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INTRODUCTION

Public health is an increasing global concern.[1] Governments have ranked public health as among their foremost concerns.[2] "[H]ealth care is an important social value, so fundamental to the realization of other rights, that it should be given particular legal protection and promotion within our society."[3] During the survey period,[4] the Tenth Circuit decided three significant cases pertaining to health law. Since health law encompasses so many aspects of American law,[5] these recent Tenth Circuit decisions are quite disparate. This article analyzes these decisions. Part I provides a general background of health law. Part II explores the abortion issue. Part III examines dietary supplement regulations, and Part IV discusses the physician/hospital relationship, paying particular attention to a physician's hospital privileges.

I. GENERAL BACKGROUND

The United States Constitution does not explicitly give the federal government the authority to regulate public health.[6] The Commerce

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1. Virginia Leary et al., *Health, Human Rights and International Law*, 82 AM. SOC'Y INT'L L. PROC. 122, 122 (1988) (indicating that Acquired Immune Deficiency Syndrome (AIDS) has international implications).

2. *See* Ashley W. Warren, Comment, *Preemption of Claims Related to Class III Medical Devices: Are the Federal Objectives of Public Health and Safety Furthered or Hindered?*, 49 SMU L. REV. 619, 621 (1996); *see also* LAURENE A. GRAIG, HEALTH OF NATIONS: AN INTERNATIONAL PERSPECTIVE ON U.S. HEALTH CARE REFORM 3 (1993) (indicating that concern around the world is focused on developing strategies to manage the rapidly increasing health care costs); Edward O. Correia, *State and Local Regulation of Cigarette Advertising*, 23 J. LEGIS. 1, 6 n.22 (1997) (stating that public health is among a local government's primary concern); *Conquering Disease as an Enemy of Empire*, TIMES LONDON, Aug. 15, 1997, at 9, *available in* 1997 WL 9222940 (indicating that the maintenance of public health was a high priority in Victorian Britain); *Mozambican President Pledges to Improve Workers' Living Conditions*, XINHUA ENGLISH NEWSWIRE, May 1, 1997, *available in* 1997 WL 3759913 (stating that public health is ranked as Mozambique's government's priority); P.K. Roy, *India: On a District Formation Spree*, HINDU, May 12, 1997, at 17, *available in* 1997 WL 9971024 (stating that public health is among the Indian government's priorities for which they use very limited funds).

3. *See* Carlo V. DiFlorio, Comment, *Assessing Universal Access to Health Care: An Analysis of Legal Principle and Economic Feasibility*, 11 DICK. J. INT'L L. 139, 160 (1992).

4. The survey period extended from September 1, 1996 through August 31, 1997.

5. Aspects of civil law that affect health care regulation include tort law, contract law, and governmental regulations. ROBERT D. MILLER, PROBLEMS IN HEALTH CARE LAW 2 (1996). Health law increasingly involves criminal law as the government expands its use of the criminal law system to create systemic changes in the health care industry. *Id.*

6. The United States Constitution declares that among the common goals of the people, is the goal to "promote the general Welfare." U.S. CONST. preamble; *see also* Kellen McClendon, *Do Hospitals in Pennsylvania Relieve the Government of Some of Its Burden?*, 67 TEMPLE L. REV. 517, 573 (1994). It is interesting to note that in other countries, health care is considered a human right and provided for all citizens. *See* Jeanne M. Woods, *The Fallacy of Neutrality: Diary of an Election*

Clause[7] delegates to the federal government the ability to regulate interstate commerce.[8] As such, the federal government may regulate public health insofar as it affects interstate commerce.[9] The responsibility for the maintenance of public health, however, mostly resides with state governments under the police powers.[10] Under the police powers, the state has extensive authority to regulate its' public health.[11] Traditionally, state governments have delegated some of this authority to local governments.[12]

The controversy surrounding health care coverage has gained national attention in recent years. In theory, health care insurance is available to all Americans through four avenues. The government provides Medicare[13] for the elderly and disabled; and Medicaid[14] for those with

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Observer, 18 MICH. J. INT'L L. 475, 523 (1997) (indicating that health care is included in South Africa's new constitution).

7. U.S. CONST. art. I, § 8.

8. Gibbons v. Ogden, 22 U.S. 1, 189-203 (1824).

9. Joy Elizabeth Matak, Note, *Telemedicine: Medical Treatment Via Telecommunications Will Save Lives, But Can Congress Answer the Call? Federal Preemption of State Licensure Requirements Under Congressional Commerce Clause Authority & Spending Power*, 22 VT. L. REV. 231, 245 (1997).

10. *See* Hellebust v. Brownback, 42 F.3d 1331, 1335 (10th Cir. 1994) (stating that pursuant to the state's police powers, the state may guarantee the quality of meat and dairy products that everyone in the state consumes, ensure the accuracy of the scales as the basis for charging consumers, control the use and diversion of water, and regulate the use of pesticides). Congress and the Clinton administration agreed on a 1998 budget provision allotting $24 billion to states to fund children's health initiatives. *See* Karen Jacobs, *On Your Own: Gloria Brown Wants to Buy Health Insurance; She Just Can't Afford It*, WALL ST. J., Oct. 23, 1997, at R10; *see also* Howard D. Cohen & Taylor Mattis, *Prepayment Rights: Abrogation By the Low-Income Housing Preservation and Resident Homeownership Act of 1990*, 28 REAL PROP. PROB. & TR. J. 1, 32 (1993).

