GROVE CITY COLLEGE

JOURNAL OF LAW & PUBLIC POLICY

ARTICLES

Volume 4 Spring 2013

GROVE CITY COLLEGE

JOURNAL OF LAW & PUBLIC POLICY

Volume 4 Spring 2013

CONTENTS

The *Grove City College Journal of Law & Public Policy* invites submissions of unsolicited manuscripts, which should conform to *The Bluebook: A Uniform System of Citation* (18th ed. 2005). Manuscripts should be submitted electronically in Microsoft Word™ format to LawJournal@gcc.edu.

The editors strongly prefer articles under 15,000 words in length, the equivalent of 50 *Journal* pages, including text and footnotes. The *Journal* will not publish articles exceeding 20,000 words, the equivalent of 60 *Journal* pages, except in extraordinary circumstances.

To facilitate our anonymous review process, please confine your name, affiliation, biographical information, and acknowledgements to a separate cover page. Please include the manuscript's title on the first text page.

Please use footnotes rather than endnotes. All citations and formatting should conform to the 18th edition of *The Bluebook*.

Selection takes place on a per-volume basis; thus, a piece is selected for a particular volume, but not necessarily a particular edition. Submissions are reviewed on a rolling basis, beginning in February and concluding when the volume is filled, typically around mid-October.

For additional information about the *Grove City College Journal of Law & Public Policy*, please email us at LawJournal@gcc.edu or visit us online at www.gcc.edu/lawjournal.

*The views expressed within these articles are those of the authors and do not necessarily reflect the policies or opinions of the *Journal*, its editors and staff, or Grove City College and its administration.

GROVE CITY COLLEGE

JOURNAL OF LAW & PUBLIC POLICY

FACULTY ADVISOR

EDITORIAL BOARD

RECOGNITION OF DONORS TO THE *JOURNAL*

The Center for Vision & Values

Grove City College Law Society

Office of Development

Office of the President

Libertarian Press, Inc.

Joshua C. Bachman '05

Eric E. Brandt '91

Robert T. Burgess '02

Ronald W. Brandon '64

Raymond V. Fryan, Jr. '08

Bruce C. Gridley '69

James B. Griffin III '80

Kevin A. Hoffman '11

Laura A. Jenks '91

Robert L. Lackey '74

Harvey A. Miller Jr. '40

John R. Owen III '80

Keith M. Paterson '10

Jagan N. Ranjan '00

James F. Rutherford '64

Milton W. Shlapak '59

William C. Stewart '61

Clair A. Smith, Jr. '97

John W. Thatcher '71

Michele M. Tysiak '92

The *Grove City College Journal of Law & Public Policy* is published annually and operates solely on readers' donations. You may continue to receive the *Journal* at no cost; however, any monetary donation would be greatly appreciated. If at any point you no longer wish to receive the *Journal*, please contact the editors in order to be removed from our database. Address all written correspondence and mailed monetary donations to our business address: *Grove City College Journal of Law & Public Policy*, 100 Campus Drive, Grove City, Pennsylvania 16127.

GROVE CITY COLLEGE

Grove City College was founded in 1876 in Grove City, Pennsylvania. The College is dedicated to providing high quality liberal arts and professional education in a Christian environment at an affordable cost. Nationally accredited and globally acclaimed, Grove City College educates students through the advancement of free enterprise, civil and religious liberty, representative government, arts and letters, and science and technology. True to its founding, the College strives to develop young leaders in areas of intellect, morality, spirituality, and society through intellectual inquiry, extensive study of the humanities, and the ethical absolutes of the Ten Commandments and Christ's moral teachings. The College advocates independence in higher education and actively demonstrates that conviction by exemplifying the American ideals of individual liberty and responsibility.

Since its conception, Grove City College has consistently been ranked among the best colleges and universities in the nation. Recent accolades include: The Princeton Review's "America's Best Value Colleges," Young America's Foundation "Top Conservative College," and U.S. News & World Report's "America's Best Colleges."

GROVE CITY COLLEGE JOURNAL OF LAW & PUBLIC POLICY

The *Grove City College Journal of Law & Public Policy* was organized in the fall of 2009 and is devoted to the academic discussion of law and public policy and the pursuit of scholarly research. Organized by co-founders James Van Eerden '12, Kevin Hoffman '11, and Steven Irwin '12, the *Journal* was originally sponsored by the Grove City College Law Society. The unique, close-knit nature of the College's community allows the *Journal* to feature the work of undergraduates, faculty, and alumni, together in one publication.

Nearly entirely student-managed, the *Journal* serves as an educational tool for undergraduate students to gain invaluable experience that will be helpful in graduate school and their future careers. The participation of alumni and faculty editors and the inclusion of alumni and faculty submissions add credence to the publication and allow for natural mentoring to take place. The *Journal* continues to impact educational communities around the country and can now be found in the law libraries of Akron University, Regent University, Duquesne University, the University of Pittsburgh, and Pennsylvania State University. The *Journal* has been featured by the Heritage Foundation and continues to be supported by a myriad of law schools, law firms, and think tanks around the nation.

EDITOR'S PREFACE

Here we are. Another edition of the *Grove City College Journal of Law & Public Policy*. Another compilation of excellent articles on a diverse array of topics. Another letter from a proud editor in chief whose words cannot hope to encapsulate the efforts of her staff or the value of the text following these introductory pages. The *Journal* has achieved an established place in Grove City College and on the desks of its students, faculty, alumni, and friends. That privilege should be enough for us to breathe our sighs of relief and comfortably rest in our accomplishment.

Of course, for the kind of students who were daring enough to found an undergraduate law journal, this was not enough. We inherited their persistence. Our goal as successors is to realize their dreams while generating ideas of our own. This year, we redesigned our production schedule, introduced an online preview, and welcomed student authors from outside the College. The enclosed articles share a wide range of perspectives on as wide a range of topics, some familiar to many, some unnoticed by all but a few. All, however, are thoughtful discussions of law and public policy by students with genuine concerns and insights. These students' efforts are truly admirable, and I am honored to share them with you.

I am equally honored to serve alongside my capable, untiring peers who staff the *Journal*. Although you may not read their words, their work is represented by each page. My gratitude extends to the beneficence of our Editorial Board and our sponsors. Thank you for validating our purpose. Thank you for allowing us to enter the discussion of law and public policy. These students' voices deserve to be heard. Dear readers, thank you for listening.

Julia L. Haines '14
Editor in Chief

FOREWORD

Dear Reader,

It brings me great joy to present you with Volume Four of the *Grove City College Journal of Law & Public Policy*. The task of preparing a student-edited academic journal is not one for the faint of heart. This time-honored process includes painstaking efforts spent to secure quality articles as well as endless hours of editing and source-checking.

These tasks are not what most would consider "fun." The students responsible for what you are about to read did not get paid or receive academic credit for their work. Their labors were completed for the joy of learning and for the sake of knowledge, and that is what makes the *Journal* one of the purest examples of academic success remaining in America's undergraduate institutions.

In this edition, the *Journal* expands its reach to include submissions from student colleagues at other premier institutions. At the same time, the editors have continued the tradition of addressing timely and important topics, and this time with a special focus on current issues within the pharmaceutical industry.

Brandon Herring, Duquesne University School of Law '13, begins this edition with a discussion of the 2011 U.S. Supreme Court ruling that overturned a Vermont statute banning the practice of "detailing." Mr. Herring supports the Court's holding in *Sorrell v. IMS Health, Inc.* that restricting the sale of pharmaceutical information amounts to a violation of the First Amendment.

Kristie Eshelman '13 presents an updated look at the evolution of the right to privacy within the Supreme Court's jurisprudence. Ms. Eshelman's analysis peaks at the 2001 case of *Kyllo v. United States* and praises the majority opinion of Justice Scalia for upholding both the intent of the American founders and the fundamental rights of individuals.

Kyle Marchini '14 argues for a revolution in how intellectual property is treated within the pharmaceutical industry. His discussion asserts that the current system is holding back progress and that a pharmaceutical market free from the limitations of modern patent law would be more adaptable and innovative as a whole.

Samuel Williams '14 delves deeply into the Supreme Court's interpretation of the First Amendment through the case of *Good News*

Club v. Milford Central School. Mr. Williams supports the idea that once the government creates a "limited public forum," all viewpoints must be accepted, even if that acceptance may be incorrectly perceived as a violation of the Establishment Clause.

Catherine Ettman, Princeton University '13, examines the difficulties arising from the medical procedure known as Preimplementation Genetic Diagnosis. This procedure is intended to rule out specific genetic diseases during in vitro fertilization; however, it failed in the case of Gabriel Bergero. Miss Ettman uses this case to analyze the social impact of the procedure.

Each of these articles makes a fine addition to the legacy of the *Journal*. As someone who was "in the room" the day that the idea for this publication was born, I am quite proud to see what it has become. Far beyond that however, I am most excited by the fact that this edition is the last one that will ever be published with an original student member on the staff, meaning that next year, as the *Journal* continues to improve, it will have taken on a life of its own. A life that is all thanks to the tremendous hard-working students of Grove City College who continue to make me so proud to call myself a Grover.

With much respect and admiration,

Kevin A. Hoffman '11
Regent University School of Law
J.D. Candidate, 2014

-ARTICLES-

SORRELL v. IMS HEALTH, INC.

Brandon M. Herring *

ABSTRACT: *This article examines the United States Supreme Court's recent opinion IMS Health, Inc. v. Sorrell. It begins with an exploration of Justice Kennedy's majority opinion and Justice Breyer's dissenting opinion. Next, a brief history of the commercial speech doctrine in First Amendment jurisprudence is elaborated. Finally, the author reflects on the merits of the decision and finds that Justice Breyer's approach in the case is preferable as it is more predictable and more closely adheres to the purposes of the commercial speech doctrine.*

---

* Brandon Herring is a third year law student at Duquesne University School of Law, where he is a Senior Staff Editor on the Duquesne Law Review and the Chair of the Public Interest Law Association. His primary legal interests are constitutional and criminal law. He hopes to one day practice in the field of criminal defense. He would like to express his gratitude to Associate Professor of Law Bruce Ledewitz at Duquesne University for being his advisor for this project.

I. The Facts and Procedural History of *Sorrell v. IMS Health, Inc.*

In 2007, Vermont passed the Prescription Confidentiality Law, which included a provision intended to curtail the practice of detailing.[1] "Detailing" is a process through which pharmaceutical companies obtain data on the prescription practices of an individual doctor in order to specifically target him or her with presentations and advertisements.[2] The purpose of these presentations is to give the doctor the opportunity to receive information about the product and to ask questions, with the goal of persuading the doctor to utilize the product.[3] Pharmaceutical providers obtain doctor's prescription practices by purchasing the information from data miners who have purchased the information from pharmacies.[4] Pharmaceutical companies generally only use detailing on new or high-selling drugs because the process can be prohibitively expensive otherwise.[5]

The statute had three central provisions that would eliminate detailing: it barred pharmacies and organizations from selling prescriber-identifying data without the prescriber's consent, it barred health organizations from allowing the data to be used for

---

1 Vt. Stat. Ann. 18, V.S.A. §§ 4631 (2007)

2 *Sorrell v. IMS Health Inc.* 131 S. Ct. 2653, 2659 (2011).

3 *Id.*

4 *Id.* at 2660. Pharmacies are obligated under federal law and Vermont state law to receive the medication prescriber's identifying information. 21 U.S.C. § 353(b) (2011); Vt Bd. of Pharmacy Admim. Rule 9.1 (2009); Rule 9.2. After purchasing the prescriber's information from the pharmacy, data miners lease the information to pharmaceutical manufacturers. *Sorrell*, 131 S. Ct. at 2660. The lease is subject to a non-disclosure agreement.

5 *Id.*

marketing purposes without consent, and it barred pharmaceutical companies from using prescriber information for marketing purposes.[6] The statute had several exceptions for alternative uses of prescriber-identifying information, some of which included permitting the sale of prescription practices.[7] The Vermont legislature found that allowing the detailing process was contrary to the state's public policy of trying to control health care costs.[8]

Three Vermont data mining operations and an association of pharmaceutical companies brought separate suits challenging the Prescription Confidentiality Law, which were consolidated.[9] They alleged that Vermont's Prescription Confidentiality Law violated their First Amendment right to free speech as incorporated against the states by the Fourteenth Amendment, calling for an injunction on enforcement of the law.[10] The District Court of Vermont denied relief for the plaintiffs, holding that the state's public policy interest in limiting the cost of prescription drugs was sufficient to permit the legislation.[11] The Court of Appeals for the Second Circuit

---

6 *Sorrell*, 131 S. Ct. at 2660

7 *Id.* The statute, *inter alia*, allowed for the information to be used for "health care research;" to ensure that health insurance formularies were followed; for "care management educational communications" given to patients on such topics as "treatment options," for law enforcement and "for purposes otherwise provided by law. *See* VT. STAT. ANN. tit. 18, § 4631(e).

8 *Id. at* 2661. The Prescription Drug Confidentiality Law included legislative findings that the "marketplace for ideas on medicine safety and effectiveness is frequently one-sided in that brand name companies invest in expensive pharmaceutical marketing campaigns to doctors" which included "incomplete and biased information." Vt. Acts No. 80, § 1: § 1(3): § 1 (4).

9 *Sorrell*, 131 S. Ct. at 2661

10 VT. STAT. ANN.18.V.S.A. §§.4631; U.S. Const. amend. I.; U.S. Const. amend; XIV. *Sorrell*, 131 S. Ct. at 2661.

11 IMS Health, Inc. v. Sorrell, 631 F.Supp. 2d 434 (D. Vt. 2009), *rev'd*, 630 F.3d 263 (2d. Cir. 2010), *overruled by* 131 S.Ct. 2653 (2011).

reversed and remanded the case, finding that the interests of the state of Vermont did not outweigh the First Amendment infringement upon the pharmaceutical companies.[12] Recognizing a split in the circuit courts in interpreting the constitutionality of this statute and similar statutes, the Supreme Court granted certiorari.[13]

The issues before the Court were whether the text of Vermont's Prescription Confidentiality Law should be subject to increased judicial scrutiny as a restriction upon the First Amendment rights of pharmaceutical companies and, if the statute is found to be a restriction, whether Vermont can provide sufficient justification.[14] Vermont contended that the legislation was a legitimate regulation of commercial speech because it only prevented selling or distributing the prescriber information for the purposes of marketing and that the pharmacies and similar entities could not sell the information for any reason aside from the statutorily enumerated exceptions.[15] The respondents maintained their posi-

12 IMS Health, Inc. v. Sorrell, 630 F.3d 263 (2d. Cir. 2010), *overruled by* 131 S. Ct. 2653 (2010).

13 *Sorrell v. IMS Health Inc.*, 131 S. Ct. 857.

14 *Sorrell*, 131 S. Ct. at 2663.

15 *Id.* at 2662; VT. STAT. ANN. tit. 18 § 4631(e). The Court noted that there was a discrepancy between Vermont's interpretation of the statute at the District Court and Court of Appeals and that presented during oral argument to the Court. *Sorrell*, 131 S. Ct. at 2662. At the court of appeals, Vermont put forth the interpretation that VT STAT. ANN. tit. 18 § 4631(d) allowed companies to sell or distribute the information for any purpose other than marketing..*Id.* During oral argument for the Court, Vermont shifted its interpretation and claimed that VT STAT. ANN § 4631(d) prevented the sale of information by these entities of information for any purpose other than those offered as exceptions in VT STAT. ANN § 4631(e). The majority noted that this discrepancy was prejudicial to the plaintiffs under the rule in *Houston v. Hill*, 482 U.S. 451 (1987)). The difference in interpretation of the statute was ultimately not determinative of the outcome of the case. *Id.*

tion that the law violated their First Amendment rights to make trade speech.[16]

II. The United States Supreme Court Opinions in *Sorrell*

A. *Justice Kennedy's Majority Opinion*

Justice Kennedy, delivering the opinion of the Court, found that Vermont's law imposed both content and speaker-based prohibitions upon selling and using prescriber information.[17] The majority noted that entities that fall within the scope of the exceptions set forth in the Prescription Confidentiality Law, such as educational organizations, could buy and use prescriber information, amounting to speaker-based discrimination against the plaintiffs.[18] By preventing the use of the information for marketing, the Court found that Vermont targeted a specific type speech for its content.[19] Justice Kennedy observed that the discriminatory purpose of the legislation was completely supported by the record of the legislative findings of the Vermont legislature.[20]

The Court noted that in any situation where a law has content-based speech restrictions a heightened level of judicial scrutiny is warranted.[21] While the First Amendment does allow for certain

---

16 *Sorrell*, 131 S. Ct. at 2662.

17 Justice Kennedy's opinion was joined by Chief Justice Roberts and Justices Scalia, Thomas, Alito, and Sotomayor. *Id.* at 2659.

18 *Id.*

19 *Id.*

20 *Sorrell*, 131 S. Ct. at 2663. Vermont's legislature found that the mission of detailers to sell expensive drugs "[is] often in conflict with the goals of the state" to control healthcare costs. *See* 2007 Vt. No. 80, § 1(3).

