own fields.

There are inevitably bad outcomes with any technology, and when those problems arise in a dramatic setting, media attention and public concern will follow. A risky pharmaceutical that was not fully tested could kill the child of a celebrity. A prominent woman who was carrying multiple embryos could die during childbirth. Of course, there are risks in all human endeavors. But the strength of Huber’s and Sunstein’s analyses of old versus new risks stems in part from the fact that with old risks we have a frame of reference spanning generations. Coal miners have died before, while nuclear accidents remain relatively novel.

The avenues for prompt government regulation of new technologies are wide and well-known. Most prominently, the government has broad constitutional power to attach strings to the funding it provides.⁸⁸ Science spending is not exempt. The requirement of Institutional Review Boards for research funded by the government came about because of abuses relating to research involving human subjects.⁸⁹ So even in the absence of direct regulation, new pharmaceuticals and IVF face the reality of government regulation precisely because they are often government-funded.

The imposition of federal regulation tied to federal money is not the only threat facing unregulated new technologies. High-profile problems will also bring forth a rash of tort suits, where the absence of generations of experience will present plaintiffs with the possibility of high payoffs.

85. Terence Kealey, *End Government Science Funding*, CATO INSTITUTE DAILY DISPATCH, Apr. 11, 1997, <http://www.cato.org/dailys/4-11-97.html>.

86. JUDITH AREEN ET AL., *LAW, SCIENCE AND MEDICINE* 346, 350 (3d ed. 2005).

87. *Id.* at 346.

88. *See, e.g.*, *South Dakota v. Dole*, 483 U.S. 203 (1987).

89. *See, e.g.*, John A. Robertson, *The Law of Institutional Review Boards*, 26 UCLA L. REV. 484 (1979).

If a new drug that has only gone through Phase I testing turns out to be costly, ineffective, and more deadly than Phase I indicated, consumers are not going to sit back and accept the risks they originally embraced. They are going to sue. And if the availability of Phase I drugs makes it impossible to run clinical trials, there are going to be more costly, ineffective, and deadly drugs on the market. The *Abigail Alliance* lawsuit would appear to open up new markets for the pharmaceutical industry, but drug companies have opposed the result in *Abigail Alliance*.⁹⁰ They may well believe that the prospect of tort liability outweighs immediate sales.

Similarly, the IVF industry is kidding itself if it believes that it cannot be hurt if public attention is drawn to bad outcomes, whether they concern the implantation of an embryo that might have been exposed to mad cow disease⁹¹ or the more general problems arising from the lack of any limit on the number of embryos that are implanted in the uterus.⁹² There are already calls for increased tort liability for the IVF industry,⁹³ and that kind of liability can be the precursor of administrative regulation.

I continue to believe that prudent regulation of technology is not an anti-progress strategy, but just the opposite. If new developments do not meet societal expectations for safety, they will, in the long run, be weakened.⁹⁴ The desire for new drugs and fertility treatments will not change that reality. Funded libertarianism is unlikely to carry the day.

90. Kathleen Kerr, *Wantagh Man Trying to Persuade Pharmaceutical Companies to Give Him Access to an Experimental Drug*, NEWSDAY, June 2, 2006, at A47.

91. *Jane Doe v. Irvine Scientific Sales Co.*, 7 F. Supp. 2d 737 (E.D. Va. 1998).

92. Moriarty, *supra* note 49, at 508-10.

93. Kleinfeld, *supra* note 51.

94. Steven Goldberg, *The Reluctant Embrace: Law and Science in America*, 75 GEO. L.J. 1341, 1380-85 (1987).