11. *See* Cohen & Mattis, *supra* note 10, at 32; *see also* Maria O'Brien Hylton, *The Economics and Politics of Emergency Health Care for the Poor: The Patient Dumping Dilemma*, 1992 BYU L. REV. 971, 975 n.13 (1992) ("Over the years, state government responsibility for public health expenditures has varied from about 12 to 14%, while federal government responsibility has varied from 11 to 30% [which has] led to a power struggle between the national and state governments in terms of who will pay what, who will cover what, and who is actually running the program.").

12. *See* Josephine Gittler, *Controlling Resurgent Tuberculosis: Public Health Agencies, Public Policy, and Law*, 19 J. HEALTH POL. POL'Y & L. 107, 108 (1994).

13. The Medicare program is administered by the Social Security Administration of the U.S. Department of Health, Education, and Welfare. 42 U.S.C. § 1395 (1994). Medicare does not cover prescription drugs or long-term care and, until recently, Medicare did not cover liver transplants. Robert Baker, *Rationing, Rhetoric, and Rationality: A Review of the Health Care Rationing Debate in America and Europe*, *in* ALLOCATING HEALTH CARE RESOURCES 57, 60 (James M. Humber & Robert F. Almeder eds., 1995).

14. Hylton, *supra* note 11, at 1022 n.13. Medicaid is designed to provide funds to the blind, the disabled, and families receiving aid for dependent children in order to cover selected health services. *Id.* Medicaid does not cover all expenses. It is jointly subsidized by federal and state governments. *Id.* (indicating that "over the years, state government responsibility has varied from about 12 to 14%, while federal government responsibility has varied from about 11 to 30%"). The Medicaid program is administered by individual states according to a plan the state adopted in conformity with federal regulations. 42 U.S.C. § 1396 (1994). As a result, benefits are inconsistent from state to state. Hylton, *supra* note 11, at 1022.

low incomes or certain disabilities.[15] In addition, some employers provide subsidized coverage for their employees.[16] Finally, coverage can be purchased on an individual basis.[17] Health Maintenance Organizations (HMOs) pride themselves on providing preventative care for individuals.[18] Ironically, however, individuals suffering from chronic illness, those who stand to gain the most from preventative medicine, are often denied coverage under HMOs' cost-cutting policies.[19]

Americans increasingly call upon medical care and health care[20] to satisfy the needs of a changing and expanding population. The public outcry for universal health coverage[21] pressures the health care system to reform.[22] Rapid technological advances are required to meet society's demand for improved medical care.[23] Medical advances can create new opportunities for people suffering from chronic illnesses,[24] but these technological advancements must be regulated to ensure the safety of the consumer.[25]

The issue is no longer just whether the health care field should be regulated by the government, but instead, how much regulation is necessary and within constitutional limits.[26] The government must weigh the

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15. *See* DiFlorio, *supra* note 3, at 148.

16. *See id.*

17. *Id.*

18. *See* Nancy Ann Jeffrey, *Test Over Time: Managed Care is Geared Toward Preventing Illness; But What About People with Chronic Ailments?*, WALL ST. J., Oct. 23, 1997, at R6. Preventative care includes such things as regular checkups, in other words, medicine designed to keep healthy people healthy. *Id.* In the long run, huge savings result from preventative medicine through early diagnosis. *Id.*

19. *See id.*

20. The difference between medical care and health care is that providing access to health care does not guarantee that everyone will get the same medical care. EMERGENCY! HEALTH CARE IN AMERICA (ABC News 1992) (interviewing Dr. June Osborne, Dean of the University of Michigan School of Public Health).

21. The current health care system in the U.S. lacks a social definition of equity, feebly attempts to contain costs, inadequately covers millions of Americans, and does not cover another 37 million Americans. DiFlorio, *supra* note 3, at 139.

22. The discontent with the current health care system consistently inspires proposals for reform. Louise G. Trubek & Elizabeth A. Hoffman, *Searching for a Balance in Universal Health Care Reform: Protection for the Disenfranchised Consumer*, 43 DEPAUL L. REV. 1081, 1081 (1994) (indicating that the health reform project has been attempted several times without success during the 40 years prior to 1994).

23. *See* Chris J. Katopis, *Patients v. Patents?: Policy Implications of Recent Patent Legislation*, 71 ST. JOHN'S L. REV. 329 (1997) (discussing the conflict between a desire for improved health care and granting patents to inventors of medical advancements).

24. *See* Jeffrey, *supra* note 18 (discussing chronic illnesses like diabetes and asthma).

25. *See* Arti Kaur Rai, *Rationing Through Choice: A New Approach to Cost-Effectiveness Analysis in Health Care*, 72 IND. L.J. 1015, 1015-16 (1997) (reporting that the rapid pace of developments of medical technology challenges the health care profession because "funding all interventions that would provide some health benefit to some patient would preclude spending on any other desirable social good"); *see also* Brad Dallet, Note, *Economic Credentialing: Your Money or Your Life!*, 4 HEALTH MATRIX 325, 325 (1994) (indicating the relationship between the physician and patient is changing along with the economic changes in health care).

26. *See* McClendon, *supra* note 6, at 573. McClendon stated:

interest in preserving and promoting life[27] against an individual's constitutional rights.[28] These issues are particularly relevant in light of recent health crises, including AIDS,[29] assisted suicide,[30] and the controversy surrounding abortion.[31]

Central to most medical care issues is the medical care provider, the physician. State governments administer the majority of the physician licensing standards.[32] Medical care below the standard may result in injury to the patient and the patient may have a malpractice claim.[33] A physician's misdiagnosis is not considered negligence if the patient does not

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> When the public health is involved, a person's liberty to choose how to care for himself or herself gives way to the requirement of the state. . . . [W]hen medical care is involved, the concern is for the good of the individual; when public health is involved the concern is for the good of the public.