21 A content-neutral speech regulation is one in which it is "*justified* without reference to the content of the regulated speech" (emphasis in the original). *Sorrell*, 131 S. Ct. at 2663; Renton v. Playtime Theatres, 475 U.S. 41, 48

limited exceptions where the restriction upon speech is incidental to the larger purpose of the law, Justice Kennedy observed that the Vermont statute's purpose expressed in its language and practical application directly regulates speech based upon the content and speaker.[22] The Court noted that the basis for much of the speech individuals engage in—like that regulated in this statute—has an economic basis and discrimination premised merely upon economic purpose lacked justification.[23]

Vermont took the position that the Prescription Confidentiality Law does not act to regulate speech; rather, it acts to limit access to prescriber information, and, since the information is generated by government mandate, it should be viewed as government-produced information.[24] Justice Kennedy noted that Vermont's position was somewhat supported by *Los Angeles Police Department v. United Reporting Publishing Corp.*, 528 U.S. 32 (1999) where the Court found that the plaintiff could not raise a facial challenge where the government instituted a content-based restriction upon government-held information.[25] However, the majority of

---

(1986). The First Amendment also requires increased scrutiny whenever content-based restrictions are placed upon speech because the government does not agree with its purpose. *See Sorrell*, 131 S. Ct. at 2664 and *Ward v. Rock Against Racism*, 491 U.S. 781, 791 (1991). Justice Kennedy noted that a law can be unconstitutional, even if it uses language that on its face is neutral toward speakers or content, if its purpose is to suppress speech and its burdens are not outweighed by its benefits.

22 *Sorrell*, 131 S. Ct. at 2664-65, one such example is antitrust laws would prohibit agreements in restraint of trade. *See* Giboney v. Empire Storage & Ice Co., 336 U.S. 490, 502 (1949).

23 *Id.*

24 *Id.*

25 *Los Angeles Police Department vs. United Reporting Publishing Corps*, 528 U.S. 32 (1999).

the Court distinguished *United Reporting* from the present case, because the plaintiffs in *United Reporting* were suing for access to information that the government had exclusive control over, whereas the Vermont statute at issue here attempted to prevent pharmaceutical companies from using information that pharmacies already have dominion over and can otherwise exchange.[26] The Court noted that there is a general invocation of free speech rights whenever information that an individual is in possession of is subjected to restraint.[27]

The Court also distinguished *United Reporting* from the instant case on the grounds that the plaintiff in that case had not yet applied for access to the information and therefore had not yet sustained a First Amendment injury and would have to make a facial challenge premised on injuries to others.[28] The Court found support for the respondents' argument here that their free speech rights have been restricted by not having access to government-held information similar to that discussed in Justice Scalia's concurring opinion in *United Reporting*, which indicates that a restriction upon access to information held by others can constitute a free speech violation.[29] As a result, the Court indicated that the respondents were not required to make a facial attack upon the legislation because their own free speech rights are directly at

---

26 *Sorrell*, 131 S. Ct. at 2665.

27 *Id.*

28 *Los Angeles Police Department vs. United Reporting Publishing Corps*, 528 U.S. 41 (1999).

29 Justice Scalia observed that a restriction upon access to information that has been revealed to the press but is restricted based upon the intended use of another party constitutes a restriction upon free speech. *Id.* at 42.

issue.[30]

The Court next addressed Vermont's argument that heightened scrutiny is not required because selling, using, and exchanging prescriber information should be viewed as conduct, rather than speech.[31] Justice Kennedy noted that this argument is supported by the findings of the First Circuit; however, the Supreme Court has consistently held that production and distribution of information fall within the scope of the First Amendment because facts are the necessary starting point for all speech.[32] The Court also declined to accept Vermont's argument that separate standards should be used for commercial speech cases than in other speech cases.[33]

The Court moved to the commercial speech inquiry, indicating that Vermont, as the State actor, has the burden of proof of establishing that the law is within the constitutional scope of the First Amendment by showing that the statute puts forward a substantial governmental interest and that it is targeted to fulfill that interest.[34] Justice Kennedy articulated the standard for establishing the constitutionality of the statute is *Board of Trustees of the State University of New York v. Fox*, which indicates that the purpose of

---

30 *Sorrell*, 131 S. Ct. at 2666.

31 *Id.*

32 Evaluating a statute similar to Vermont's Prescription Confidentiality Law, the Court found that commodities like information are subject to no greater protection than the term "beef jerky." *Sorrell v. IMS Health Inc.*, 131 S.Ct. 2653, 2682 (2011); *Sorrell*, 131 S. Ct. at 2667.

33 The Court noted that the outcome of previous cases has not been altered where a commercial speech inquiry or a heightened standard is utilized. *See Sorrell*, 131 S. Ct. at 2667. *See Greater New Orleans Broadcasting Assn., Inc. v. United States*, 527 US. 173, 184 (1994)).

34 *Id.* at 2667-68.

the legislature and the methods of the statute must coincide.[35] Justice Kennedy further noted that the purpose of this standard is to ensure that the state's interest is proportional to the harm inflicted to speech rights contained within the law.[36] Vermont offered two justifications for the Prescription Confidentiality Law: the law is necessary to ensure the privacy of medical professionals, doctor-patient privilege, and to prevent doctors from being harassed by drug companies, and the statute promotes the state's public policy objectives of overall public health promotion and limiting health-care costs.[37] Justice Kennedy rejected both of these arguments.[38]

The Court found that the statute failed to protect doctors' privacy rights because it only limited the use of their prescribing information in the specific context of marketing and allowing others, such as the state, journalists, and educators, access to the information without the doctor's consent.[39] The Court observed that Vermont's law may have been found constitutional had it contained more well-defined goals for addressing the problem of physician confidentiality.[40] However, as written, the information is available to too wide of an audience without sufficient justifica-

---

35 492 U.S. 469, 480 (1989).

36 *Sorrell*, 131 S. Ct. at 2668.

37 *Id.*

38 *Id.*

39 The Court also rejected Vermont's argument that other laws provide additional protections, finding that they are insufficient to justify the specificity of § 1439(b). *Id.*

40 The Court specifically cited the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. § 1320d-2 (2010). The difference between Vermont's legislation and this legislation is that the Act operates within narrow limits and has only limited and well-articulated exceptions to its prohibition in contradistinction of VT. STAT. ANN., tit. 18 § 1439(b). *Id.*

tion for the limit upon the respondents' access. Justice Kennedy also rejected Vermont's argument that the statute's requirement of consent by the doctor avoids a First Amendment issue, citing the lack of a real choice for the doctor because of the broad state-sanctioned audience that can obtain the information without the consent of the doctor.[41] The Court found that the limited privacy options available to the doctor evidences the State's actual goal is to restrict the speech of the respondents.[42] The Court also rejected the State's goal of protecting doctors from being harassed by salespeople from drug companies as insufficiently justified by the record, and as a disproportional remedy, because a doctor can simply decline to meet with a sales representative.[43] The majority also rejected the argument that the patient-doctor relationship was corroded by the intervention of drug marketers, because the State targets the drug companies merely because they are persuasive and their speech is disfavored.[44]

The majority also rejected Vermont's argument that the Prescription Confidentiality Law promoted the State's public policy objectives of reducing healthcare costs and the general promotion

---

41 Justice Kennedy referred to the choice as "contrived" by the Vermont state legislature. *Sorrell*, 131 S. Ct. at 2668, 2669.

42 *Id.*

43 Vermont legislature's found that "a few" doctors felt that they had been "coerced and harassed" by marketers. *Id.* The Court saw no reason to extend greater privacy protections to doctors than is available to the average citizen, who can decline to meet with anyone he so chooses. *Sorrell*, 131 S .Ct. at 2669-70.

44 The State presented evidence that some doctors and patients were uncomfortable with the practices of detailing, but the Court found that the State's argument was based more upon the persuasiveness of marketers and the State's obvious bias against their message. *Id.*

of well-being, finding that the statute does not achieve these goals in a constitutional fashion.[45] The Court's analysis revealed that the State's efforts were predicated upon the assumption that the public would make poor healthcare decisions if presented with the factually correct information revealed through marketing, which constituted a content-based burden on speech that did not directly serve the state's interest.[46] Further undermining the State's argument was the finding that some doctors like the detailing process, believing it to be instructive for making medical decisions, which the majority saw as evidence that the state targeted marketers specifically for the content of their message.[47]

The Court outlined situations where state regulation can be justified due to a neutral policy justification or, on related grounds, to prevent false or misleading statements.[48] The Court indicated that the State can have a legitimate interest in the regulation of the content of otherwise protected speech where there is a commercial harm upon consumers susceptible to neutral observation.[49] The majority found no indication that the statements made by the

---

45 The Court noted that there was a discrepancy between the legislative findings that joined the statute and the argument set forth by the State at oral argument—the State seemed unwilling to defend this argument; Nevertheless, the Court addresses the argument in its entirety. *Id.*

46 the court cites to language in *44 Liquormart*, stating "[t]he First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good." *Id.* at 2671.

47 *Id.*

48 *Id.* at 2672.

49 The Court offered the example of *R.A.V. v. City of St. Paul, Minnesota* where it was held that the State may regulate the price of a particular industry over another industry where there is a significant risk of fraud not present in other industries. *Id.*

pharmaceutical marketers in this instance fall within the scope of false or misleading statements that are not entitled to First Amendment protection, finding instead that the expression of the detailers was merely being restricted because of a conflict of viewpoints with the State.[50]

B. Justice Breyer's Dissenting Opinion

Justice Breyer, dissenting from the opinion of the Court, rejected the majority's use of a heightened standard of judicial scrutiny, because the State's action was tantamount to an ordinary attempt at commercial regulation.[51] Justice Breyer drew a distinction between speech that is at the "core" of the First Amendment and commercial speech, arguing that the standard for commercial speech is not as strict as that for core speech.[52] The dissent contended that the evaluations of commercial speech should be very deferential to the legislature. In so doing, the dissent advocated following the standard proposed in Justice Brandeis' dissent in *New State Ice Co. v. Liebmann,* 285 U.S. 262 (1932) assess-

---

50 *Id.*

51 Justice Breyer was joined in dissent by Justices Ginsburg and Kagan.

52 *Snyder v. Phelps*. 131 S. Ct. 1207, 1220 (2011), (distinguishing between speech at the "core" of the First Amendment, which expresses ideas that contribute to the "marketplace of ideas" and speech with lesser protections, like that which proposes a commercial transaction). *Id.* at 2673. In his dissent, Justice Breyer notes that the Court drew a distinction between promoting a vibrant "marketplace of ideas," which warrants significantly more protection, and a free marketplace for goods and services. *Sorrell*, 131 S .Ct. at 2672. In *Ohralik v. Ohio State Bar Association*, the Court applies an "intermediate" test in order preserve the "commonsense distinction between speech proposing a commercial transaction, *which occurs in an area traditionally subject to government regulation*, and other varieties of speech." *Ohralik v. Ohio State Bar Association,* 436 U.S. 447, 455-56 (1978).

ing only if the legislature had effectively determined there was an issue that required regulatory intervention.[53] Justice Breyer expressed fears that applying the "heightened scrutiny" of the Majority would open the door to returning to the era of *Lochner v. New York*, where judges arbitrarily substituted their own policy preferences when hearing cases about economic issues.[54]

In Justice Breyer's view, this regulatory action by the State of Vermont does not fall outside of the scope of typical state action.[55] The dissent argues that imposing restrictions upon the use of data to which vendors have access is a common regulatory practice, substantiated by sound public policy.[56] In order to be effective, Justice Breyer notes that regulations must differentiate based on content and speaker.[57] If a heightened level of judicial scrutiny was employed for free speech concerns, Justice Breyer argued that a wide sphere of widely-recognized regulation would suddenly be subject to judicial evaluation.[58] To Justice Breyer, regu-

---

53 Justice Brandeis said that "Our function. . . is only to determine the reasonableness of the legislature's belief in the existence of evils and in the effectiveness of the remedy provided." *Crowell vs. Benson*, 285 U.S. 262, 286-87 (1932).

54 *Lochner vs. New York*, 198 U.S. 45, (1905).*Sorrell*, 131 S. Ct. at 2675 (Breyer, J., dissenting).

55 *Id.*

56 Justice Breyer uses the example of car dealers, who are permitted to use credit scores when evaluating customers but are not permitted to acquire and use credit scores to pursue new customers. *Id.*

57 Justice Breyer noted that regulators must regularly make speaker-based evaluations based upon the composition of the industry, even where other actors in an industry are permitted to speak with less restriction. *Virginia Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 761- 62 (1976);
Sorrell, 131 S.Ct. at 2678.

58 *Id.*

latory activity necessarily reflects a policy evaluation about the given subject, and the task of the Court should be to evaluate only whether that policy ground is sufficient, not evaluate its content.[59]

The dissent found that the goals of the Vermont legislature of promoting public health and cutting healthcare costs were both sufficient to justify this legislation under the intermediate speech evaluation standard for commercial speech.[60] Justice Breyer observed that the reports produced by the Vermont legislature about the ills of the detailing process were more persuasive than the majority allowed.[61] Additionally, prescriber information was not as widely distributed as the majority's opinion reflects. Further, allowing the information to be used for detailing purposes constitutes a major expansion of the accessibility of information that would otherwise be confidential.[62] The dissent noted that this demonstrated a compelling privacy interest for the State to ground its actions upon.[63]

III. The Precedent Leading to *Sorrell*

A. The Rejection of the Commercial Speech Exemption and Nascent Balancing Test

Although some states independently articulated commercial speech protections under their own constitutions, commer-

59 Justice Breyer observed that "[t]he related statutes, regulations, programs, and initiatives almost always reflect a point of view, for example, of the Congress and the administration that enacted them and ultimately the voters." *Id.* at 2679.

60 *Id.* at 2681.

61 *Sorrell*, 131 S.Ct. at 2682 (Breyer, J. dissenting).

62 *See* Vt. Stat. Ann., 18, V.S.A.§§.4631(e) (2010).

63 *Sorrell*, 131 S.Ct. at 2683 (Breyer, J., dissenting).

cial speech did not exist as a unique category of protected speech under the First Amendment until 1975 in *Bigelow v. Virginia*, 421 U.S. (809).[64] The Supreme Court of Virginia had rejected the appellant's contention that the statute was a violation of his First Amendment rights.[65] Instead, it was held that, as a commercial advertisement not entitled to First Amendment protection, the material was within the scope of the State's police power.[66]

The issue before the Court in *Bigelow* was whether the Commonwealth of Virginia's statute making it a criminal offense to advertise abortion services constituted a restriction upon free speech rights in violation of the First Amendment.[67] Justice Blackmun, in his majority opinion, rejected the Supreme Court of Virginia's assumption that commercial speech was not entitled to First Amendment protection merely by virtue of its financial

---

64 *See e.g.* Pennsylvania State Bd. of Pharmacy v. Pastor, 272 A.2d 487 (Pa. 1971). The *Pastor* Court noted that Pennsylvania had a long history of applying due process in a more stringent way than the Supreme Court of the United States would. The Pennsylvania Supreme Court employed the due process clause to create a balancing test not dissimilar from those later adopted by the Supreme Court of the United States (discussed *infra*) to find that a ban on advertising the price of pharmaceuticals was unconstitutional incommensurate with the Commonwealth's objective of limiting access to dangerous prescription drugs. *Id.* at 494; *Bigelow v. Virginia* , 421 U.S. 809 (1975).

65 Bigelow was a newspaper publisher who published an advertisement for a New York-based abortion provider offering services in New York. *Bigelow v. Virginia*, 421 U.S. 809, 812 (1975).

66 *Id.* at 814.

67 VA. CODE ANN. §§.18.1-63 (1960), the statute provided, inter alia, that "If any person, by publication, lecture, advertisement, or by the sale or circulation of any publication, or in any other manner, encourage or prompt the procuring of abortion or miscarriage, he shall be guilty of a misdemeanor." Numerous abortion issues that arose in light of the *Roe v. Wade*, 410 U.S. 113 (1973) and *Doe v. Bolton*, 410 U.S. 179 (1973) decisions coming down during the appeal of this case are not relevant to the speech inquiry here. *Bigelow*, 421 U.S. at 815.

motivation.[68] Declining to determine the precise level of regulation that a state may engage in with regard to commercial speech, Justice Blackmun articulated a balancing test between protecting the First Amendment rights of the commercial speaker against the legitimate state interest motivating the regulation.[69]

The Court held that Virginia's statute clearly failed to satisfy the balancing test.[70] Virginia's asserted interest in passing the statute was to regulate the health of its citizens, which the Court agreed was a legitimate interest upon which to ground State regulatory activity.[71] However, because the material in question was an advertisement of services both available in and provided in New York State, the Court found that Virginia's interest in regulating the content of the commercial speech was outweighed when balanced against the speaker's First Amendment rights.[72]

The Court had the opportunity to expand upon its commercial speech determinations in the next term with *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976).[73] The plaintiff in *Virginia Citizens Consumer Coun-*

---

68 Justice Blackmun cited *Ginzburg v. United States*, holding that "[t]he existence of commercial activity, in itself, is no justification for narrowing the protection of expression secured by the First Amendment. *Bigelow*, 421 U.S at 818; *Ginzburg*, 383 U.S. 463, 474 (1966).

69 *Bigelow*, 421 U.S at 818.

70 Justice Blackmun noted that this outcome was so obvious that the matter need not be remanded to the Virginia Supreme Court. *Id.* at 827.

71 *Id.*

72 The Court noted that the advertisement's indication that abortion services were legal in New York could also be viewed as informative speech, highlighting the hybrid commercial-informative nature commercial speech can possess. *Id.* at 827, 828

73 *Virginia Pharmacy Board vs. Virginia Consumer Council*, 425 U.S. 748, (1976).

cil was a private citizens' organization which challenged, on First Amendment grounds, a Virginia statute barring pharmacists from engaging in any prescription price advertising.[74] The first issue before the Court was whether First Amendment protection could be extended to the plaintiffs as those in receipt of the speech.[75] Justice Blackmun, again writing for the majority, noted that the Court had recognized in previous cases that the First Amendment naturally includes a general right to "receive information and ideas."[76]

Virginia argued that, even if listeners had a right to receive information, there should be a commercial speech exception to First Amendment protection.[77] Citing *Bigelow*, Justice Blackmun indicated that the time had come for the Court to rule on the issue of whether purely commercial speech devoid of any informational value, is protected under the First Amendment.[78] The Court found that economic information can be just as important, if not more so, than information regarding political debates.[79] Additionally, society has a distinct interest in making commercial information as

---

74 VA. CODE ANN. §§54-524.35 (1974); *Va. Citizens Consumer Council, Inc.*, 425 U.S. at 755.

75 *Id.*

76 *Kleindiesnt v. Mandel*, 408 U.S. 753, 763, (1972); *Va. Citizens Consumer Council, Inc.*, 425 U.S. at 757.

77 Justice Blackmun noted that several past cases indicated that commercial speech was entitled to very little protection. *Va. Citizens Consumer Council, Inc.*, 425 U.S. at 758-59. *See* Valentine v. Chrestensen, 316 U.S. 52, 54, (1942) (holding ban on handbill and circular advertising does not infringe upon First Amendment rights).

78 *Id.* at 761.

79 Justice Blackmun argued that limitations upon the availability of pharmacy prices will disproportionately affect the poor and elderly, whose incomes are tighter and would benefit more from the savings. *Id.* at 763.

freely available as possible.[80] However, the Court recognized, as it did in *Bigelow*, that a legitimate state interest can overcome the commercial speech protection. Following the *Bigelow* example, the Court once again found that the state interest claimed to be protected in the statute was invalid.

B. The Development of a Full Balancing Test

Both *Bigelow* and *Virginia Citizens Consumer Council, Inc.* indicated that a balancing of the state interest and First Amendment protection must be used, and the Court had the opportunity to develop the criteria for the balancing test in *Central Hudson Gas & Electric Corporation v. Public Service Commission of New York.*[81] The *Central Hudson* Court devised a four-pronged test to evaluate whether commercial speech could be regulated: first, the speech must have a lawful activity as its purpose and not be misleading; second, the government must have a substantial interest in engaging in regulating the speech; third, the government interest must actually be advanced by the regulation; finally, the regulation must be as narrow as possible to satisfy the government's objective.[82]

Applying this test to the ban on power company advertising instituted by the Public Service Commission of New York, the Court found the regulation unconstitutional.[83] Finding no issue

---

80 *Va. Citizens Consumer Council, Inc.*, 425 U.S. at 764. Availability of price information is generally important in a free enterprise economy in order to make informed economic decisions. *Id.*

81 *Central Hudson Gas and Electric vs. Public Service Commission of New York*, 447 U.S. 557, (1980).

82 *Id. at* 564-66.

83 *Id.* at 567.

with legality or misleading information, the Court moved to the second prong of the test, rejecting the Commission's argument that Central Hudson's speech had minimal value.[84] The Commission asserted that its goal was energy conservation, and that Central Hudson's advertisements would serve to increase energy utilization, an interest which the Court agreed was substantial.[85] The Court further agreed that the ban on advertising was a means through which to advance the interest of the state, and therefore the third prong of the test was satisfied.[86]

The central issue for the commercial speech inquiry was the final prong of the test: whether a complete ban on advertisements generally protected by the First Amendment was as narrow as was required to further the State's interest in energy consumption.[87] Justice Stewart placed the burden to satisfy this prong squarely on the state actor to establish that the means used was the narrowest way through which to satisfy the regulatory objective.[88] The Court found that the broad-based nature of this regulation, while certainly able to achieve the State's objective, went beyond the

---

84 The Commission argued that Central Hudson, as a monopolistic corporation, could not meaningfully influence consumers with its advertisements. *Id.* The Court rejected this argument, finding that "[e]ven in monopoly markets, the suppression of advertising reduces the information available for consumer decisions. . . . [a] consumer may need information to aid his decision about whether or not to use the monopoly service at all, or how much of the service he should purchase." *Id.*

85 *Id.* at 568.

86 The Court observed that "[t]here is an immediate connection between advertising and demand for electricity. Central Hudson would not contest the advertising ban unless it believed that promotion would increase its sales." *Id.* at 569.

87 *Id.* at 569.

88 *Id.* at 570.

most limited scope possible and forecloses information that could be beneficial to the state's goal.[89] As a result, the regulation was found to be unconstitutional.[90]

The fourth prong of the *Central Hudson* underwent significant scrutiny and was distinguished to be more permissive for state action.[91] Justice Scalia, writing for the majority, noted in *Bd. of Tr. of the State Univ. of New York v. Fox,* 492 U.S. 469 (1989) that the narrowness requirement in *Central Hudson* had been applied unevenly due to the "substantially excessive" nature of the violations.[92] Additionally, in cases where the regulation was upheld, the Court was more lenient than the holding in *Central Hudson* would seem to have allowed.[93] Justice Scalia's analysis concluded that the "necessary" language of the forth prong of the *Central Hudson* test must be interpreted to require that the means chosen by the state must have a "reasonable fit" with the objectives of policy.[94] Other cases decided by the Court further restricted State action to limit commercial speech where there was a clear alternative that

89 The Court observed that Central Hudson would be unable to advertise its energy-saving products due to the overbroad nature of the regulation. *Id.*

90 *Id.* at 572.

91 *Bd. of Tr. of the State Univ. of New York v. Fox,* 492 U.S. 469 (1989) (addressing ban on advertising at state college campuses).

92 *Board of Trustees at State University of New York vs. Fox*, 492 U.S. at 469.

93 *Id.* at 478. *See* Ward v. Rock Against Racism, 491 U.S. 781, 799 (1989), stating that "we have not insisted that there be no conceivable alternative, but only that the regulation not burden substantially more speech than is necessary to further the government's legitimate interests."

94 *Fox*, 492 U.S. at 480-81. Justice Scalia noted the great difficulty that would accompany a least-restrictive means test, finding that this reading of *Central Hudson* relieves some of the burden of proof on the legislative and executive branches. *Id.*

would achieve the objective without requiring any restrictions on speech.[95]

C. Central Hudson *Called into Question*

The essential holding in *Central Hudson* established the basic framework within which evaluation of commercial speech cases occurred over the course of the next 20 years without major changes.[96] However, the potentially subjective nature of the test caused some critics to view it as generating anomalous results, leading to unpredictability in commercial speech jurisprudence.[97] The groundwork for potentially reevaluating the *Central Hudson* test was established with the Court's divisions in *44 Liquormart v. Rhode Island*.[98]

Before the Court were two statutes barring advertisement of alcohol prices in Rhode Island. 44 Liquormart, an alcohol distributor, was charged with violating the statutes by preparing an advertisement including cheap food generally consumed with alcohol and images of alcoholic beverages.[99] The issue before the Court

---

95 *See e.g.* Rubin v. Coors Brewing Co., 514 U.S. 476, 490-91 (1995).

96 Daniel E. Troy, *Advertising: Not "Low Value" Speech*, 16 Yale L.J. on Reg. 85 (1999).

97 Troy, *supra* note 128, at 129-38. The author particularly noted the confusion engendered in lower courts, where varying levels of deference was given to state legislatures. *Id.*

98 *44 Liquormart vs. Rhode Island*, 517 U.S. 484 (1996). Although the Court unanimously agreed with the ruling, only a plurality decision was issued, with three separate concurrences (discussed *infra*). *Id.*

99 R.I. GEN. LAWS § 3-8-7 (1987); R.I. GEN. LAWS § 3-8-8.1 (1987). The State argued that including the alcoholic beverages with an advertisement for cheap products, such as potato chips and drink mixers, implied that the alcoholic products were also sold at a discounted price and therefore violated the advertising ban even though no prices had been listed. *44 Liquormart vs. Rhode Island*, 517 U.S 484, 492-93 (1996).

was whether the broad ban upon the advertising of alcohol was a violation of vendors' First Amendment rights to engage in commercial speech.[100] Justice Stevens, speaking for the Court's plurality, opened his opinion with a discussion of the United States' general history of protecting commercial speech.[101] After taking stock of the case law, Justice Stevens determined that the mere fact that proposals for commercial engagements are included within a regulation does not dictate what sort of constitutional analysis is appropriate, signaling openness to potentially depart from *Central Hudson*.[102] However, the plurality noted that there was clearly no departure from a commercial transaction in the present case, and therefore the *Central Hudson* test was the appropriate form of analysis.[103]

Finding that temperance, as Rhode Island's stated goal, was a compelling enough state interest, the plurality moved to analyze whether the means of achieving this objective were commensurate with the regulatory goal.[104] Justice Stevens, applying the

---

100 *44 Liquormart*, 517 U.S. at 495-96. Because the case involved the sale of alcohol, Rhode Island raised the Twenty-Fourth Amendment as a shield against federal intervention in the case. *Id.* This issue is not relevant to the present inquiry and will not be discussed.

101 *Id.* Justice Stevens noted that Benjamin Franklin, in his work *An Apology for Printers*, defended freedom of speech using an advertisement for voyages to Barbados. *Id.* It is this history of protection that Justice Stevens believes colored the Court's protection of commercial speech as a distinct class of speech in *Bigelow* and other foundational cases. *Id.*

102 *Id.* at 501. Justice Stevens drew a distinction between regulations targeting truthful, informative speech and those proposing a mere commercial transaction, with state action being more justified in the latter rather than the former, and suggesting that the former would require a more stringent test. *Id.* at 501-06.

103 *Id.* at 501.

104 *Id.* at 505.

fourth prong of *Central Hudson* to analyze whether the regulation of speech was too broad, determined that other forms of regulation could have been pursued by Rhode Island that would not have included bans on speech,[105] even when considering legislative discretion.[106] Justice Stevens noted that it can be even more detrimental to regulate speech rather than conduct, making him all the more skpetical of regulations enforcing bans on speech.[107] As a result, Justice Stevens found the Rhode Island provisions unconstitutional.[108]

Justice Scalia's concurring opinion voiced his displeasure with the *Central Hudson* test as well as paternalistic regulation regimes.[109] Justice Scalia argued that the history of First Amendment jurisprudence, as well as freedom of speech provisions in place at the time of the First and Fourteenth Amendments were helpful in adjudicating these issues.[110] Although he had reservations with *Central Hudson*, he was unwilling to explicitly reject

105 The plurality indicated that the facts in the record actually would tend to support that the ban on speech would not have the intended effect of reducing temperance. *44 Liquormart*, 517 U.S. at 506-07. Although lack of advertising could raise prices, theoretically making alcohol less affordable, there is no indication that alcoholics would be deterred from purchasing alcohol in any way. *Id.* Additionally, an expert from the State conceded that taxation or price controls would have been just as effective as Rhode Island's regulation. *Id.*

106 Justice Stevens specifically rejected broad legislative discretion, instead embracing a more strict regulation where "paternalistic" purposes on the part of the legislature are in play. *Id.* at 509.

107 Justice Stevens cites the old proverb that it is better to teach a man to fish than it is to catch him one, noting that speech restrictions prevent the teaching from occurring. *Id.* at 511.

108 *Id.* at 516.

109 *44 Liquormart*, 517 U.S. at 517 (Scalia, J., Concurring).

110 *Id.*

the test or to propose an alternative in its place.[111]

Justice Thomas was less reserved in his dissenting opinion, finding that any interest the state purports to have that is intended to keep otherwise legal information from the general public in an effort to keep them in the dark about their options in a market is a *per se* First Amendment violation regardless of any distinctions between commercial and non-commercial speech.[112] Justice Thomas strongly rebuked the Court for even adopting a distinction between commercial and non-commercial speech, as he found it both historically and philosophically indefensible.[113] However, he nevertheless applauded both Justices Stevens and O'Connor, as he viewed the plurality and Justice O'Connor's concurring opinion as adopting a much more stringent version of the fourth prong of *Central Hudson*, which would bring future cases more in line with his own reasoning.[114] Only Justice O'Connor's concurring opinion endorsed the traditional *Central Hudson* test, although she also called for a stricter application of the fourth prong test requiring regulation to be as narrow in scope as possible.[115]

D. Continuing Use of the Central Hudson *Test*

Although *44 Liquormart* called the viability of the *Central Hudson* test into question, the Court has thus far continued to rely

---

111 *Id.*

112 *Id.* (Thomas, J., concurring).

113 *Id.* at 522.

114 *44 Liquormart*, 517 U.S. at 524

115 Justice O'Connor suggests that a more stringent approach to the fourth prong of *Central Hudson*, although this case does not require it as Rhode Island's statute is clearly violates even a generous reading of the prong. *Id.* at 532.

upon *Central Hudson* in commercial speech cases.[116] The majority and dissenting opinions in *Thompson v. Western States Medical Center* clearly articulated the divergent positions that the justices have applied in using the test. The issue in *Western States* was whether a federal regulation barring pharmacists from advertising drug compounding was in violation of the First Amendment.[117] The majority opinion, authored by Justice O'Connor, was critical of the State's position that regulating compounding was a substantial state interest, finding that the State also had a competing interest in protecting the practice of compounding.[118] The majority applied the fourth prong of the *Central Hudson* test stringently, particularly focusing upon alternative policies that would avoid speech regulation with a general wariness of allowing government to engage in "paternalistic" regulatory practices.[119]

Justice Breyer's dissenting opinion was more deferential to the legislature, giving more weight to the substantiality of the government's stated policy objectives.[120] The dissent's applica-

116 *Thompson v. Western States Medical Center*, 535 U.S. 357 (2002).

117 *Id.* at 377. Not all of the Justices believed the test should be used—Justice Thomas, while joining with the majority's decision, authored a concurring opinion rejecting the *Central Hudson* test generally, or at least where there is an issue of limiting information available to the public. *Id.* at 377. Compounding is a process where a pharmacist formulates a drug specifically for a patient who is unable to use a mainstream drug for health reasons. *Id.* at 361. The individualized nature of these drugs puts them outside of regulation by the Food and Drug Administration. *Id.*

118 *Id.* at 369.

119 Justice O'Connor suggested that placing warning labels on compounded drugs would satisfy the State's goal of patient safety without having to restrict speech. *Id.* at 376.

120 Justice Breyer noted that the regulation targets both drugs that are traditionally manufactured by drug companies en masse and preventing those who do not need compounding drugs from receiving them. *Id.* at 379. Justice

tion of the fourth prong of the *Central Hudson* test also would have given the government more leeway to act within a range of acceptable regulatory practices, including the restriction on free speech.[121] Viewing the *Central Hudson* test as flexible, Justice Breyer admitted that some truthful, informative speech would be barred by the statute but found that such restrictions are sufficiently warranted by the government's "substantial interest" in regulating compounded drugs.[122]

IV. Analysis: The Failure of *Sorrell*

A. Preference for Justice Breyer's Dissenting Approach Over the Majority in Sorrell

Although the very nature of the *Central Hudson* test may invite judicial subjectivity into its analysis, the Court has significantly limited the scope of government objectives that are deemed constitutionally permissible under the test over time. In *Sorrell*, Justice Kennedy essentially rejects the legislative findings Vermont used to provide its justification for restricting the detailing process without seriously exploring their ramifications. This

---

Breyer further explained that the majority focused only on mass produced drugs and not the policy interest in favor of restricting compounded drugs for patients who do not need them. *Id.* An extensive review of the record was included in this analysis that demonstrated the pernicious effect of allowing compounded drugs to be advertised to the general public. *Id.* at 380-85.

121 *Thompson vs. Western States Medical Center*, 535 U.S. at 386. The dissent engaged in a broad policy analysis of potential alternatives to the free speech restriction and explained why they were insufficient to satisfy the government's objectives. *Thompson vs. Western States Medical Center*, 535 U.S. at 386.

122 *Id.* at 387-88. The dssent observed that the test is necessarily broad because commercial speech is not entitled to absolute protection under the First Amendment. *Id.*

rejection is consistent with the general trend established in *Western States*.[123]

Justice Breyer's deferential approach in his dissenting opinions to *Sorrell* and *Western States* would be a much more consistent means of analysis than the Court's *ad hoc* approach in each of these cases. The merit of Justice Breyer's approach is its predictability—he evaluates only the sufficiency of the evidence, not his personal preference for the policy positions evinced by the legislative findings.[124] The Dissent in *Sorrell* astutely observed that a regulatory scheme *necessarily* articulates a policy position on the part of the legislature.[125] This approach has the benefit of pragmatically recognizing that the burden of proving the "neutrality" of a regulation toward a speaker is only effectively possible where the court evaluates the sufficiency of the evidence and observes that the legislature is responding to an observed problem and wielding its authority to remedy it.

Justice Breyer's analysis would also recognize that the exceptions in the Prescription Confidentiality Law allow doctors' prescribing practices to be used for truly informational purposes, such as by educational institutions and state regulatory agencies. There is no informational aspect for drug companies to use the prescribing practices in order to solicit prescriptions from doctors for more expensive medications.[126] As Justice Breyer noted, the Vermont legislature clearly found that the detailing process was

123 *Id.* at 386.

124 *See supra*, Note 72.