Id. But "'[i]t is legitimate for state government to regulate the conduct of an individual where that conduct presents a risk to the health, safety, or welfare of others, but it also may be legitimate where the regulation is only for the protection of that individual.'" *Id.* (quoting KENNETH R. WING, THE LAW AND THE PUBLIC'S HEALTH 20 (2d ed. 1995)).

27. *See* U.S. CONST. preamble.

28. *See* Washington v. Glucksberg, 117 S. Ct. 2258, 2271, 2775 (1997) (addressing the notion that the "lives of terminally ill, disabled, and elderly people must be no less valued than the lives of the young and healthy"); Planned Parenthood v. Casey, 505 U.S. 833 (1992) ("At the heart of liberty is the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life. Beliefs about these matters could not define the attributes of personhood were they formed under compulsion of the State."); Cruzan v. Director, Mo. Dep't of Health, 497 U.S. 261, 282 (1990) (stating that a government has an "unqualified interest in the preservation of human life"); *see also* Samantha Catherine Halem, Note, *At What Cost?: An Argument Against Mandatory AZT Treatment of HIV-Positive Pregnant Women*, 32 HARV. C.R.-C.L. L. REV. 491, 492 (1997) (concluding that a mandatory AZT treatment regime for people with AIDS would be unconstitutional).

29. *See* Susan Fox Buchanan, *Medical Ethics at the Millennium: A Brief Retrospective*, COLO. LAW., June 1997, at 141, 142 (1997) (asserting that the physician/patient confidentiality may have an exception in the case of "hazardous communicable diseases" such as AIDS); Margaret Salmon Rivas, *The California AIDS Initiative and the Food and Drug Administration: Working at Odds with Each Other?*, 46 FOOD DRUG COSM. L.J. 107 (1991) (discussing why the United States has fallen behind other countries in adopting a national policy on AIDS); Halem, *supra* note 28, at 491 (analyzing the constitutionality of mandatory AZT treatment of pregnant women).

30. *See, e.g.*, Vacco v. Quill, 117 S. Ct. 2293 (1997) (upholding a New York statute prohibiting assisted suicide); Washington v. Glucksberg, 117 S. Ct. 2258, 2271, 2775 (1997) (indicating that the "asserted 'right' to assistance in committing suicide is not a fundamental liberty interest protected by the Due Process Clause" and that "Washington's ban on assisted suicide is at least reasonably related to [the] promotion and protection" of the state's interests); *see also* Leonard J. Deftos, *Physician Assistance in Dying: The Supreme Court Should Limit But Not Prohibit*, POSTGRADUATE MED., June 1, 1997, at 13 (reviewing *Vacco* and *Glucksberg*); Linda C. Fentiman, *Law and Ethics at the End of Life: High Court Speaks, Where do We Stand After Decisions on Physician Assisted Suicide?*, 218 N.Y. L.J. 5 (1997).

31. *See, e.g.*, *Casey*, 505 U.S. at 833; Belotti v. Baird, 443 U.S. 622 (1979); Planned Parenthood v. Danforth, 428 U.S. 52 (1976); Roe v. Wade, 410 U.S. 133 (1973).

32. *See* Katopis, *supra* note 23, at 386-87.

33. DAVID CUNIFF & MARY ELLEN MCCARTHY, THE RIGHT MEDICINE 223 (1994). Patients may take legal action when physicians make mistakes. *See, e.g.*, SAL FISCINA & JANET B. SEIFERT, LEGAL CHECK-UP FOR MEDICAL MALPRACTICE: ESSENTIAL GUIDE FOR THE HEALTH CARE TEAM 40, 46-47 (1997) (describing situations in which legal action was taken against physicians who made mistakes).

disclose information central to the diagnosis, despite the physician's inquiry.[34] However, if a physician finds conflicting information and has reason to question it, she must take proper steps to clarify the issue.[35]

The most extensively regulated institutions include health care facilities and hospitals.[36] Health care facilities are held liable for mistakes related to care[37] and hospitals may be held responsible for its physicians' actions.[38] Therefore, many facilities have established a peer review process among the medical staff in an effort to guarantee that physicians perform adequately.[39] The review committee evaluates each physician's performance, and compares the care offered with what a "reasonable physician [would] be expected to know and do under the specific circumstances presented."[40]

II. ABORTION

A. *Background*

The term abortion is derived from the Latin word "aboriri," to miscarry.[41] The word evolved into the present, common usage of a "deliberate termination of a pregnancy."[42] Abortion is an issue that has divided America.[43] Current law dictates that a woman has a limited constitutional right to an abortion.[44] Courts considering abortion issues must confront the validity of the legal justification for limiting legislative power to regulate the availability of abortions.[45]

The text of the Constitution does not specifically make reference to abortion nor a right to privacy.[46] However, the Supreme Court has inter-

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34. *See* FISCINA & SEIFERT, *supra* note 33, at 46.

35. *See id* at 47. Physician care for different types of patients is delineated. *Id.* at 67-70. The duty a physician owes to a non-patient is determined partly by the relationship the physician has with the actual patient in connection with the non-patient. *Id.* at 83.

36. MILLER, *supra* note 5, at 43.

37. Dallet, *supra* note 25, at 326-27.

38. *Id.*

39. *Id.*

40. *See* FISCINA & SEIFERT, *supra* note 33, at 45.

41. *See* Gwendolyn Prothro, *RU 486 Examined: Impact of a New Technology on an Old Controversy*, 30 U. MICH. J.L. REFORM 715, 717 (1997).