125 *Id.*

126 VT. STAT. ANN.18, V.S.A.§§.4631(e) (2010);

designed to cause doctors to write more prescriptions for more expensive medications than they would otherwise.[127] The goal of drug companies with the detailing process is clearly not to educate the public in any meaningful way. The informational value of their speech would not be hindered by not being aware of the prescribing policies of the doctor. Justice Kennedy's view that detailing information should be available to the public completely ignores the exception in Vermont's Prescription Confidentiality Law that specifically allows prescribing practices to be used to inform patients of their treatment options. In protecting the free speech rights of the drug companies to advance their information, the Court essentially renders it impossible for the State of Vermont to control health care costs in this fashion. These policy arguments should not have been categorically rejected by the majority in *Sorrell* without critical analysis.

B. Undermining the Substantiality of Government Interests in the Majority's Application of the Central Hudson *Test*

The majority's reduction of Vermont's regulatory action to a mere "difference of opinion" with drug companies is an oversimplification which allows the Court to undermine the fourth prong analysis of *Central Hudson*. This renders any action taken by the state as incommensurate with the state's objective, as diminished by the Court. In so doing, the Court can avoid giving the legislature deference under the *Central Hudson* test as modified by Justice Scalia's Opinion in *Fox* to allow the government to argue only

127 *Sorrell v. IMS Health Inc.*, 131 S.Ct. 2653, 2682 (2011).

that the means of regulation is a "reasonable fit" with the objective of the government.[128] Applying the test in such an unbalanced fashion causes the analysis to be tipped significantly further in the favor of the non-state plaintiff without justification. The Court should honestly evaluate the merits of the state actor's objectives in the second prong of the test in order to properly engage in a *Central Hudson* fourth-prong analysis.

If the justices in the majority find very limited circumstances where the means of the regulation can fit with the state actor's selected means, then they should articulate that position during the fourth prong analysis and not through minimization of the impact of the government's objectives. If the majority seeks to overrule *Central Hudson* and articulate a test that is more deferential to the non-state plaintiff than intermediate review, then they should do so directly.

C. *Future Implications of* Sorrell

Referring to data in its raw form as protected commercial speech throws many regulatory schemes into question, and it remains to be seen how the Court will evaluate regulations in unrelated areas in light of the *Sorrell* decision. Businesses challenging regulations as infringements upon commercial speech could have an economically destabilizing effect by thrusting uncertainty into an already fragile marketplace, potentially exacerbating the country's economic woes. Placing mere data under the aegis of First Amendment protection extensively broadens the Supreme Court's

128 *Bd. of Tr. of the State Univ. of New York v. Fox*, 492 U.S. 469, 477 (1989)

commercial speech jurisprudence and has the potential to elevate that status of a tremendous amount of corporate statements to the level of protected speech.

Sorrell also casts doubt upon the ability of the federal government to respond to the health care crisis. Whatever its deficiencies, the Patient Protection and Affordable Care Actis an attempt to remedy these serious problems.[129] Critics of the bill have argued that health care solutions should originate in the states. *Sorrell* could act as a barrier to effective state action at the federal and local level under the guise of protecting "commercial speech." As Justice Breyer fears, this country may be bound for a new *Lochner* era, where justices will substitute their own policy preferences in favor of businesses for fidelity to the law.[130]

129 42 U.S.C.A. § 18001 (2010).

130 198 U.S. 45 (1905).

KYLLO V. UNITED STATES: INNOVATIVE OR ORIGINALIST?

Kristie L. Eshelman *

ABSTRACT: *When the American Founders crafted the Fourth Amendment to the Constitution, they could not have foreseen the impact of twentieth-century technology on warrantless "search and seizure." Consequently, originalist rulings, such as* Olmstead v. United States *or* Goldman v. United States, *favored the federal government's use of technology to "search" citizens, since the government was not physically going beyond the bounds set by the Fourth Amendment.* Katz v. United States *reversed this precedent, but it was Justice Scalia's opinion in* Kyllo v. United States *which truly returned to the original intent of the Fourth Amendment, setting objective boundaries for governmental "search and seizure" by designating the home as a "constitutionally protected area."*

---

* Kristie Eshelman is a senior history major at Grove City College. She has written press releases for congressional candidates, contributes to the college newspaper, and worked this past summer as a Koch Institute intern.

The development of new technology has complicated the founder's intent for the Fourth Amendment, which has historically protected United States citizens from unreasonable searches or seizures. Techniques such as thermal imaging or wiretapping give the government the potential to strip citizens of nearly all their privacy unless the Supreme Court rules that the Fourth Amendment protects against such intrusion. Anticipating this, Justice William O. Douglas cautioned that the "'privacy and dignity of our citizens is being whittled away by sometimes imperceptible steps.' As a consequence of technological developments, we risk creating 'a society in which government may intrude into the secret regions of man's life at will.'"[1] *Katz v. United States,* 389 U.S. 347 (1967), which ruled that "reasonable expectation of privacy" exempted information from search and seizure, expanded the scope of the amendment but repudiated historical precedent by doing so. *Kyllo v. United States,* 533 U.S. 27 (2001) similarly upheld individual privacy rights by defining a thermal scan as an impermissible search. Yet while *Kyllo v. United States* depended heavily on the precedent set by *Katz,* it also departed from it significantly but subtly, revealing inconsistencies in the *Katz* decision and significantly changing how the Fourth Amendment had been interpreted. Ultimately, the ruling in *Kyllo* would uphold the traditional privacy of the individual granted by the the Fourth Amendment. At the same time, the Supreme Court broadened its interpretation to maintain its original purpose of protecting citizens from search

1 Thomas P. Crocker, *The Political Fourth Amendment*, 88 Wash. U. l. Rev. 303, 303 (2010).

and seizure in an era where technology was expanding government power.

The Fourth Amendment reads, "The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue, but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized."[2] According to legal scholar Thomas Davies, the Framers of the Constitution sought to protect against general search warrants in private homes because this was the most common violation of Fourth Amendment type rights in their era. Due to this "inherent illegality of any searches or seizures that might be made under general warrants," the Founders never envisioned "the warrantless officer as being capable of posing a significant threat to the security of person or house,"[3] since no one took the warrantless officer seriously during colonial times. As a result, they found no need to further specify the meaning of the phrase "unreasonable searches and seizures," which they understood to mean house searches under general warrants, to include warrantless searches. Yet as warrantless searches began to increase in the late nineteenth century, mainly to enforce the Interstate Commerce Act of 1887, the Sherman Anti-Trust Law of 1890, and—most importantly—the National Prohibition Act of 1919, the Judiciary began to address the constitutionality of warrantless searches apart from those with general warrants,

2 *U.S. Const.* amend. IV.

3 Thomas Y. Davies, *Recovering the Original Fourth Amendment*, 98 Mich. L. Rev. 547, 551 (1999).

concluding that warrantless searches, especially those within the home were unconstitutional.[4]

The early twentieth century confronted the amendment with another challenge as federal agents began using technology to obtain information. In this situation, the judiciary proved less willing to modify its application of the Fourth Amendment as it had done by specifically extending protection against warrantless searches to respond to changing circumstances. This reluctance occurred because the wording "secure in their persons, houses, papers, and effects" had always indicated physical security.[5] *Olmstead v. United States,* 277 U.S. 438 (1928) questioned whether the government's use of wiretapping in Roy Olmstead's office building to convict him of bootlegging constituted an unreasonable search and seizure under the Fourth Amendment. Strictly adhering to historical precedent but failing to adequately consider the massive changes in law enforcement capabilities, the Supreme Court ruled:

> [Neither] the cases we have cited nor any of the many federal decisions brought to our attention hold the Fourth Amendment to have been violated as against a defendant unless there has been an official search and seizure of his person, or such a seizure of his papers or his tangible material effects, or an actual physical invasion of his house "or curtilage" for the purpose of making a seizure.[6]

---

4 Id. at 552; Nelson B. Lasson, *The history and development of the Fourth amendment to the united states constitution* 106 (1937).

5 Davies, *supra* note 3, at 552; Thomas K. Clancy, *The Fourth Amendment: Its History and Interpretation* 310 (2008).

6 *Olmstead v. United States*, 277 U.S. 438, 466 (1928).

Similarly, *Goldman v. United States*, 316 U.S. 129 (1942) ruled that the use of a dictaphone by federal agents to overhear the conversation of the defendant in his office did not violate the Fourth Amendment.[7]

Until the late 1960s, then, the Court upheld the standard interpretation of the Fourth Amendment, even as rapidly developing technology was empowering the government to collect information about its citizens. However, the landmark case *Katz v. United States* overturned the ruling in *Olmstead*, marking a significant change in the way in which the Court viewed the powerful impact of technology as a means of invading privacy. The FBI had suspected that the defendant, Charles Katz, had made numerous phone calls to engage in illegal interstate gambling, noticing that he consistently made these calls in Los Angeles telephone booths at the same time each day. The Bureau attached microphones and tape recorders to the outside of these booths, recording only the phone calls of the defendant for the span of a week. Based on this evidence, a trial court convicted Katz of interstate betting. The defendant's attorneys contested that the government had conducted a warrantless search that violated his Fourth Amendment rights, but the Court of Appeals for the Ninth Circuit rejected his argument, relying on precedent from *Olmstead* and *Goldman v. United States* to rule that since the microphone had been placed on the exterior of the phone booths, the FBI had not violated Fourth Amendment stipulations.[8]

---

7 *Goldman v. United States*, 316 U.S. 129, 135 (1942).

8 Edmund W. Kitch, *Katz v. United States: Limits to the Fourth Amendment*, 1968 Sup. Ct. Rev. 133, 135 (1968).

On appeal, the Supreme Court agreed to hear the case and overturned the ruling of the Court of Appeals, declaring that the government had violated the Fourth Amendment. Famously stating that "the Fourth Amendment protects people, not places," Justice Potter Stewart refused to consider whether the telephone both was a constitutionally protected area, and he instead relied on a new "reasonable expectation of privacy" test based on whether the defendant rationally assumed that he would enjoy freedom from observation.[9] With this rationale, Justice Stewart concluded, "The premise that property interests control the right of the Government to search and seize has been discredited."[10] Instead, the case depended on whether the defendant harbored a legitimate reason to believe that his correspondence would remain private, regardless of where his actions occurred.

Since the defendant did not suspect that anyone was listening to his conversation in the telephone booth, the Court held that the FBI had conducted an unreasonable search without a warrant, violating an individual's rights. In his concurrence, Justice John Marshall Harlan II added to Stewart's new interpretation of the Fourth Amendment by developing a "two-part test" which requiring that an individual not only have a subjective expectation of privacy but that society accepts this expectation as rational.[11] However, the majority ruled that electronic, as well as physical intrusion into a constitutionally protected area constituted a search which required a warrant, rendering the wiretapping in *Katz* unconstitu-

9 Katz v. United States, 389 U.S. 347, 351 (1967).

10 *Id.* at 354.

11 *Id.* at 361.

tional. Thus, in contrast to the rulings in *Olmstead* and *Goldman*, the opinion in *Katz* discarded the "trespass" doctrine of the Fourth Amendment that only protected against search and seizure of private possessions and material objects. In doing so, it replaced the reliance on location with a focus on subjective expectation as a determining factor. Recognizing that technology could render the Fourth Amendment ineffectual, *Katz* broke with historical precedent and attempted, with mixed success, to adapt the Constitution to the changing times.[12]

While *Katz* appropriately sought to address the government's growing ability to obtain information through technology, it ultimately proved to be inadequate. First, Justices Harlan and Stewart offered no constitutional rationale for their "reasonable expectation of privacy" test, seeming to formulate this standard arbitrarily. Most importantly, while the two-part test applied well to the *Katz* descision, it was too vague to use as an objective standard. Individual and even societal conceptions of privacy could vary, proving controversial and giving the judicial branch arbitrary power in deciding the nature of a search. Edmund Kitch observes, "*Olmstead*, decided 5 to 4, was probably overripe for extinction....But Olmstead did provide a principled ground for decision. It is the responsibility of the Court, not only to abandon the old law, but to build the new. The brave, broad reading of the Fourth Amendment in Katz has a hollow ring when tested against the Court's [decision in *Olmstead*]."[13] According to Melissa

12 Asheen J. Radshan, *The Case for Stewart over Harlan on 24/7 Physical Surveillance*, 88 Tex. L. Rev. 1475, 1476 (2010).

13 Kitch, *supra* note 8, at 152.

Arbus, post-*Katz* cases often forced defendants to go to "extraordinary measures" to protect their Fourth Amendment rights under the new *Katz* precedent. For instance, in *Florida v. Riley*, 488 U.S. 445 (1989), the Florida State Supreme Court ruled that the Fourth Amendment did not protect the defendant's greenhouse because parts of it were open to aerial observation, through no ordinary passer-by could see into it. Clearly, the ruling in this case against the defendant differed greatly from that in *Katz,* demonstrating the malleable standards developed from the latter.[14] Similarly, the post-*Katz* cases used the "third-party" doctrine, the idea that "a person loses Fourth Amendment protections over anything she knowingly exposes to another person."[15] The problem arose when Justices began applying this rule even if the evidence was visible only through technological monitoring, like the heat emissions from marijuana cultivation coming from the mobile home of the defendant in *United States v. Ford* 34 F.3d (11th Cir. 1994). Clearly, by the 1990s, courts across the United States were manipulating the opinion in *Katz* to mean the opposite of what Stewart and Harlan had intended, giving more power to the government to conduct warrantless "searches" and to violate the civilians' expectations of privacy.[16]

The decision in Kyllo v. United States marked another attempt to expand Fourth Amendment rights to accommodate technological advances, this time to address the impact of heat-

14 Melissa Arbus, *Legal U-Turn: The Rehnquist Court Changes Direction and Steers Back to the Privacy Norms of the Warren Era*, 89 Va. L. Rev. 1729, 1763 (2003).

15 Crocker, *supra* note 1, at 305.

16 Arbus, *supra* note 14, at 1765.

detecting sensors to monitor activity in the home. The Bureau of Land Management had become confident that defendant Danny Kyllo was growing marijuana in his home, based on information from informants and Kyllo's abnormally high utility bills. As a result, an investigator scanned Kyllo's home from a car at about 3 a.m. using a thermal imager. He found abnormally high heat emissions on one side of the house, which the police used obtain a warrant to physically search Kyllo's home. They found marijuana plants as well as illegal weapons. The trial court found Kyllo guilty, ignoring the defendant's claim that the thermal scan constituted an unreasonable search under the Fourth Amendment and required a warrant. On appeal, the United States Court of Appeals for the Ninth Circuit agreed to hear the case. The justices initially concluded that the scan did constitute a warrantless search, but later they ruled that the search was reasonable because it revealed no intimate details of the home, only revealing warm spots on the home's exterior.[17]

When the case reached the Supreme Court, the close and unusual voting alignment among the justices highlighted the difficult nature of the issue. Political scientist Thomas Hensley notes that Justices Antonin Scalia and Clarence Thomas allied with the more liberal Stephen Breyer, Ruth Bader Ginsburg, and David Souter in upholding individual privacy rights while William Rehnquist, Sandra Day O'Connor, Anthony Kennedy, and John Paul Stevens argued for the government's right to conduct

17 Thomas B. Colbridge, *Kyllo v. United States: Technology Versus Individual Privacy*, 70 FBI Law Enforcement Bulletin 25, 27 (2001).

the scan. Yet they united on one issue: "the important emphasis within the Fourth Amendment on the privacy of one's home and the need for law enforcement officials to obtain a warrant before searching a home."[18] In writing for the majority, Scalia drew upon the ruling in *Silverman v. United States* 365 U.S. 505 (1961) to determine the legitimacy of the defendant's expectation of privacy, concluding that the government had no right to intrude upon a person's home: "'At the very core' of the Fourth Amendment 'stands the right of a man to retreat into his own home and there be free from unreasonable governmental intrusion.'"[19] Drawing upon precedent and his understanding of common law, Scalia affirmed the decision in *Katz* but departed from the two-part test to uphold the privacy of the home as the basis for protection against warrantless searches. Instead, he returned to the pre-*Katz* standard of using physical location as the primary determinant of the individual's right to privacy.[20]

However, by focusing on location as the most important standard for Fourth Amendment protections, Scalia did not return to the stance in *Olmstead*. He recognized that technology had the potential to significantly limit the autonomy of the individual and that a completely originalist approach to the Fourth Amendment was obsolete: "The question we confront today is what limits there are upon this power of technology to shrink the realm of

---

18 Thomas R. Hensley with Kathleen Hale, Carl Snook, *The Rehnquist Court* 159 (2006).

19 *Kyllo v. United States*, 533 U.S. 27, 31 (2001).

20 Richard Henry Seamon, *Kyllo v. United States and the Partial Ascendance of Justice Scalia's Fourteenth Amendment*, Wash. U. L. Q. 1, 3 (2002).

guaranteed privacy."[21] Citing the decision in *Katz* to classify the wiretapping of the phone booth as a warrantless search despite the fact that technology had not actually penetrated the booth, Scalia upheld the two-part test as a legitimate means of determining the constitutionality of a non-physical search. In doing so, he departed from the pre-*Katz* understanding of the Fourth Amendment which only protected against physical searches.[22] In response to the dissent's contention that the scan in Kyllo revealed "no intimate details of the home," Scalia responded:

> We think that obtaining by sense enhancing technology any information regarding the interior of the home that could not otherwise have been obtained without physical "intrusion into a constitutionally protected area," *Silverman*, 365 U. S., at 512, constitutes a search at least where (as here) the technology in question is not in general public use. This assures preservation of that degree of privacy against government that existed when the Fourth Amendment was adopted.[23]

Thus, *Kyllo* upheld all the privacy protections in *Katz*, clarifying the intent of the latter but also adding another protection based on common law: the immunity of the home from warrantless searches.

However, law professor Richard Henry Seamon points out that in addition to upholding and clarifying the two-part test, *Kyllo* also criticized the opinion in *Katz* for several reasons. First, Jus-

---

21 Kyllo, *supra* note 19, at 34.

22 Seamon, *supra* note 20, at 9.

23 Kyllo, *supra* note 19, at 34.

tice Scalia disagreed that it had departed so far from its original application to property, becoming a mere measure of opinion.[24] According to Scalia, the whole purpose of the Fourth Amendment was to preserve "that degree of respect for the privacy of persons and the inviolability of their property."[25] In addition, the subjectivity of the test rendered it "notoriously unhelpful" when applied as the lone standard to cases. Finally, he acknowledged that relying on the two-part test alone gave too much power to judges in deciding when privacy expectations were "reasonable."[26] To Scalia, returning the focus to the location of the search and giving the home express protection against inspection significantly remedy these ambiguities.

In the dissent, Justice Stevens accused the new standards framed by the majority opinion of being "at once too broad and too narrow, and he argued that the Court's explanation did not justify its adoption."[27] Stevens argued the Scalia's opinion went too far in limiting the use of imaging devices, saying, "I would not erect a constitutional impediment to the use of sense-enhancing technology unless it provides its user with the functional equivalent of actual presence in the area being searched."[28] However, his complaint ignores the contention that if the results of technological search can expose details that an observer could not have historically obtained without a physical search and can provide

24 Seamon, *supra* note 20, at 15.

25 David A Sklanski, *Back to the Future: Kyllo, Katz, and Common Law*, 89 Miss. L.J. 143, 162 (2005).

26 Seamon, *supra* note 20, at 15.

27 Kyllo, *supra* note 19, at 47.

28 *Id.*

the means of obtaining a warrant, governmental use of technology should require some sort of warrant itself.

Additionally, Stevens criticized the majority for establishing arbitrary guidelines which had no basis in precedent and were too vague for future search and seizure cases. In particular, he expressed concern that the ruling would prevent future searches from obtaining "information concerning the outside of the building that could lead to (however many) inferences 'regarding' what might be inside."[29] However, the hypothetical situations that he uses to illustrate his point—such as labeling as a search the use of an infrared camera to learn whether someone likes pizza—seem unlikely to occur under reasonable standards and seem preferable to an invasion of privacy within the home, one of the only places where one goes to seek seclusion from curious onlookers outside. David Sklanski agrees that *Kyllo* approached the Fourth Amendment in a new way, while also signifying a return to the past by emphasizing the importance of the location of the surveillance:

> The originalism in *Kyllo* is not the originalism the Court has applied in other recent Fourth Amendment cases…the Court has shifted its attention…from the content of eighteenth-century rules of search and seizure to what those rules accomplished. In these respects, the methodology of *Kyllo* itself represents something of a return to the past—albeit a past more open to the future.[30]

Thomas Davies agrees that though *Kyllo* combined the

29 *Id.* at 48.

30 Sklanski, *supra* note 25, at 3.

precedent of *Katz* with more original, property-focused interpretations of the Fourth Amendment, it ultimately signaled a return to the original intent of the Founding Fathers as well as the majority in *Katz*. Ultimately, Davies argues, the Framers desired to limit police power and uphold the security of the individual, putting the burden of proof on the government when it sought to justify any expansion to its power of search and seizure.[31] Thus, Scalia had a firm basis both for adhering to *Katz* by upholding individual privacy. Yet his departure from it and return to pre-*Katz* emphasis on property and location also relied on precedent and protected the intent of the Fourth Amendment in the modern age.

As a landmark Supreme Court decision on such a complex, controversial issue as Fourth Amendment interpretation, *Kyllo* wields a great amount of influence in criminal and constitutional law. Most obviously, it clarified that use of thermal imagers and other similar technologies as searches require warrants, at least on private premises, though law enforcement may still use these devices without a warrant on public property or in a dangerous situation such as a kidnapping where there is no time to obtain a warrant.[32] More importantly, the decision has larger constitutional implications, the most significant being its recognition that a person has a reasonable expectation of privacy inside his home, though he forfeits that when he appears in public or when evidence is clearly visible to a third party without the aid of a technological device. Thus, even the non-physical scrutiny of the home

31 Davies, *supra* note 3, at 750.

32 Colbridge, *supra* note 17, at 29.

constitutes a Fourth Amendment search if it is seeking to obtain information that is not visible to the naked eye. By clarifying *Katz* when it upheld individual privacy over government security, *Kyllo* eliminated the need for citizens to take "extraordinary precautions" to keep their actions from "public exposure" to qualify for Fourth Amendment protection.[33] Most importantly, Scalia's opinion has set a balanced, coherent precedent which favors the rights of individuals for future court cases involving search and seizure.

The decision in *Kyllo v. United States* has given government officials, lawmakers, and judges rational guidelines for protecting the safety of American citizens without invading their privacy. Scalia's respect for individuals combined with his deference to precedent, common law, and the intent of the Founders has resulted in an opinion in *Kyllo v. United States* which upheld the ruling in *Katz* but offered a more objective, historical approach to the issue. While his stance represented a new way of approaching the Fourth Amendment, it also sustained the original interpretation of the Fourth Amendment by protecting privacy in an age where unrestrained police power and technological abilities have the capacity to destroy American freedom.

33 Arbus, *supra* note 14, at 1761-1765.

PATENTS AND INNOVATION IN THE PHARMACEUTICAL INDUSTRY

Kyle A. Marchini *

ABSTRACT: *For more than a century protections on intellectual property have been used to encourage innovation in a wide range of industries. This article argues that patents in the pharmaceutical industry discourage innovation on net by stifling sequential innovation and skewing the research that does occur. In the absence of patent protections, firms would be able to recover research costs through first-mover advantages and temporary technological monopoly which leads to a more dynamic and innovative industry.*

* Kyle Marchini is a junior double-majoring in economics and music at Grove City College. After graduation, he plans to pursue his Ph.D. in economics.

Fritz Machlup concluded his 1958 analysis of the U.S. patent system by writing: "If we did not have a patent system, it would be irresponsible, on the basis of our present knowledge of the economic consequences, to recommend instituting one."[1] While the current system may be too ingrained in the business and legal culture of America to ever entirely banish, rigid intellectual property protections may do more harm than good to the promotion of innovation. In few places is this understanding more important than in the pharmaceutical industry. While patents are widely thought to be necessary for the creation of new drugs and treatments, the opposite is true. Patents discourage innovation on net and skew innovation in the unhampered market. This results in misallocation of resources and inefficiencies for all firms in the market.

In many ways, the pharmaceutical industry is a poster child for proponents of intellectual property. No one disputes the social necessity of a thriving pharmaceutical industry; the historical benefits have been clear. This industry is also unique in the extremely high fixed costs of innovation, due to regulations on drug testing and certification. The estimated average cost of bringing a single new drug to market exceeds $400M.[2] Much of the cost of producing a new drug lies in the research and development stage rather than actual production, since drug manufacturing tends to face significant economies of scale across a large range of production.

---

1 S. REP. NO. 15 at 80 (1958).

2 Joseph A. Dimasi, Ronald W. Hansen & Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151, 151 (2003).

Thus, it is feared that enabling competitors to enter the market and produce new drugs without incurring the innovator's research costs would almost immediately strip him of profits, rendering further development nearly impossible. Based on this analysis, many scholars assume that the pharmaceutical industry simply could not operate without patent protection.[3]

The second reason to critically analyze intellectual property (IP) in the pharmaceutical industry is the integral nature of sequential innovation in medicine. Sequential innovation is highly dependent on prior technology or research for its existence. While all innovation is sequential by nature since it expands on what has already been discovered, particular areas exhibit more dependency than others, such as the use of gene sequences in pharmaceutical research. Because gene sequences are not merely discrete molecules but also pieces of information, they provide a foundation for many other areas of innovation from diagnosis to targeted treatments.[4] This means that monopolistic restrictions, such as patents, on the foundational technology can significantly limit other firms' ability to innovate in related areas. In other highly sequential fields this has resulted in a significant decrease in innovation when IP protections were initially applied.[5]

Because regulation which enables patents on pharmaceuticals creates significant factors that both encourage and discour-

---

3 S. REP. NO. 15 at 77 (1958).

4 Brian Jackson, *Innovation and Intellectual Property: The Case of Genomic Patenting*, 22 J. POL'Y ANALYSIS & MGMT. 5, 10 (2003).

5 James Bessen & Eric Maskin, *Sequential Innovation, Patents, and Imitation* 2 (Mass. Inst. of Tech. Dep't of Econ., Working Paper No. 00-01, 2000), *available at* http://www.researchoninnovation.org/patent.pdf.

age innovation, it is impossible to determine the net effect from a purely theoretical analysis. However, an overview of the incentives created on both sides of the equation is necessary for evaluating the historical cases and determining the underlying causal factors. The benefits accrued from being granted a monopoly on the production of a particular good, including substantial profits from the restriction of competition, provide a direct incentive to innovate. Balancing that incentive are increased innovation costs for all other firms in the market, whether from direct legal prohibition or from rents paid for the use of a patent. This is especially pernicious when a significant body of research rests upon a patented technology, as is the case with gene sequences. Third, patenting skews the type of innovation in which firms engage. By preventing direct competition for the most efficient means to produce a given drug, patents encourage companies to research "work alike" drugs in an attempt to capture market share from the monopolist.

Indisputably, protections on IP are beneficial to the monopolist. The firm that owns patented technology receives guaranteed monopoly profits through direct restriction of competition. Potential competitors are prevented from utilizing cheaper production methods even if they are discovered. Advocates of IP argue that this is necessary because reverse engineering is likely less expensive than the original production of a new drug. DiMasi et al. estimated the cost of bringing a new drug to market exceeds $400M pre-tax dollars. Assuming a discount rate of 11 percent annually over the time of development and certification, this figure adjusts

to a cost estimate of $802M prior to the approval of the drug.[6] If competitors were able to reverse engineer the new drug at a fraction of the cost and bring it to market, it would be difficult for the original innovator to recoup the costs of research, presumably rendering research a competitive liability rather than an asset.[7] While the monopolist will incur some additional costs in obtaining the patent, they will be small relative to increased revenues from monopoly pricing.

For some, the benefits accrued by holding a patent provide a direct incentive to increase the pace of innovation while discouraging competitors. Not only are firms guaranteed monopoly profits, but to the extent that they are able to identify lucrative future areas of innovation, they can prevent competitors from bringing products to market based on those technologies.[8] While these strategies ultimately aim to restrict competitors' ability to innovate, each approach requires the firm itself to be highly innovative since other companies are also attempting to stake their claim to the emergent technologies. In abstract, this cannot be said to increase or decrease net innovation, as it may be offset by the restrictions on competition stemming from reduced market access.

Competitors' initial costs stem from the direct restriction of market access imposed by patents. Any firm wishing to enter the market for a patented drug must purchase that patent from the owner or face legal sanction. For the monopolist, there are signifi-

6 DiMasi et. al., *supra* note 2, at 151.

7 Earl L. Grinols & James W. Henderson, *Replace Pharmaceutical Patents Now*, 25 PHARMACOECON. 355, 357 (2007).

8 Michele Boldrin and David K Levine, AGAINST INTELLECTUAL MONOPOLY 183 (Cambridge University Press) 2008.

cant incentives to block competitors' access to the market, as outlined above. A firm cannot only guarantee monopoly profits, but also significant future revenue from preventing other companies from building on their technology, thus putting future competitors at a disadvantage. Perversely, the larger the potential area controlled by the patent, the more likely a firm is to retain ownership and thus retain their future options.[9] This results in inefficiency for potential competitors, who are prevented from accessing the most efficient technologies and from innovating.

For firms allowed to enter the market, the rent in royalties will likely be prohibitive. In perfect market conditions the price to purchase even temporary patent use will fall between the opportunity costs of the monopolist's loss of the patent and the competitor's expected gain. This price would include the discounted revenue stream from development of the innovation, the benefit the monopolist gains from restricting its competitors, and the expected benefit from future innovation based on the product. These costs would not exist in a normal market without government intervention. In cases where innovation is highly sequential and dependent upon the ability to use and reproduce particular preexisting technologies, the restrictions imposed by patents can dramatically reduce competitors' ability to innovate.[10] To illustrate, the example of gene sequences in the pharmaceutical industry may again prove useful. Because they are not simply a particular molecule, as with

9 Rita Gunther McGrath & Atul Nerkar, *Real Options Reasoning and a New Look at the R&D Investment Strategies of Pharmaceutical Firms*, 25 STRATEGIC MGMT. J. 1, 16 (2004).

10 Jackson, *supra* note 4, at 17.

many drugs, but also a means of conveying biological information, a given gene sequence may have the potential to provide the basis not only for direct treatment, such as gene therapy, but also for diagnoses, genetically targeted traditional treatment, and other potential developments.[11] In many cases, a patented gene sequence or genetic protein can be an effective moratorium on any downstream innovation as there are no substitutes for the information contained in the gene sequence.[12]

When innovation does occur from firms attempting to enter into competition with a patent monopolist, the type of innovation that occurs will also be of a substantially different form than would occur in an unhampered market. When a firm patents a particularly lucrative drug, other firms are unable to compete on the basis of efficiency by discovering alternate production methods or by allocating resources more efficiently within their firm. This drives companies to create "work alike" drugs or products which are distinct from the patented product, but result in the same medical effect. A successful "work alike" drug will enable the competitor to capture a share of the disputed market and consequently diminish of the monopolist's profits. In some cases, these drugs may be even more effective than the original product and become dominant within the market. Lichtenberg and Philipson term this "between-patent competition," distinguishing it from "within-patent competition" which occurs once the patent has expired and the monopolist now competes with essentially identical products, i.e.

---

11 *Id.* at 10.

12 Michele Boldrin & David K. Levine, *The Economics of Ideas and Intellectual Property*, 102 PROCEEDINGS NAT'L ACAD. SCI. 1252, 1255 (2005).

name brand competition with generic products.[13] Between-patent competition creates two contradictory effects relevant to the question of patent effect on innovation. First, it provides a direct incentive for firms to innovate in competition to patent monopolists, since they are able to gain access to the market and a share of profits from lucrative products. Second, it reduces initial incentive to innovate by decreasing the potential profits a patent holder can gain.[14]

The reduction of monopoly profits has an especially important role in reducing the ability of patents to encourage innovation. Between-patent competition can result in as much as twice the reduction in monopoly profits compared to the effect of introducing generic copies of the product when the patent expires.[15] In addition, this reduction can happen far earlier because it does not require the patent to expire. This means that the losses compound over the expected time the drug is on the market. The actual outcome of these two effects will depend on the quality of the initial product and whether the competitors' ability to innovate is restricted by any other factors. Regardless of whether the original monopolist maintains dominant market share or competitors effectively claim the market, competition will be less efficient than in unhampered markets since competitors are still blocked from finding more effective means to produce the original drug.

---

13 Frank Lichtenberg & Thomas J. Philipson, *The Dual Effects of Intellectual Property Regulation: Within- and Between-Patent Competition in the U.S. Pharmaceuticals Industry* 644 (Nat'l Bureau of Econ. Research, Working Paper No. 9303, 2002).

14 *Id.* at 645.

15 *Id.* at 663.

Even with full consideration of the incentives created by intellectual property protections, one cannot come to a determination of patents' net effect without considering the incentive structures that exist in their absence. In some respects, the incentives against innovation intensify without patent protections such as through the reduction of profits from innovation when other firms are able to reverse engineer a product. Yet, many incentives still exist that render it necessary for entrepreneurs to innovate if they wish to stay competitive.[16]

The firm that develops a new drug enjoys an immediate competitive advantage from the fact that they are the only company capable of producing the new product for a period of time until some other firm is able to reverse engineer the product and mass produce it. Assuming a new product is something valued by consumers, temporary technological monopoly guarantees significant profits for the patent holder and provides a means for regaining research and development costs.[17] The principle benefit of a technological monopoly rather than a legal one is that other firms in the industry may displace the monopolist by finding a cheaper or more efficient means or producing the drug, encouraging further innovation. Yet, in the unhampered market this innovation will only be pursued if it is societally beneficial and an efficient use of resources.[18] If the monopolist is not generating substantial inefficiencies by overpricing their good or artificially lowering sup-

16 S. REP. NO. 15 at 80 (1958).

17 Boldrin & Levine, *supra* note 12, at 1252.

18 MURRAY ROTHBARD, MAN, ECONOMY, AND STATE WITH POWER AND MARKET 750 (Ludwig von Mises Institute, 2009).

ply, factors the monopolist uses for innovative competition may be used more efficiently elsewhere. Therefore, without artificial monopoly and monopoly profits created by patents, innovation is more likely to be conducted in an efficient manner to maximize the valued use of scarce resources.

Temporary technological monopoly is not the only benefit for an original innovator. The first firm to enter a market gains a significant first-mover advantage from being able to capture the market through an established reputation. Post-patent competition under the current regime indicates the importance of the first-mover advantage in competition. A 1991 study found that prices for the original drug were not highly responsive to the entry of generic competition, even though generic brands were priced far below the original drug. The brand-name drug's price fell just 4.5 percent for the mean number of generic drugs entering the market, even though the generic drugs may be priced as low as 17 percent of the brand-name drug's price.[19] Another study found that generic drugs never capture greater than 50 percent of a given market, despite being priced far below their name-brand competition.[20] This is admittedly an imperfect situation, since patent protection gives firms a substantially longer time to establish their reputation and therefore likely results in a stronger first-mover effect than would exist without government intervention. However, the striking results indicate that there is a positive and significant advan-

19 Richard E. Caves et al., *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, 1991 BROOKINGS PAPERS ON ECON. ACTIVITY. MICROECON. 1, 44-45 (1991).