42. *See id.* at 717; Theodore Joyce et al., *The Impact of Mississippi's Mandatory Delay Law on Abortions and Births*, 278 JAMA 653 (1997) ("Of the approximately 6.5 million pregnancies in the United States in 1992, 1.5 million or 23% were voluntarily terminated.").

43. *See* American Academy of Pediatrics Committee on Adolescence, *The Adolescent's Right To Confidential Care When Considering Abortion*, PEDIATRICS, May 1, 1996, at 746; Prothro, *supra* note 41, at 715-16.

44. *See* Prothro, *supra* note 41, at 721. *See also* 141 CONG. REC. E1690 (daily ed. Aug. 5, 1995) (statement of Rep. Hoekstra) (indicating that hospitals are now required to incorporate mandatory training for abortions as part of their family planning instruction but medical students whose moral or religious beliefs prevent them from performing abortions are exempted).

45. *See* 141 CONG. REC. E1690 (daily ed. Aug. 5, 1995) (statement of Rep. Hoekstra).

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

preted the Constitution to protect enumerated rights[47] and certain unenumerated rights.[48] In order to determine if the Constitution provides for an unenumerated right, the Court considers the degree to which these rights are a part of the traditions of the United States.[49] The Supreme Court's decisions have been relatively consistent, recognizing unenumerated rights in its decisions.[50] For example, the right to privacy is considered an unenumerated, fundamental right;[51] the Due Process and Equal Protection Clauses provide the foundation for protection of the privacy of its citizens.[52] The fundamental right to privacy has been extended to include marriage, contraception, abortion, child-rearing, education, and family relationships.[53]

The development of abortion case law paralleled the case law on the right to use contraceptives.[54] The Court recognized the right of marital privacy[55] and a married couple's right to use contraceptives.[56] As a result, the Court determined that abortion, unlike assisted suicide,[57] is a funda-

47. For example, the Constitution explicitly grants that citizens possess the rights to free speech, to keep and bear arms, and to confront witnesses against defendants in criminal trials. U.S. CONST. amends. I, II, VI.

48. *See Oversight Hearing on the Origins and Scope of* Roe v. Wade *Before the Subcomm. on the Constitution of the House Comm. on the Judiciary*, 104th Cong. (April 22, 1996), *available in* 1996 WL 10162661 (statement by Mark Tushnet, Professor of Constitutional Law, Georgetown University Law Center, regarding the history of abortion rights and *Roe v. Wade*) [hereinafter Tushnet]. Unenumerated rights define a set of constitutional rights which, although necessary, are not provided in the text of the Constitution. Ronald Dworkin, Exchanges, *Unenumerated Rights: Whether and How Roe Should Be Overruled*, 59 U. CHI. L. REV. 381, 386 (1992). Among these rights are the right of travel and the right of association. *Id.*

49. Stephen Aaron Silver, Note, *Beyond* Jafee v. Redmond*: Should the Federal Courts Recognize a Right to Physician-Patient Confidentiality?* 58 OHIO ST. L.J. 1809, 1835 (1998). The sources of unenumerated rights are state law or a "natural law of fundamental rights." *See* Tushnet, *supra* note 48 ("Once we recognize unenumerated rights based on a higher law, it is hard to understand why only the national government has to respect those rights.").

50. *See* Skinner v. Oklahoma, 316 U.S. 535 (1942) (striking down involuntary sterilization of certain recidivist felons as violative of the basic human right to procreate); Fletcher v. Peck, 10 U.S. 87, 139 (1810) (recognizing "general principals which are common to our free institutions"); Calder v. Bull, 3 U.S. 386 (1798) (identifying "certain vital principles in our free Republican governments").

51. *See* KAREN O'CONNOR, NO NEUTRAL GROUND?: ABORTION POLITICS IN AN AGE OF ABSOLUTES 40 (1996) (discussing Griswold v. Connecticut, 381 U.S. 479 (1965)).

52. *See* Tushnet, *supra* note 48.

53. *See* Joan E. Schaffner, *The Essence of Marriage*, 66 GEO. WASH. L. REV. 195, 212 (1997). In the future the right to privacy may extend to apply to homosexual relationships. *Id.*

54. *See* Planned Parenthood v. Casey, 505 U.S. 833, 853 (1992).

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

56. *See id.*; *see also* Carey v. Population Servs. Int'l, 431 U.S. 678 (1977). The Court also identified the right of unmarried couples' use of contraceptives. Eisenstadt v. Baird, 405 U.S. 438 (1972).

57. Fentiman, *supra* note 30, at 5 (discussing Cruzan v. Director, Mo. Dep't of Health, 497 U.S. 261 (1990)).

mental right, and consequently the Court is constitutionally justified in regulating the legislative determinations on abortions.[58]

The Supreme Court exercised this power in *Roe v. Wade*, which established a woman's constitutional right to an abortion.[59] The *Roe* Court determined that the viability of the fetus[60] was the first point at which the state could declare an interest in the fetal life, and could constitutionally ban non-therapeutic abortions.[61] Prior to viability, if the government were to attempt to interfere in the woman's right to an abortion, it would have to establish a "compelling"[62] reason.[63] The first trimester of a woman's pregnancy cannot be regulated.[64] During the second trimester, the government can only interfere to the extent that the interference safeguards the mother's health.[65] Thereafter, whenever fetal viability is reached, the government may interfere to protect the interests of the fetus, provided an abortion is not necessary to protect the woman's health.[66]

Since 1973, subsequent cases have interpreted and limited this right.[67] *Planned Parenthood v. Danforth*[68] recognized the *Roe* Court's determination that "viability" was a medical judgment and the essence of the term was to remain flexible to interpretation.[69] Upholding *Roe*, *Danforth* determined that is was not the role of legislatures or courts to specifically define viability, that is, to determine at which point viability is actually achieved.[70] Rather, it is a medical decision influenced by various factors unique to each pregnancy.[71] In *City of Akron v. Akron Center for Reproductive Health*[72] the Court stated that parental involvement for minors was constitutionally permissible, but a bypass mechanism providing

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58. *See* Tushnet, *supra* note 48.