20 Boldrin & Levine. *supra* note 12, at 1254.

tage to being the first firm to enter a field. Since this advantage persists despite price disparities between brand-name and generic competition, the historical evidence indicates that without patent protection, innovators would be able to recoup their research costs and maintain a positive incentive for innovation.

In the absence of intellectual property protections, barriers to sequential innovation would be significantly lower. As technology becomes more complex and dependent on specific inputs, the costs of patent restrictions in terms of foregone opportunities rise rapidly. Without patent protections, all firms would be free to use past innovations as the basis of new technologies, products, or services. This dramatically lowers the cost of bringing new innovation to the market. In the computer, software, and semiconductor industries, which are similar to the pharmaceutical industry in that most innovation is both sequential and complementary, these industries experienced high rates of innovation despite historically weak patent protections. When a series of court cases strengthened intellectual property protections, contrary to expectations at the time, research and development spending either remained steady or declined across the industry.[21] This is consistent with what one would expect in an industry that is as dependent on prior innovation as the computer or pharmaceutical industries. Any increased incentive to innovate is countered by decreased opportunity and increased cost as a result of restricted market access.

This analysis is broadly consistent with historical cases of patent reform in the United States where strengthened intel-

21 Bessin & Maskin, *supra* note 5, at 19.

lectual property protections did not lead to substantially greater innovation. In 1980, the Bayh-Dole Act enabled federally funded research institutions such as universities to patent their research and to grant licenses for these patents to other parties.[22] Prior to the act, there were relatively few intellectual property protections afforded to these kinds of institutions. Given the importance of the research university to medical and pharmaceutical innovation in the United States, one would expect the effect on these institutions to be broadly consistent with the effect on the industry as a whole. Coinciding with the implementation of Bayh-Dole was a dramatic increase in patent filings by U.S. universities and efforts to license these patents and a disproportionate share of these were biomedical inventions.[23] However, the increase in patenting and marketing efforts began before the act. This indicates the strengthened intellectual property regime is unlikely to dramatically increase innovation at U.S. research universities, and the change in the composition of university research can be traced to other factors.[24]

While the relationship between innovation and intellectual property rights is necessarily complex and will likely vary with the nature of a given country's research environment, the effect of intellectual property protections is negative given the current state of the U.S. pharmaceutical industry. Patent competition and the overall effect of cooling the research environment through increased innovation cost and restricted market access undermines

22 David C. Mowery & Arvids A. Ziedonis, *Numbers, Quality, and Entry: How Has the Bayh-Dole Act Affected U.S. University Patenting and Licensing?*, 1 INNOVATION POL'Y & ECON. 187, 191 (2000).

23 *Id.* at 193.

24 *Id.* at 214.

much of the positive impact on innovation one would expect from the protection of monopoly profits. In contrast, while a system without patent protection would still face barriers to innovation such as the high costs of pharmaceutical research, existing market phenomena like technological monopoly and first-mover advantage would allow innovators to retain a profit from their invention. The unhampered market would also be able to gain these benefits without distortions created by allowing monopoly profits. Possibly the most important factor in the relationship between patents and innovation is the highly sequential nature of pharmaceutical research. When firms have the ability and incentive to block potential competitors from innovating in all downstream technologies, the results are dramatic and often detrimental. For this reason, strengthening intellectual property protections in industries like pharmaceuticals frequently fails to create positive change in innovative activity. Overall, in the pharmaceutical industry intellectual property protections work in opposition to their intended purpose, deterring research on net and skewing innovation that does occur away from the most efficient use of resources.

AGE EQUALITY FOR THE ESTABLISHMENT CLAUSE

Samuel M. Williams *

ABSTRACT: *When a government creates a limited public forum and specifies a subject matter, all groups speaking on that issue must be accepted. To deny an individual or group the right to equally participate in the limited public forum because of a specific belief that group holds is to violate the right of free speech and to engage in unconstitutional viewpoint discrimination. Concerns about the Establishment Clause, however, have arisen when a religious group's use of a government facility via a limited public forum gives the relevant audience the perception of a government endorsement of religion. In cases involving adult and near-adult audiences, the Supreme Court has ruled that a reasonable person would not perceive a government certification of religion from allowing a religious group equal access. In Good News Club v. Milford Central School, the Court addressed the concern that children seeing a religious group using government facilities, even through a limited public forum, might understand this as a government sanction of that religion. In its decision, the Court ruled that government must maintain a posture of neutrality and eschew viewpoint discrimination, even in cases where children may misperceive government endorsement of religion.*

* Sam Williams is a junior double-majoring in Economics and Political Science and is from Geneseo, New York. He plans to pursue a juris doctorate upon graduation from Grove City College.

The United States Constitution protects the right of free speech and against the establishment of a religion by government. While these two protections seem natural for a society dedicated to liberty of thought and conviction, they come into tension when one uses public resources to exercise religious free speech. This inevitably brews conflict among governments, organizations, and individuals, and the federal courts have been the final arbiter in these issues. One area where the legal system needs coherent and consistent court interpretation is on the treatment of the Establishment Clause as dependent on the age of the audience receiving the religious communication. The Supreme Court has frequently expressed concern that the impressionability and immaturity of youth can be a barrier to perceiving distinctions between free speech and government sponsorship. This conflict is shown clearly in *Good News Club v. Milford Central School*, 533 U.S. 98 (2001) in which the Milford School was concerned about the appearance of public school-sponsorship of a Christian club for children. In its decision, the Supreme Court established that a government engaging in viewpoint discrimination while operating a limited public forum is unconstitutional even in cases when otherwise children may mistakenly see government endorsement of religion.

In 2001, the Supreme Court reached a decision on *Good News Club v. Milford Central School*. Milford Central School had opened its school to use by the community weekdays after school for uses such as the teaching of morals.[1] The Good News Club,

1 *Good News Club v. Milford Central School*, 533 U.S. 98, 102 (2001).

a Christian organization for youths between the ages of six and twelve years old, applied to use a room in the school for weekly meetings. The Milford school district superintendent rejected the application after deciding that the meetings were not a "discussion of secular subjects such as...development of morals from a religious perspective, but were in fact the equivalent of religious instruction itself."[2] The Supreme Court, however, ruled against Milford Central School, arguing that the Good News Club was engaging in the development of morals, albeit from a religious perspective.

Since the school had created a limited public forum by opening its facilities to public use, it had the right to limit that forum to specific subjects. The Court ruled in *Rosenberger v. Rector and Visitors of University of Virginia,* 515 U.S. 819 (1995) that when creating a limited public forum, the government does not need to allow persons to participate in every type of speech, but rather, it may warranted "in reserving [its forum] for certain groups or for the discussion of certain topics."[3] However, as previously established in *Rosenberger* and *Lamb's Chapel v. Center Moriches Union Free School District*, 508 U.S. 384 (1993), the government is limited in what it can restrict in a limited public forum.[4] Once it has opened the forum to a particular topic, it cannot restrict the expression of different beliefs within that subject; to do so violates free speech. This is the Court's distinction between acceptable and necessary subject matter discrimination and unconstitutional viewpoint discrimination.

---

2 *Good News Club*, 533 U.S. 98, at 104.

3 *Id.* at 106.

4 *Id.* at 109-110.

In *Milford Central School*, the school district argued that even if it were engaging in viewpoint discrimination, such discrimination was necessary to avoid an Establishment Clause violation.[5] The majority rejected that argument. The majority used two similar cases as precedent where the Court did not uphold the Establishment Clause concern as valid. First, in *Lamb's Chapel v. Center Moriches Union Free School Dist.*, the Court ruled that showing a video series produced by the Christian organization, Focus on the Family, in a public school did not violate the Establishment clause because the school property had been used by a number of other private groups, the series was not being shown during school hours, was not supported by the school, and was open to anyone who wished to attend.[6] Because of these factors, no one could reasonably consider the school to be sponsoring the religious views of the group showing the videos. In the second case, *Widmar v. Vincent,* 484 U.S. 263 (1981), the State University of Missouri at Kansas City tried to deny a religious student group from meeting in university facilities. The Court, however, held that the Establishment Clause does not require state universities to limit access to their facilities by religious organizations when a university had already opened its forum to numerous other organizations.[7] Similarly, the public forum provided by Milford Central School was open to other groups, and the Good News Club met after school and was open to all students who wished to

---

5 *Id.* at 112.

6 *Lamb's Chapel v. Center Moriches Union Free School Dist.*, 508 U.S. 384, 388, 395 (1993).

7 *Widmar v. Vincent,* 454 U.S. 263, 272-274 (1981).

attend, provided they had a parental permission.[8] The main difference between *Good News Club, Widmar,* and *Lamb's Chapel* was the age of the participants.

The Supreme Court has often differentiated between age groups when considering the risk that perceived government sponsorship of religion existed. In *Edwards v. Aguillard*, 482 U.S. 578 (1987), the Court affirmed that elementary students are especially "impressionable" and therefore adherence to the Establishment Clause is even more important.[9] In *Grand Rapids School District v. Ball,* 473 U.S. 373 (1985), the Court ruled that special attention must be given to Establishment Clause considerations involving young children because they are still in their formative years and, accordingly, their beliefs are largely determined by their environment.[10] The Court decided in *Lee v. Weisman*, 505 U.S. 577 (1992) that having a student led prayer at a high school graduation was an Establishment Clause violation.[11] While an adult might be able to ignore the prayer and sit respectfully through it, students in primary and secondary school have a harder time actively dissenting. In *Lee*, the Court went so far as to state that psychological research shows youths have a difficult time resisting peer pressure, especially in when it comes to societal conventions.[12] Following the *Lee* decision, the Court struck down prayer before football games

8 *Good News Club v. Milford Central School*, 533 U.S. 113 (2001).

9 Chelsea Chaffee, *Making a Case for an Age-Sensitive Establishment Clause Test*, 1, BYU Educ. & L.J. 257, 271 (2003).

10 *Lee v. Weisman,* 505 U.S. 577, 609 (1985).

11 Brian Wheeler, *The Pledge of Allegiance in the Classroom and the Court: An Epic Struggle Over the Meaning of the Establishment Clause of the First Amendment,* 2, BYU Educ. & L.J. 281-324, 291 (2008)

12 *Lee v. Wiseman,* 505 U.S. 577, 593 (1992)

in *Santa Fe Independent School District v. Doe,* 530 U.S. 290 (2000) because of the unacceptable situation it put upon school-age children who possessed beliefs not shared by the majority.[13]

This same reasoning has also been influential in Supreme Court cases on claims of Establishment Clause violations involving older students. In *Board of Education v. Mergens,* 496 U.S. 226 (1990), the Court ruled that "secondary school students are mature enough and are likely to understand that a school does not endorse or support student speech that it merely permits on a non-discriminatory basis."[14] With *Tilton v. Richardson*, 403 U.S. 672 (1971) and *Marsh v. Chambers,* 463 U.S. 783 (1983), the Court declared that college students and adults are less vulnerable, more mature, and less susceptible to "religious indoctrination."[15] Even in *Widmar*, it was affirmed that college students "are less impressionable than younger students" and can be expected to understand the school's policy of neutrality.[16] In many of these cases the older age, and expected maturity, of the students was used to bolster the rulings the majority reached, which were that no Establishment Clause abuses were present.

A number of the amicus briefs submitted for *Good News Club* argued the importance of age in deciding what constitutes a breach of the Establishment Clause. They presented psychological research showing young children are less mentally developed and will see any programs conducted in the school as supported

13 *Santa Fe Independent School Dist. v. Doe,* 530 U.S. 290, 305 (2000)

14 *Board of Education v. Mergens,* 496 U.S. 226, 2507 (1990)

15 Chaffee, *supra* note 9 at 272.

16 *Widmar,* 454 U.S. at 274.

by the school.[17] Famed psychologist Jean Piaget found that pre-adolescent youths are incapable of abstract logic, hypothetical reasoning, and independent thinking.[18] Psychologist Eric Erikson found that pre-adolescent children lack "the ability to make distinctions between his views, others' views, and the views of his school."[19] Another psychological study, showing that younger children are more susceptible to peer pressure, sparked worries that children would be pressured to attend the Good News Club and then be socially coerced to become a Christian.[20] This is an intrinsic danger to pre-adolescents.

Despite the young age of the students involved, the Supreme Court did not find an Establishment Clause violation in a 5-3 decision with Justices Thomas, Rehnquist, O'Connor, Scalia, and Kennedy in the majority and Justices Stevens, Souter, and Ginsburg dissenting.[21] Justice Breyer concurred in part but argued in a concurring opinion that "a child's perception that the school has endorsed a particular religion or religion in general may also prove critically important."[22] The majority had five main arguments by which they arrived at their decision. First, the Establishment Clause calls for government programs to be neutral with regards to religion.[23] The majority found that the most neutral policy possible is to treat religious organizations like every other

17 Chaffee, *supra* note 9, at 273.
18 *Id.*
19 *Id.*
20 *Id.* at 274
21 *Good News Club*, 533 U.S. at 101.
22 *Id.* at 128.
23 *Id.* at 114.

group.[24] For a limited public forum, this principle implies allowing a religious group to speak on the same issues with the same opportunity as others.

Secondly, the Court argued that the relevant community is parents, because children could not attend the Club without a signed permission form.[25] This avoided the threat of children being coerced into attending by social pressures.

Third, the Court distinguished the precedents cited in *Milford* for a stricter interpretation of the Establishment Clause from *Milford* itself. In fact, the Supreme Court had never used the presence of young children as a reason to invoke the Establishment Clause and prohibit religious activity at schools after the school day was over.[26] *Lee v. Weisman* involved a mandatory attendance graduation exercise, *Santa Fe Independent School District v. Doe* dealt with a school-run sporting event, and *Edwards v. Aguillard* addressed the impressionability of students in a mandatory class with a state endorsement of a religion.[27] The Establishment Clause concerns in these cases do not apply when the religious teachings are after school with leaders who do not work for the school, and parental permission is required to attend.[28]

The fourth consideration is that even if it is considered important that children could potentially assume a relationship

---

24 *Id.* at 114.

25 Barry Hankins, *Is the Supreme Court Hostile to Religion?: Good News Club et al. v. Milford Central School (2001) and Santa Fe v. Doe (2000)*, Journal of Church & State, 681, 684 (2001)

26 *Good News Club*, 533 U.S. at 115.

27 *Id.* at 115-116.

28 *Id.* at 117.

exists between religion and government, the Good News Club's usage of the Milford Central School facilities still did not violate the Establishment Clause. Young students should be capable of distinguishing the difference between the Club and an official class. This is made obvious by the fact that they needed to get written permission from their parents to attend the meeting.[29] Also, the meetings were not held in an elementary classroom, were not led by a teacher, and had ages ranging from six to twelve present.[30] All of these factors make clear, even to a young child, the difference between an official class and one of the Club's meetings.

The final issue weighing against employing the Establishment Clause against the religious group was the risk of misperception in the opposite direction. If the Good News Club is not allowed equal access to the facilities, individuals might interpret this as school-sanctioned hostility towards the Club. This effect would not be limited to elementary students, but would apply to all students and community members who become informed of the rejection. In *Rosenberger v. Rector and Visitors of Univ. of Va.*, the Court established that government viewpoint discrimination can cause the "chilling of individual thought and expression" by stifling creative exchange.[31] In summary, the majority decided that religious free speech cannot be restricted because of "what the youngest members of the audience might misperceive."[32]

---

29 James Kozlowski, *Bible Youth Group Excluded from School Open for Community Use*, 8, Parks & Recreation, 36, 38 (2001)

30 *Id.* at 45

31 *Rosenberger v. Rector and Visitors of Univ. of Va.*, 515 U.S. 819, 835-836 (1995)

32 *Good News Club*, 533 U.S. at 119.

Despite their strong arguments that differences in age should not impact Establishment Clause jurisprudence, the majority was still careful to argue that even if age does play a role in what is constitutionally allowable, it did not matter in this case. Justice Souter's dissenting opinion attacked this decision by the majority by arguing that the core components for the decisions in *Lamb's Chapel* and *Widmar* were not present.[33] The *Widmar* case involved college students at a university which had a significant number of groups that met on campus.[34] In *Lamb's Chapel*, the religious video shown was open to anyone and was geared especially for adults. Also, the school in that case had been used by numerous other private groups.[35] Clearly, the age difference between the students affected in *Good News Club* and the other two cases is a significant because six to twelve year olds are not be able to comprehend concepts like religious neutrality the same way an older individual would. Furthermore, only four total outside groups were using the Milford Central School at the time, which lends the appearance of school-favor to the Good News simply because they were the one of the only groups using the facility.[36] Also, the Club began its meetings immediately after school ends. This near-seamless flow from the classes to the meeting might prevent young students from discerning the break from school activities to the religious meeting.

After the decision, several critiques of the majority opinion

---

33 *Id.* at 141

34 *Id.*

35 Rob Boston, *Evangelism, Public Schools and the Supreme Court*, 1, Journal of Church & State 54, 42 (2001)

36 *Id. at 144.*

emerged as well. The determination that parents were the audience of importance came under criticism because the Club was attempting to interact with children and not parents.[37] Critics assert that the real audience was the student body, all of whom could have seen the Good News Club's presence as an endorsement from the school.[38] Similarly, the majority's argument that students can be inoculated from misperceptions regarding the attitude of the school towards the religion by requiring permission slips is undermined by the fact that some school-sponsored activities such as field trips also require permission slips.[39]

Both sides of the debate presented reasonable arguments to marshal to their viewpoints regarding whether the allowing the Good News Club access to the limited public forum would cause misperceptions of government establishment of religion. The time that the Club met, the very young age of some of the students, and the lack of other groups meeting at the school all will factor into children's perspectives. However, the necessity of parental permission, the fact that it is not run by teachers, and the fact that it has multiple grade levels makes it likely that many students would be able to see the difference between school and the Club. Parental involvement, necessitated by the permission slip requirement, allows parents to be discerning on behalf of their child. While a permission slip does not automatically mean that students will no longer see any school endorsement of the activity, it does significantly diminish the threat of children being peer-pressured into

37 *Id. at* 277.

38 Chaffee, *supra* note 9, at 278.

39 *Id.*

going. Instead of hiding children from things which might appear confusing, it involves parents and an opportunity for the child to understand the world better.

Although some six-year-old students may not understand the school's policy of neutrality towards an organization, that is not a constitutionally sufficient reason to deny the organization's right to have a voice. The rule of law, not perceptions, must be maintained. In *Good News Club*, the majority found that prohibiting access to the Club could create a perception of government hostility towards religion and that the Establishment Clause calls for treating religious organizations neutrally. Overzealous legal attempts to protect children from fallaciously ascertaining government support for religion can actually do greater harm. If *perceptions* of the government's attitude towards religion become the basis for Establishment Clause jurisprudence, even if only in cases involving youths, there will be no objective standard to adjudicate free exercise disputes. Furthermore, freedom of speech and the free exercise of religion are among America's most cherished rights and should not be held hostage to the potential misunderstandings of society's most immature members. As Justice Thomas wrote in the majority opinion, it would become a "heckler's veto, in which a group's religious activity can be proscribed on the basis of what the youngest members of the audience might misperceive."[40] For these reasons, the Court ruled that government must maintain a posture of neutrality and eschew viewpoint discrimination.

40 *Good News Club*, 533 U.S. at 119.

THE AMBIGUOUS ROLE OF PGD IN SOCIETY:
AN ANALYSIS OF PREIMPLANTATION GENETIC DIAGNOSIS POLICY AND ITS PUBLIC PERCEPTION

Catherine K. Ettman *

ABSTRACT: *Gabriel Rubell Bergero's wrongful life lawsuit against the University of Southern California Keck School of Medicine in 2004 shed new light onto the issue of Preimplantation Genetic Diagnosis. While PGD has proven benefits, it also has the potential to raise serious legal, social, and ethical controversies--ones that regulators have yet to seriously address. Bergero's case in particular exhibits just some of these controversies, and reveals the dire need for regulation especially with regard to patient-doctor relationships. These regulations include both federal and state mandates designed to better educate and inform patients about PGD and ensure adequate funding for those who opt to use such procedures.*

---

* Catherine Ettman is a senior at Princeton University studying at the Woodrow Wilson School of Public and International Affairs with certificates in Gender & Sexuality Studies and African American Studies. Her independent research focuses on the intersection of women and the workforce. Catherine was born and raised in Miami Beach, FL. She has two older sisters. They and her parents are her inspiration. She hopes to work in public policy after graduation.

In 2004, Gabriel Rubell Bergero filed a wrongful life lawsuit against the University of Southern California Keck School of Medicine. He was one year old. Gabriel's mother, Eve Rubell was undergoing IVF treatment in 2003 with USC Keck School of Medicine when she learned she was a carrier for Fabry disease. Fabry causes pain, especially for boys, from an early age in the hands and feet. In adulthood, Fabry leads to kidney failure, heart failure, and stroke. Rubell had never heard of Preimplantation Genetic Diagnosis (PGD), but her genetic counselor and doctor encouraged her to try the new procedure to implant only an embryo that was free of the Fabry gene. The doctor and genetic counselor wrote strong letters to Rubell's insurance Kaiser to convince them to cover the procedure. In it they described the benefits of PGD and the savings that Kaiser would make over time by not covering a sick child with Fabry. The company agreed. Rubell signed waivers that noted the 3-4% risk in the procedure. After PGD, scientists separated the embryos that had and did not have the Fabry trait. They claimed to implant the non-Fabry embryo, but three months into her pregnancy, Rubell learned through amniocentesis that her child had the disease. Shortly after Gabriel Rubell Bergero was born, Rubell and her husband filed the suit on behalf of their son suggesting negligence in PGD. In 2009 the court of appeals sided with the doctors from the University, who had gotten Rubell's written consent before the procedure. Gabriel is now eight years old and must live with Fabry, though his parents tried their best to de-select his birth.

Gabriel Rubell Bergero's case raises questions about the ethics of Preimplantation Genetic Diagnosis (PGD). While the case was ultimately fought as a "wrongful life" suit, it also discusses the broader issues surrounding genetic diagnosis: the concept of informed consent, misunderstandings between patients and medical experts, and errors in gray regulatory areas. This case may serve as a cautionary tale of the potential outcomes that arise from using this relatively new technique. While there are many stakeholders in the conversation on PGD, this paper will focus on the tension between patients and medical professionals (i.e. genetic counselors and doctors) raised by the Bergero case. Medical professionals play a significant role through the whole process of electing to use PGD: they inform patients about the very option to use PGD, choose which embryo diagnosis methodology to use, and actually implant the embryos. Given little regulatory oversight in the United States, the decisions about PGD fall mainly on the shoulders of professionals and patients; therefore, the tension in their relationships is a timely and important issue to discuss. Opportunities for regulation exist in providing greater education to patients, redefining standards for obtaining consent, and establishing guidelines to minimize human error during the procedure.

The dependence of patients on medical professionals for information about the existence and limitations of PGD creates a power dynamic that regulators may want to standardize. The legal, social, and ethical controversies surrounding PGD give it a precarious placement in the medical community. Religious values, political values, moral values, values of fairness, and long-

term societal wellbeing inform views both for and against PGD. The potential to eradicate genetic diseases for IVF children could positively impact on the economy and overall health of the nation; however, misuse of the technology could lead to a new social class segregated by genetic engineering or contribute to a crisis questioning the definition of human life. Inherent in the two views is the tension between accepting the benefits and risks to society associated with using PGD.

PGD was developed in the early 1990s at a time when in vitro fertilization was becoming a more widely accepted, understood, and utilized service. Meanwhile, genetic testing was becoming more affordable, prompting some individuals who had formerly left genetic inheritance to fate to seek information about their own conditions and the ways they could pass their genetic material to their offspring. Despite its creation in 1990, PGD was used relatively few times in its first decade: some cite doctor's reluctance to "play god" and introduce a more controversial fertilization service to patients while others describe a larger lack of knowledge around the technology across the medical community.[1]

Moral, legal, and political controversy surrounds the broad use of PGD in society. Once used only to test for single gene disorders, PGD now has the capacity to test for non-medical traits such as gender, eye color, or deafness. The latter category generates moral confusion as parents may ask doctors to select embryos that *have* disorders like deafness or dwarfism so that they may share an

1 Amy Harmon, "Couples Cull Embryos to Halt Heritage of Cancer." *New York Times*. September 3, 2006.

identity with the parents.[2] The former group brings about ethical questions of "designer babies" that may someday be engineered to have socially desirable traits of beauty, intelligence, or height.[3]

I. Infertility

Approximately one in eight couples in the U.S. has attempted fertility treatment to assist them in pregnancy.[4] Treatment can range from taking pills to stimulate ovulation to more invasive in vitro fertilization, in which zygotes are joined in a lab and several embryos are inserted into a woman's uterus for pregnancy. Fifteen states in the U.S. require insurers to cover infertility diagnosis and treatment.[5] One cycle of IVF costs from approximately $11,000-$13,000 for medication and implantation. For an additional $3,000 (not covered by insurance), parents can opt for additional procedures to specifically choose which embryos get implanted and which do not get implanted in the uterus.[6]

II. Preimplantation Genetic Diagnosis

PGD allows doctors to test embryos created in vitro for certain genetic characteristics. Only the embryos with desired genetic traits are implanted in the womb. The process occurs two to four

---

2 Darshak Sanghavi. *New York Times*, "Wanting Babies Like Themselves, Some Parents Choose Genetic Defect," December 5, 2006.

3 B. Stankovic, "'It's a designed baby!' - opinions on regulation of preimplantation genetic diagnosis." *UCLA Journal of Law & Technology*, 3, 2005, 1.

4 National Conference of State Legislatures, 2012

5 Ibid.

6 Amy Harmon suggests that the out of pocket expenses for IVF and PGD are around $25,000. See "Couples Cull Embryos to Halt Heritage of Cancer." *New York Times*. September 3, 2006.

days after the egg has been fertilized when embryos consist of roughly eight cells. Geneticists remove one to two cells by biopsy. There are various methods to obtain samples: polar body biopsy, cleavage stage biopsy, and blastocyst biopsy.[7] In the first method, scientists take the cells that have been "cast off" by the egg as it matures. Scientists use these "polar body cells" to understand the characteristics of the egg.[8] A limit to this method is that these cells will only include genetic material from the mother and cannot test for paternally inherited diseases. In the other methods of extraction, scientists wait two to four days after the egg has been fertilized for the embryo to develop, and then they remove one to two cells. In cleavage stage biopsy, the most commonly used method, a laser is used to create a hole to access the blastomeres, which are often removed by pipette. The last method is called blastocyst biopsy. The benefit is that the blastocyst stage provides more cells for analysis; most cells in vitro do not make it to this stage and if they do they have little time to be analyzed.[9]

Once cell particles are removed from the embryo, there are two ways to analyze the extracted material: "FISH" (fluorescent in-situ hybridization), which allows researchers to determine the number and structure of chromosomes, and "PCR" (polymerase chain reaction), in which researchers make copies of individual

---

7 Karen Sermon, "Current Concepts in preimplantation genetic testing diagnosis (PGD): a molecular biologist's point of view," *Human Reproductive Update*, 2002, 12.

8 Genetics & Public Policy Center.

9 Karen Sermon, "Current Concepts in preimplantation genetic testing diagnosis (PGD): a molecular biologist's point of view," *Human Reproductive Update*, 2002, 13.

genes to examine their DNA sequences.[10] FISH, used to determine the sex of embryos, has a 10% error rate.[11] PCR has been used to reduce the likelihood of having a child with genetic disorders. PCR testing now extends to test the status of many diseases ranging from Alzheimer's to Breast Cancer to Cystic Fibrosis to Fabry. The Reproductive Genetic Institute boasts positive testimonials on its website: "Benjamin is the first child ever to be born using PGD to prevent another life from being burdened with dystopia," signed by "Happy Parents." For couples that fear passing genetic disorders on to their children, PGD provides a better alternative to prenatal testing, abortion, or caring for a sick child.[12] However, many people are concerned about the ethical implications of using FISH to select the sex of babies and other non-medical characteristics such as eye color or hair color. Bratislav Stankovic describes people's fears of "Designer Babies" that are selected for non-medical traits.[13] This paper will focus on electing PGD for medical purposes because this one option has enough disagreement for a whole paper to itself.

III. Impact of PGD on child health

Though relatively few PGD procedures and births have

10 Genetics & Public Policy Center, 2006, and Sermon, 2002.

11 Karen Sermon et al., "Preimplantation Genetic Diagnosis," *The Lancet*. Vol. 363, 2004.

12 B. Tur-Kaspaa et al. "PGD for all cystic fibrosis carrier couples: novel strategy for preventive medicine and cost analysis," *Reproductive Biomedicine Online*, 2010.

13 B. Stankovic, "'It's a designed baby!' -Opinions on Regulation of Preimplantation Genetic Diagnosis." *UCLA Journal of Law & Technology*, 3, 2005, 2.

occurred, early research shows promising signs for children. As of 2006, between 1000 and 2000 children were born after PGD.[14, 15] Exact estimates of the number of PGD children born vary, but this number is quite small relative to the 1 million children born through in vitro fertilization.[16, 17] Studies show that babies who underwent PGD show signs of similar health to other babies conceived in vitro as well as naturally conceived babies. Researchers note that children born from multiple pregnancies (twins, triplets or more) have higher risks for health conditions.[18]

Given that the risks associated with PGD are low and that the reward of giving birth to a child without genetic disorder is so high, many parents with the means necessary pursue the technology. PGD has been used to help parents bear children that are free of a range of hereditary diseases. We will now look closely at one

---

14 Genetics & Public Policy Center, 2006

15 According to Andrew LaBarbera, president of the American Society for Reproductive Medicine, as quoted by Nicholas Wade in *In New Methods for Stem Cells, Viable Stem Cells: Objection to Use*, NYT, about 2000 babies were born from PGD as of 2006. The 100% discrepancy in total number of children born after PGD shows the lack of formal data gathering and registration across the medical community.

16 Preimplantation Genetic Diagnosis: A Discussion of Challenges, Concerns, and Preliminary Policy Options Related to the Genetic Testing of Human Embryos. Genetics & Public Policy Center. http://www.dnapolicy.org/images/reportpdfs/PGDDiscussionChallengesConcerns.pdf

17 According to the 2012 Reproductive Genetics Institute website around 1500 children have been born to date after PGD. To put these numbers in perspective, consider the fact that couples in the U.S. gave birth to 61,000 babies conceived through IVF in 2008 alone (NCSL, 2012). PGD is being done on a much smaller scale due to costs, technology, and lack of awareness of the procedure, possibly driven by doctors' fears of personal and social impact.

18 L. Liebaers, "Report on a consecutive series of 581 children born after blastomere biopsy for preimplantation genetic diagnosis," *Human Reproduction*, 2010.

of those diseases, Fabry, which was the core of the Bergero case.

IV. Fabry Disease

Fabry disease is an X-linked recessive disorder. The gene creates reduced amounts of the enzyme alpha galactosidase, which prevents buildup of lipids in cells throughout the body.[19] Without the enzyme, lipids build up to harmful levels in eyes, kidneys, the autonomic nervous system, and the cardiovascular system.[20] Symptoms begin in childhood and include a burning feeling in the hands and feet, skin blemishes, cloudiness of cornea, and impaired circulation.[21] These symptoms are associated with an increase in heart attack or stroke. Approximately 1 in 40,000 to 60,000 males have the disease.[22] In a study of individuals in the Fabry Registry, the life expectancy of men with Fabry disease was 16.5 years lower than that of men in the general population. The most common cause of death of people within that group was cardiovascular disease.[23][24] Lastly, all individuals who died early as a result of Fabry had the common theme of late diagnosis of Fabry.[25] The FDA has approved enzyme replacement therapy to

---

19 Bergero v. USC Keck School of Medicine, 2009

20 National Institute of Neurological Disorders and Stroke, 2010. http://www.ninds.nih.gov/disorders/fabrys/fabrys.htm

21 Ibid.

22 Genetics Home Reference. 2013. http://ghr.nlm.nih.gov/condition/fabry-disease

23 Waldek, S. "Life expectancy and cause of death in males and females with Fabry disease: findings from the Fabry Registry," *Genetic Medicine*, 2009, 1. http://www.ncbi.nlm.nih.gov/pubmed/19745746

24 Waldek et al. used data from 2848 patients in the Fabry Registry. As of 2008, the authors found that 75 of 1422 men and 12 of 1426 women registered in the Fabry Registry had died.

25 The median age of diagnosis was age 40 for men and age 55 for women.

reduce lipid build up in organs. Other interventions include medications, renal replacement therapy, and kidney transplant.[26]

Because of the painful outcomes associated with Fabry disease, parents may seek genetic counseling. As stated above, Fabry is an X-linked recessive disorder. If a female carrier has a child, a boy will have a 50% chance of inheriting the disorder and a girl will have a 50% chance of being a carrier.[27] If a father is a carrier, all of his female children will inherit the gene and none of his male children will inherit the gene.[28] Since women have two X-chromosomes, the normal gene on the unaffected X-chromosome may produce enough of the necessary enzyme to compensate for the deficient gene on the other chromosome.[29] Thus, the effects of Fabry in females are milder.

Like many other parents who are aware of genetic disorders they may carry, Eve Rubell wanted to avoid passing the gene to her potential offspring. Rubell had previously attempted treatment for infertility when she learned that she was a carrier for Fabry after a routine eye exam showed swirling around the cornea.[30] Afraid that a child would inherit the gene, she and her husband sought counseling. A genetic counselor from Kaiser suggested PGD as one of three options and recommended specialist Dr. Hughes. Rubell

---

Because of diagnosis at this point in mid-late adulthood, the disease had progressed a good deal before it was treated.

26 National Institute of Neurological Disorders and Stroke, 2010. http://www.ninds.nih.gov/disorders/fabrys/fabrys.htm

27 Ibid.

28 "What is Fabry Disease?" Fabry Support & Information Group. http://www.fabry.org/fsig.nsf/pages/fabry

29 Bergero v. USC Keck School of Medicine, 2009

30 Ibid.

could do PCR (used to study genes; commonly used to determine presence of a single gene diseases) or FISH (used to study chromosomes; commonly used to test gender). Hughes recommended using PCR because if they did FISH they would have to get rid of all male embryos (since FISH would not be able to distinguish which embryos were affected with Fabry). Rubell understood this to mean that she would have more embryos to implant with PCR than FISH, and so she chose PCR to increase the odds of having a successful pregnancy.