59. *See* Roe v. Wade, 410 U.S. 113, 152-53,154 (1973); O'CONNOR, *supra* note 51, at 46; LAURENCE H. TRIBE, ABORTION: THE CLASH OF ABSOLUTES 11 (1990) (stating that *Roe v. Wade* codified the right to an abortion as a privacy right as had been determined by earlier cases).

60. *Roe*, 410 U.S. at 160-61.

61. *See id.* at 163-64. A therapeutic abortion is when the abortion is "necessary to preserve the life or health of the mother." *Id.*

62. *Id.* at 162-63.

63. *See* TRIBE, *supra* note 59, at 11-12.

64. *Roe*, 410 U.S. at 164.

65. *Id.*

66. *Id.*; *see* TRIBE, *supra* note 59, at 12.

67. *See* Jennifer L. Stevenson, *Supreme Court Rulings on Abortion*, ST. PETERSBURG TIMES, Jan. 29, 1997, at 4D (stating that since 1973 there have been 26 cases related to abortion on the U.S. Supreme Court's docket); *see also* 139 CONG. REC. S195 (daily ed. Jan. 21, 1993) (discussing the Freedom of Choice Act and the need for its affirmation to ensure that a woman's fundamental right to chose is preserved as according to *Roe*).

68. 428 U.S. 52 (1976).

69. *Danforth*, 428 U.S. at 62-63.

70. *Id.* at 64.

71. *Id.*

72. 462 U.S. 416 (1983).

for approval by a judge must also be available for those minors who cannot obtain parental permission.[73]

In a series of cases, the Court articulated the difference between a direct interference with a woman's right to choose an abortion and an indirect deterrence on that right.[74] In 1989, *Webster v. Reproductive Health Services*[75] challenged the *Roe* precedent.[76] The abortion opponents argued for mandatory testing that would ascertain the viability of the fetus.[77] Because the composition of the Court had changed since *Roe*,[78] many questioned whether the right to choose an abortion would survive, but *Roe* was upheld.[79]

Justice O'Connor was the motivating force. O'Connor articulated the standard of evaluation established by *Roe* and subsequent cases[80] as the "undue burden" test.[81] In *Webster*, the Court determined that the regulations at issue did not place an "undue burden" on the woman, and therefore the state regulations were upheld.[82] O'Connor's decision left *Roe*

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73. *Akron Center for Reproductive Health*, 462 U.S. at 427 n.10.

74. *See* TRIBE, *supra* note 59, at 16 (stating that "in the years following *Roe* one could safely predict that *direct* restrictions on abortions would be overturned"); *see, e.g.*, Harris v. McRae, 448 U.S. 297 (1980) (stating that a denial of federal Medicaid funds for a therapeutic abortion was not unconstitutional); Poelker v. Doe, 432 U.S. 519 (1977) (stating that a public hospital owned by the city was not required to provide nontherapeutic abortions); Maher v. Roe, 432 U.S. 464 (1977) (determining that a state regulation that denied state Medicaid funds for non-therapeutic abortions was constitutional).

75. 492 U.S. 490 (1989).

76. *See* TRIBE, *supra* note 59, at 20 (stating that "the government of Missouri . . . and the Bush administration both urged the Court to take the *Webster* case as an occasion to reconsider its decision in *Roe v. Wade*"). This case was so remarkable because the law being challenged provided "a restriction on the performance of abortions in public institutions, even when the woman would be paying her own bill; a preamble in the statute that declares that 'the life of each human being begins at conception;' and a regulatory requirement that a number of tests of fetal viability be performed when a woman seeking an abortion is believed to be twenty weeks pregnant." *Id.*; *see also* LESLIE J. REAGAN, WHEN ABORTION WAS A CRIME: WOMEN, MEDICINE, AND LAW IN THE UNITED STATES, 1867-1973 251 (1997) (discussing *Webster*).

77. *Webster*, 492 U.S. at 490.

78. *See* TRIBE, *supra* note 59, at 20 (stating that the additions of Justice Scalia and Justice Kennedy would really test the foundation of *Roe*).

79. *Webster*, 492 U.S. at 513-14.

80. For an early articulation of a "burden" test, see *Bellotti v. Baird*, 428 U.S. 132, 147 (1967). Even earlier, the Court articulated the "maximum destructive impact" test. *See* Griswold v. Connecticut, 381 U.S. 479, 485 (1965) (indicating that a prohibition on the use of contraceptives would have a maximum destructive impact on a marital relationship). For an abortion case that articulated a "burden" test, see *Doe v. Bolton*, 410 U.S. 179, 193-95 (1973) (articulating the "unconstitutional burden" test).

81. *See* TRIBE, *supra* note 59, at 23. Previous cases have described the test as "unconstitutionally burdensome" on the woman's right to choose an abortion. Justices Stevens, Blackmun, Brennan, and Marshall followed this standard in their opinions in *Webster*. *Id; see also* Doe v. Bolton, 410 U.S. 179 (1973). Justice O'Connor actually devised the undue burden test. TRIBE, *supra* note 59, at 23.

82. TRIBE, *supra* note 59, at 23.

open to future modifications, including the possibility of being overturned.[83]

In 1992, the *Roe* decision was slightly modified by *Planned Parenthood v. Casey*.[84] In *Casey*, the plaintiffs, abortion clinics, and physicians, challenged the constitutionality of several sections of the Pennsylvania Abortion Control Act of 1982.[85] The *Casey* Court rejected *Roe*'s trimester framework[86] and adopted the "undue burden" standard.[87] The Court determined that this standard applied in evaluating the constitutionality of legislative actions influencing a woman's right to an abortion.[88] The *Casey* Court asserted that if the statute or regulation has "the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion of a nonviable fetus," then it creates an undue burden on the woman.[89] The undue burden standard allows courts to analyze a statute under two prongs: the legislative purpose intended by the statute, coupled with the actual effect of the statute.[90] Arguably the *Casey* decision weakened a woman's right to choose an abortion.[91]

Under the guidance of this Supreme Court precedent, courts have considered what constitutes an undue burden and what makes a fetus viable. The "undue burden" standard is a determination made by the courts. Legal experts have since drawn an analogy between constitutional rights in right-to-die cases and the undue burden on the right to an abor-

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83. *Id.* at 24.

84. 505 U.S. 833 (1992).

85. *Casey*, 505 U.S. at 833. These sections included:

> [Section] 3205, which requires that a woman seeking an abortion give her informed consent prior to the procedure, and specifies that she be provided with certain information at least 24 hours before the abortion is performed; § 3206, which mandates the informed consent of one parent for a minor to obtain an abortion, but provides a judicial bypass procedure; § 3209, which commands that, unless certain exceptions apply, a married woman seeking an abortion must sign a statement indicating that she has notified her husband; § 3203, which defines a "medical emergency" that will excuse compliance with the foregoing requirements; and §§ 3207(b), 3214(a), and 3214(f), which impose certain reporting requirements on facilities providing abortion services.

Id. (citing 18 PA. CONS. STAT. §§ 3203, 3205, 3206, 3207, 3209, 3214 (1990)).

86. *Id.* at 878.

87. *Id.* at 876.

88. *Id.* at 877.

89. *Id.* The Court did not specify whether once a statute is determined to be an undue burden, it is therefore invalid or once the statute is determined to be an undue burden, a balancing test must be done to determine if the statute is invalid.

90. *See* Julie F. Kowitz, Note, *Not Your Garden Variety Tort Reform: Statutes Barring Claims For Wrongful Life and Wrongful Birth Are Unconstitutional Under the Purpose Prong of* Planned Parenthood v. Casey, 61 BROOK. L. REV. 235, 238-39 (1995); EILEEN L. MCDONAGH, BREAKING THE ABORTION DEADLOCK: FROM CHOICE TO CONSENT 132 (1996).

91. MCDONAGH, *supra* note 90, at 125 (1996) (stating that the *Casey* decision secured a woman's right to an abortion). In April 1996, the Supreme Court used the *Casey* "undue burden" standard when it refused to grant certiorari in *Janklow v. Planned Parenthood*, 116 S.Ct. 1582 (1996). The Eighth Circuit determined that a South Dakota law, requiring physicians to notify the parents of a minor seeking an abortion, S.D. CODIFIED LAWS § 34-23A-7 (MICHIE 1994), was unconstitutional because it failed the undue burden test. Planned Parenthood v. Miller, 63 F.3d 1452, 1458 (8th Cir. 1995).

tion.[92] The issue of viability, however, is still left to professional medical determination.[93]

B. Jane L. v. Bangerter[94]

1. Facts

A Utah statute contained a section regulating abortions occurring before twenty weeks gestational age.[95] Another section of the statute regulated abortions after twenty weeks gestational age.[96] The plaintiff, Jane L., challenged the constitutionality of the statute.[97]

At trial, the court determined that the statute's provision regulating abortions up to twenty weeks gestational age was unconstitutional,[98] but determined that the provision regulating abortions after twenty weeks gestational age was constitutional and severable.[99] Jane L. appealed the district court's determination as to severability and the appellate court reversed the lower court's decision.[100] After granting certiorari, the Supreme Court of the United States reversed the appellate court's determination that the provision was not severable and then remanded the case.[101]

2. Decision

The Tenth Circuit determined, on remand, that the provision regulating abortions after twenty weeks gestational age was unconstitutional because it placed an undue burden on the woman's rights to choose to obtain an abortion in three instances.[102]

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92. *Cal Thomas* (CNBC television broadcast, Mar. 16, 1996) (interview of host Cal Thomas with Dr. Richard Doerflinger of the National Conference of Catholic Bishops and Dr. Peter Goodwin of Oregon Death with Dignity), *available in* 1996 WL 7484498 (transcript of interview).

93. Patricia Schroeder, *Statement On H.R. 1833—The Partial-Birth Abortion Ban Act of 1995* (stating the concern of the American College of Obstetricians and Gynecologists that the partial-birth abortion bill attempts to establish terminology that is not even recognized by the medical community), *available in* 1996 WL 8784986.

94. 102 F.3d 1112 (10th Cir. 1996), *cert. denied sub nom.* Leavitt v. Jane L., 117 S. Ct. 2453 (1997).

95. UTAH CODE ANN. § 76-7-302(2) (1995). Such circumstances include if "the abortion is necessary to save the pregnant woman's life;" "the pregnancy is a result of rape . . . [or] incest;" or "to prevent grave damage to the pregnant woman's medical health . . . ." *Id.*

96. *Id.* § 6-7-302(3).