After PCR, Hughes found that all six of the embryos were affected with the Fabry gene. Two were female, two were male, and two were inconclusive. Given the much milder health outcomes in women with Fabry (due to the extra X chromosome to combat the enzyme deficiency), Rubell asked Dr. Hughes to implant the two known female carriers. Twelve weeks after getting pregnant, Rubell learned that the fetus was a boy with Fabry. Rubell later told the court that her top priority was to not conceive a male child with Fabry. However, she testified that she could not remember whether she had made the statement to her genetic counselor. Knowledge of this goal might have led Dr. Hughes to recommend FISH, which has a better accuracy for gender. Rubell

also lamented that no one had ever verbally reviewed the consent form with her and that they concealed the center's lack of experience with PGD from her.

The Rubell-Hughes misunderstanding serves as a warning of the potential outcomes of mismanaged expectations and end-goals of patients and their doctors. According to the case notes, "consensus among the genetic community" suggested that two people be present at the time of the embryo transfer to ensure that the correct one be implanted in the mother. However, no formal regulation on PGD existed or exists today.

V. Regulation

There is little regulation on PGD in the United States.[31, 32] However, members of the American Society for Reproductive Medicine claim that Assisted Reproductive Technologies (ART) is "already one of the most highly regulated of all medical practices in the U.S."[33] The report cites federal government, state government, and professional self-regulation as the watchdogs on ART.

Federal Regulation has been limited in its scope. As established by the 1992 Fertility Clinic Success Rate and Certification

---

31 See B. Stankovic, "'It's a designed baby!' -Opinions on Regulation of Preimplantation Genetic Diagnosis." *UCLA Journal of Law & Technology*, 3, 2005, 5-7.

32 In England, a committee was charted in a 1990 law to promote and regulate the research on embryonic cells, transfer of cells for IVF, and other genetically related procedures. Italy banned PGD, Israel promotes it (since it is a good alternative to abortion, which is prohibited by Jewish doctrine), and France is still figuring out what it should do with PGD given differences in public opinion.

33 "Oversight of Assisted Reproductive Technology," American Society for Reproductive Medicine. May 25, 2012, 3.

Act, the Centers for Disease Control created standard definitions for methods used in fertility clinics and required standard reporting of ART data. The FDA has jurisdiction over medications as well as the screening and testing of reproductive tissues. The Centers for Medicaid and Medicare and Clinical Lab Improvement Act handle diagnostic testing and regulation of embryology labs.[34] These organizations audit labs by sending blank samples that need to be identified; labs with consistently high percentages of error lose their accreditation. Authors are torn on the role of regulation, citing the impact regulation might have on different stakeholders.[35]

There are many stakeholders in a conversation about access to PGD: parents, doctors, scientists, drug companies, insurers, government agencies, and society at large. This paper focuses on the tension between patients and their medical professionals. In this paper, I conflate doctors and genetic counselors, since they as a group have more information about the technology of PGD than most patients. A separate analysis would show the differences in concerns between these two stakeholders, but due to its scope, this article will focus on the asymmetric information between patients and their medical-advisors. *New York Times* science correspondent and Pulitzer Prize winner Amy Harmon notes, "In the U.S., where technology is not regulated, decisions about when it is appropriate are left largely to fertility specialists and their

34 Ibid. 6-7.

35 Dorothy Roberts. "Race, gender, and genetic technologies: A new reproductive dystopia?" *Signs, 34*(4), 2009, 784.

patients."[36] Because there is little regulation in the U.S., many decisions regarding PGD are left up to doctors and counselors. Therefore, the tension between doctors and patients is extremely relevant in the U.S. right now.

VI. PATIENTS

Since PGD is a relatively new technology, many people are unaware of having an option to prevent passing on a hereditary trait to children. Genetic diseases have different emotional and social meanings for different people. Some people like Eve Rubell are carriers for a disease but have never been physically affected by the genetic disorder; because she was undergoing IVF and discussed the disease diagnosis with her genetic counselor, she thought that she could prevent future suffering of her child by deselecting embryos with the Fabry gene. For others, having a disease is strongly linked with personal and familial identity. Women who have seen scores of family members die from breast cancer may learn about PGD and see it as a chance to overcome a plague that has befallen generations and prevent tragedy for future genetic lines. Some breast cancer survivors who have not been presented the option of PGD feel they have been "cheated" out of an opportunity to have a cancer-free future for their children. Indeed, Offit et al. suggest that patients with various types of cancer are increasingly asking about the option to select PGD and avoid passing cancer genes to children.[37] Others experience

---

36 Amy Harmon, "Couples Cull Embryos to Halt Heritage of Cancer." *New York Times*. September 3, 2006. http://www.nytimes.com/2006/09/03/health/03gene.web.html?pagewanted=all&_r=0.

37 Offit et al., "Cancer genetic testing and assisted reproduction," *Journal of*

genetic diseases as cultural identities.

Consider the Dor Yeshorim program used to eliminate Tay-Sachs in the New York City Jewish community in the 1980s. In the program, the trusted community Rabbi signed off on every marriage. With access to genetic information about community members, Rabbi Josef Ekstein would disallow marriages where both individuals were Tay-Sachs carriers.[38] The program successfully decreased the prevalence of Tay-Sachs in the community. The Dor Yeshorim was popularly accepted because Rabbi Josef Ekstein was a trusted and respected figure within the community. While the Dor Yeshorim served as a community-led mating process to avoid passing deadly Tay-Sachs genes to offspring, PGD may be seen as a more invasive form of ensuring that a healthy child is produced. PGD is supported by genetic counselors who are not as engrained and attuned to cultural traditions as a community leader. Lastly, the Dor Yeshorim was successful because the group of individuals affected became educated and acted together to eradicate this disease.[39]

Clinical Oncology, July 13, 2006, 4775.

38 Keith Wailloo and Stephen Pemberton, *Ethnicity and Innovation in Tay-Sachs, Cystic Fibrosis, and Sickle Cell Disease: The Troubled Dream of Genetic Medicine*, The Johns Hopkins University Press, 2006, 20.

39 Because the community of cancer survivors is much larger and more heterogeneous, it might be difficult to get a group even as committed to eradicating cancer as them to promote use of PGD to deselect genes with the BRCA1/2 genes. Indeed, much research and literature has recently shown that researchers are thinking about the relationship between PGD and cancer prevention. The growing concern between cancer and PGD may be due to the large number of people in the U.S. affected by cancer in some way or because of its racially and economically free characterization: no race, ethnicity, or income status is barred from cancer. Whereas other diseases may be more specific to certain groups, getting donors to support cancer-PGD research may be easier.

In all cases, patients are trying to avoid the future suffering of their children and hoping to give birth to healthy children, whatever their fertility motivations may be. Since the majority of people considering PGD have tried IVF and have dealt with the sadness of infertility, their overriding desire is to have a successful pregnancy and give birth to a healthy child. Definitions of healthy, however, vary across patients. Some parents have, as a secondary goal, a desire to have a child similar to his or her parents. In 2006 Darshak Saghavi described the practice of parents selecting embryos with known deficiencies so that they can fit in with the family or be part of a disabled community. According to Susannah Baruch at Johns Hopkins Medical Center, 3% of couples deliberately used PGD to select an embryo with a disability.[40] These desires present a tension between individual values and collective values. Many doctors refuse to do such procedures because of the social value on "wellness."

Patients may see PGD as a way to improve fertility by selecting embryos with a higher rate of survival or as a way to avoid passing on a deadly genetic disease while conforming to religious norms. Women who were studied in Israel saw PGD as a positive option to have in trying to have a healthy child, since many women had religious beliefs preventing them from aborting fetuses.[41] Religious values can influence patients' desires in the other way, as well. Some conservative Christians may not believe in

40 Darshak Sanghavi, "Wanting Babies like Themselves, Some Parents Choose Genetic Defects," *New York Times*. December 5, 2006, http://www.nytimes.com/2006/12/05/health/05essa.html.

41 M. Sagi et al. Preimplantation Genetic Diagnosis for BRCA1/2- a novel clinical experience, *Prenatal Diagnosis*. May 29, 2009, 511.

IVF because it separates the act of procreation from sex, denying a sacred part of human creation. In addition, PGD may create an even bigger moral dilemma than abortion because of the question of what to do with the multiple leftover embryos not selected for implantation. However, PGD has been found, broadly, to decrease the number of abortions of fetuses with genetically inherited diseases: Verlinksy et al found that PGD "reduces by fourfold the spontaneous abortion rate in couples carrying translocation."[42] Thus, pro-life individuals might support PGD, depending upon their beliefs regarding the extraneous embryos. Religious values may create political complications for any regulations surrounding PGD; for example, would religious hospitals or insurance agencies have to cover expenses for IVF and PGD? The current skepticism around women's reproductive rights in the political forum will undoubtedly influence policy decisions around PGD.

As the parents of future children, patients have a large stake in determining the outcome of their potential progeny. PGD allows many couples who would otherwise be infertile to have the opportunity to have a child and continue their genetic ancestry. PGD may also prove burdensome, as parents who do not elect to use the technology may feel guilt if they see their child suffer later in life and think about what they could have done to prevent that pain. Patients may lack understanding of their own disease, of the powers of PGD, or may misunderstand the probabilities for misdiagnosis.

---

42 Verlinsky et al., "Over a decade of experience with preimplantation genetic diagnosis: a multicenter report," *Fertility and Sterility*. August 2004, 293.

VII. Medical Professionals

Medical professionals present another group within the conversation on stakeholders in the discussion on PGD. Doctors and genetic counselors want, broadly, to produce healthy children. They are responsible for conducting PGD and are held responsible if something goes wrong along the way. Doctors have stakes in maintaining their businesses, making money, and promoting healthy babies. They also have their own social, religious, or moral beliefs that may influence their decisions. For example, many doctors refused the patients who asked them to select embryos with deafness or dwarfism because of their own values of what it means to be healthy and "normal" in society.[43] Genetic counselors have stakes in keeping the field of genetics popular and lucrative; hopefully, they have it in the best interest of their patients to produce healthy children. Should they bend to the desires of their patients?

Medical professionals are essentially the gatekeepers to PGD. Whom do they choose to inform about the procedure and assist in getting coverage? Is it ethical that some parents are aware of the procedure—let alone have access to it—while others do not? Eve Rubell's genetic counselor fought hard to get coverage from Kaiser insurance for the expensive procedure.[44] What was that counselor's motive in fighting for the money despite USC's low level of experience with the procedure? How much responsi-

---

43 Darshak Sanghavi. *New York Times*, "Wanting Babies Like Themselves, Some Parents Choose Genetic Defect," December 5, 2006. http://www.nytimes.com/2006/12/05/health/05essa.html

44 Bergero v. USC Keck School of Medicine, 2009

bility do professionals have in reaching out to communities that are currently underrepresented in PGD? Dorothy Roberts suggests that culture, history, and economics influence a distrust of genetic specialists that explains the low number of African American women who receive PGD: "Blacks may find it emotionally difficult to discuss their problem with a physician, especially considering the lack of Black specialists in this field. They may also harbor a well-founded distrust of technological interference with their bodies and genetic material at the hands of white physicians."[45] Thus, genetic counselors, doctors, and specialists must overcome this distrust if they hope to reach a wider group of individuals.

Tensions exist between patients and their medical professionals because of incentives on either end: patients with disabilities may seek harmonious family life, which motivates their desire to select certain embryos. Professionals may seek to maximize the chance of pregnancy or may act in the best interest of protecting the clinic. All of these stakeholders have different values guiding their decisions, and they have one thing in common: each needs the other. Patients could not avoid passing genetic disorder to their offspring through PGD without the help of medical professionals, and, medical professionals would have no line of business if they did not have patients.

VIII. Moral, political, and religious values

PGD raises many issues. Morally, people are concerned with picking which lives get to live. Controversies include using PGD

45 Dorothy Roberts, "Race and the New Reproduction." *Hastings Law Journal.* Vol. 47, 1995-1996: 941.

as a means for an end. For example, parents may select certain embryos that have an "immunological match for a sick sibling."[46] PGD may be favorable to individuals who oppose abortion. By limiting the embryos that can lead to a pregnancy to only those of healthy quality, then women avoid the question of aborting a pregnancy.

Social and political values consider who can access PGD and whether it will give certain families unfair advantages. Dorothy Roberts discusses the double-edged sword of making IVF and PGD more accessible to all people. As current policy stands, there is little regulation of the IVF business, so the majority of women who have access to the processes are independently wealthy.[47] Roberts notes also that the vast majority of women undergoing reproductive assistance are white women.[48] While some might welcome government regulation to provide access to fertility services for low-income women and black women, the very act of regulation on reproduction may be a cause for political concern for others.

Other legal concerns question the autonomy of the fetus. Should parents deselect for diseases that do not appear until later in life or for heightened but uncertain risks such as breast cancer? In Israel, the Genetic Information Law of 2000 makes it illegal for parents to seek the genetic information of children after birth.[49]

---

46 Genetics and Public Policy Center.

47 Dorothy Roberts. Race, gender, and genetic technologies: A new reproductive dystopia? Signs, 34(4), 2009, 784.

48 Dorothy Roberts, "Race and the New Reproduction." Hastings Law Journal. Vol. 47, 1995-1996: 937.

49 M. Sagi et al. Preimplantation Genetic Diagnosis for BRCA1/2- a novel

The U.S. may look to other countries as it begins to craft its own policies on the subject.

IX. Policy Recommendations

Based on the models that have been studied in different countries, the values shared by many stakeholders, and on the experiences represented in the Bergero case, I would recommend three changes to current policy.

First, to empower patients and ensure that they are aware of all of their fertility options, medical professionals should educate known genetic carriers on the use of PGD. States could mandate that geneticists provide information about PGD (and provide counseling) to individuals over the age of 18 when they are diagnosed with diseases that can be passed on to children. This recommendation is inspired by the research of Sagi et al., who informed BRCA1/2 survivors of PGD and studied women's reactions in response to the option. In the study, all women said they appreciated having the option to use PGD to prevent implanting an affected embryo, but most did not choose to use the option.[50] In addition, the work of Kalfoglou and Quinn et al. shows that patients desire to know more about PGD as an option to prevent genetically passed disease traits, even if they do not ultimately use it as an option.[51, 52] This recommendation is particularly easy

---

clinical experience, Prenatal Diagnosis. May 29, 2009, 512.

50 M. Sagi et al. Preimplantation Genetic Diagnosis for BRCA1/2- a novel clinical experience, *Prenatal Diagnosis*. May 29, 2009, 510.

51 Dwendolyn Quinn et al., "Conflict between values and technology: perceptions of preimplantation genetic diagnosis and women at increased risk for hereditary breast and ovarian cancer," *Familiar Cancer*, 2009

52 Kalfoglou et al. PGD patients' and providers' attitudes to the use and

to implement for the cancer survivors and other genetic disease carriers who are already undergoing IVF treatment due to infertility issues. Geneticists and doctors who deliver news of diagnoses of genetic diseases would have to first learn more about the technologies of PGD and then articulate those options to their clients. Such a policy would inform patients of the full extent of fertility options.

Second, to ensure that patients who choose PGD are fully aware of the risks involved with the procedure once they decide to do it, regulation should require doctors to review consent forms verbally to ensure that their patients understand the information to which they are agreeing. Eve Rubell signed consent forms stating that she was aware PGD had an error rate of 3-5%. She received written word of the probabilities of misdiagnosis in emails, but her doctor stated that he did not review the forms with her verbally. Such a conversation may have prevented her from suing USC and may have helped her manage her expectations on the powers of PGD. Kalfoglou's research uncovered that women did not feel like "empowered consumers" of PGD and felt confused by their contractual agreements in consent forms.[53] Kalfoglou also shows that patients misunderstood the probabilities of having live births after PGD.[54] Better communication between providers and patients will improve the process by empowering patients. Edu-

---

regulation of preimplantation genetic diagnosis. *Reproductive BioMedicine Online*. 2005. 487.

53 Kalfoglou et al. "PGD patients' and providers' attitudes to the use and regulation of preimplantation genetic diagnosis." *Reproductive BioMedicine Online*. 2005. 490.

54 Ibid. 490.

cating patients about the limitations of PGD, in part by verbally discussing consent agreements, will clarify doctors' and patients' expectations.

Third, to reduce human error in PGD, states should regulate that two people check transfers at the time of single cell biopsy. In addition, having two people present at the transfer of the embryo will reduce speculation of human error in cases of misdiagnosis, which will help further develop our understanding of this technology and process. According to the notes from *Bergero v. USC Keck School of Medicine*, it is a commonly accepted practice within the "PGD community" to have two people present at the time of the transfer, but that did not happen in *Bergero*. Legislation could standardize this procedure.

Many problems still exist in regulating PGD. While most people support more equal access to the procedure, others are wary about the potential for bureaucratic processes to stifle growth in this area and would prefer to rely on self-regulation within the PGD community.[55] In addition, others are concerned about the precedent of having government further involved in reproductive politics, given abuse and oppression in the past.[56] Future research should consider fair access to PGD treatment and enforcement of the above regulations. Research should explore the possibility of expanded access through insurance coverage of PGD and the costs and benefits associated with such a policy.

Bergero serves as a good example of the tensions between

55 Ibid. 495.

56 Dorothy Roberts, "Race and the New Reproduction." *Hastings Law Journal*. Vol. 47. 1995-1996: 947.

patients and professionals in navigating the new waters of PGD. As society steers ahead with Preimplantation Genetic Diagnosis technology, professionals may be at the helm, but they will be best served if patients are by their sides.