97. Jane L. v. Bangerter, 809 F. Supp. 865, 870 (D. Utah 1992), *aff'd in part, rev'd in part*, 61 F.3d 1493 (10th Cir. 1995), *rev'd sub nom.* Leavitt v. Jane L., 116 S. Ct. 2068 (1996).

98. *Jane L.*, 809 F. Supp. at 870.

99. *Id.* at 871. Severable means that because section 302(2) is unconstitutional does not mean that section 302(3) is unconstitutional.

100. *Jane L.*, 61 F.3d at 1496-99.

101. *Jane L.*, 116 S. Ct. at 2068.

102. Jane L. v. Bangerter, 102 F.3d 1112 (10th Cir. 1996), *cert. denied sub nom.* Leavitt v. Jane L., 117 S. Ct. 2453 (1997); *see* discussion *infra* Part III.B.2.

Initially, the Tenth Circuit reiterated the principles established in *Roe v. Wade* and *Planned Parenthood v. Casey*.[103] The court determined that viability occurs when a fetus has a high chance of survival outside the womb with or without artificial support,[104] and asserted that this determination should be made by the attending physician based on the individual circumstances.[105]

The court also determined the constitutionality of section 302(3) of the Utah Code.[106] Through this statute, the legislature was effectively defining viability as occurring at twenty weeks into gestation.[107] In order to resolve these issues, the Tenth Circuit Court identified the previability standard[108] as the most appropriate standard to resolve the case because the statute affects the choices available to the woman before her fetus is viable.

The court applied the "undue burden" standard[109] and examined the purpose of the legislation and the process leading to the creation of the Utah statute.[110] It concluded that section 302(3) was "enacted with the specific purpose of placing an insurmountable obstacle in the path of a woman seeking the nontherapeutic abortion of a nonviable fetus after twenty weeks, and it therefore imposed an unconstitutional undue burden on her right to choose under *Casey*."[111]

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103. *Jane L.*, 102 F.3d at 1114-15.

104. *Id.* at 1115 ("Viability is reached when, in the judgment of the attending physician on the particular facts of the case before him, there is a reasonable likelihood of the fetus' sustained survival outside the womb, with or without artificial support.").

105. *Id.*

> Because this point may differ with each pregnancy, neither the legislature nor the courts may proclaim one of the elements entering into the ascertainment of viability—be it weeks of gestation or fetal weight or any other single factor—as the determinant of when the State has a compelling interest in the life or health of the fetus. Viability is the critical point.

Id. The court recognized that viability is a medical determination, one that courts are incapable of making, though they have attempted to make this medical decision in previous cases.); Webster v. Reproductive Health Serv., 492 U.S. 490 (1989); Planned Parenthood v. Danforth, 428 U.S. 52 (1976).

106. *See Jane L.*, 102 F.3d at 1115.

107. UTAH CODE ANN. § 76-7-302(3) (1995) (suggesting that "20 weeks gestational age, measured from the date of conception" is essentially viability).

108. *Jane L.*, 102 F.3d at 1115-16. The previability standard rejects the strict scrutiny standard. *Id.* at 1115.

109. *Id.* at 1116. The lower court had apparently applied the *Salerno* test which required "the challenger to establish that no set of circumstances exists under which the law would be valid." Jane L. v. Bangerter, 809 F. Supp. 865, 871-72 (D. Utah 1992). The Tenth Circuit determined that the *Casey* Court specifically did not apply the *Salerno* test and instead applied the undue burden test. *Jane L.*, 102 F.3d at 1116.

110. *Jane L.*, 102 F.3d at 1116.

111. *Id.* at 1117.

C. *Other Decisions*

Recently, in *Mazurek v. Armstrong*,[112] the Supreme Court reversed a federal appeals court decision blocking enforcement of a 1995 Montana law barring the performance of abortions except by licensed doctors.[113]

In 1995, the Montana legislature enacted a statute that prohibited physician assistants from performing abortions.[114] The statute was challenged by a group of physicians and the one physician assistant.[115] The district court determined that they had not met the "undue burden" standard of *Casey* and therefore denied their motion for preliminary injunction.[116] The appeals court remanded the case because the court determined that there may have been adequate evidence to meet the "undue burden" standard.[117]

The Supreme Court performed a balancing test, weighing the need to ensure safe abortions by requiring that only doctors perform the operation against the undue burden on the woman's right to choose an abortion.[118] Through this application of the "undue burden" test, the Court determined that Montana's law was not a "substantial obstacle" to a woman's right to choose an abortion.[119]

D. *Analysis*

In *Jane L.*, the Tenth Circuit applied the "undue burden" test in a manner slightly different than the one utilized by the Supreme Court, although both courts weighed the government's interest in promoting life against the constitutional rights of the women seeking abortions. In *Jane L.*, the Tenth Circuit determined that the woman's right to obtain a nontherapeutic abortion of a nonviable fetus superceded the government's stated interest in preserving life.[120] The *Jane L.* court would not allow the definition of this right to be narrowed. On the other hand, the *Mazurek* Court considered that a statute preventing physician assistants in Montana from performing abortions did not place an "undue burden" on a woman seeking an abortion.

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112. 117 S. Ct. 1865 (1997) (per curiam).

113. *Mazurek*, 117 S. Ct. at 1869.

114. *Id.* at 1865. Since there was only one physician assistant who performed abortions, the legislation seemed to be aimed at one person in particular. *Id.* at 1869-70 (Stevens, J., dissenting).

115. *Id.* at 1866.

116. *Mazurek*, 117 S. Ct. at 1866 (citing Armstrong v. Mazurek, 906 F. Supp. 561, 567 (D. Mont. 1995)).

117. *Id.* at 1866 (citing Armstrong v. Mazurek, 94 F.3d 566 (9th Cir. 1996)). The district court issued an injunction pending appeal which made the statute inapplicable to the physician assistant. *Id.*

118. *See* David G. Savage, *Court Affirms Abortion Laws: Justices Adhere to Legal Line They Adopted in 1992 Cases*, SUN-SENTINEL (Ft. Lauderdale, Fla.), June 17, 1997, at 3A.

119. *Mazurek*, 117 S. Ct. at 1867.

120. Jane L. v. Bangerter, 102 F.3d 1112, 1117 (10th Cir. 1996).

Both courts applied the "undue burden" standard and considered precedent as part of their analysis. Arguably, the two statutes regulated two different people. While the statute in *Jane L.* directly affected a woman's ability to obtain a specific abortion, the statute in *Mazurek* did not directly affect that ability. Rather, the statute in *Mazurek* directly affected the physician assistant and therefore, did not create an undue burden on the woman seeking an abortion who could receive an abortion from a licensed physician. This distinction is imperfect, however, because both statutes affect the woman's ability to obtain an abortion either by narrowing the time in which she can get the abortion, or by reducing the group of individuals who can legally administer an abortion. In rural communities where there are few doctors, it may be an undue burden to determine a physician's assistant cannot legally administer an abortion.

The *Jane L.* decision reduced the uncertainty[121] of the longevity and strength of the *Roe* decision in the Tenth Circuit. It standardized *Roe*'s conclusion that "viability" is a conclusion that can be made only by doctors. More importantly, the Tenth Circuit identified with the woman's right to an abortion without an undue burden. If this is a continuing trend, the Tenth Circuit will create a substantially solid foundation for the rights of women. Other circuits may find this approach compelling.[122] Since the *Mazurek* decision by the United States Supreme Court came after the *Jane L.* decision, however, it may limit the applicability of the *Jane L.* trend.

III. DIETARY SUPPLEMENT REGULATION

A. *Background*

As society has become increasingly health conscious, the demand for health-related products, such as vitamins and dietary supplements, increases.[123] Dietary supplements "claim to boost, balance, enhance, cleanse, uplift or otherwise benefit every bodily organ and function," and therefore have great appeal among consumers.[124] "[T]hey [are] now sold and ballyhooed in grocery and drug stores, on radio and TV, through direct mail and major magazines, and on the Internet."[125] Many fear that

121. This uncertainty was partially created by Justice O'Connor's decision. *See supra* notes 80-84 and accompanying text.

122. Recently, the House of Representatives discussed the values and demerits of a committee bill that would prohibit federal and district funds to be used to pay for abortions with an exception for endangerment of the life of the mother, rape, or incest. 143 CONG. REC. H8751 (daily ed. Oct. 9, 1997). The opposition expressed concern that language was unconstitutional because it placed an undue burden on a woman's right to obtain an abortion.

123. Jane E. Brody, *Millions Spent on Unproven Vitamins*, DENVER POST, Oct. 31, 1997, at A25.

124. Marie McCullough, *Supplements: Harmful or Helpful?*, DENVER POST, Oct. 2, 1997, at A28.

125. *Id.*

these products provide false hopes and waste consumers' money and valuable time for treatment.[126]

Like other food products, dietary supplements must meet a certain standard established by the government.[127] In the past, manufacturers used dietary supplement labels as the primary method to advertise to consumers. By limiting the content of these labels, manufacturers argue, the government effectively restricted the manufacturers' means to sell their product.[128]

In the 1980s, the FDA began an aggressive campaign against labels making unsubstantiated health claims, giving particular attention to dietary supplements.[129] As a result of this campaign, Congress passed the Nutrition Labeling and Education Act of 1990 (NLEA).[130] The NLEA applied to conventional foods, requiring standardized labeling and prohibiting manufacturers from making false claims.[131] By enacting the NLEA, Congress sought to increase the government's authority to regulate nutrition labeling and limit health claims that could be made about a product.[132] Specifically, the Act designated the Secretary of Health and Human Services as the regulator of nutritional labeling information.[133] In response to these regulations, the FDA established similar standards for dietary supplements.[134] Reacting to the FDA's increased regulation, dietary supplement manufacturers lobbied to prevent the FDA from regulating the industry by telling consumers the FDA sought to decrease the

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126. *North American Health Claim Surf Day Targets Internet Ads: Hundreds of E-mail Messages Sent*, FED. TRADE COMM'N NEWS RELEASE, Nov. 5, 1997, *available in* 1997 WL 689015 (stating that "[i]f it sounds to good to be true, it probably is," and this can lead to consumers wasting money and investing hope and time into a fraudulent therapy) [hereinafter FTC]. Often cancer and AIDS or HIV patients fall victim to the false hope of fraudulent health claims. *Id. But see* Patricia Sabatini, *Company Sells Unauthorized Diet Supplement: Pills' Health Claims Need FDA Approval*, PITTSBURGH POST-GAZETTE, Aug. 27, 1997, at C8 (quoting Arthur Whitmore, spokesperson for the FDA, that "[a] majority of the industry does abide by the rules").

127. *But see* Alexander Volokh, *Pruning the FDA*, NAT'L REV., Aug. 11, 1997, at 44 (arguing that the FDA's overzealous regulations hide helpful health information, to the detriment of the public).

128. *Labeling Rules for Supplements May Jump Start Fledgling Sector*, CHEMICAL MARKET REP., Oct. 20, 1997, at 16 [hereinafter *Labeling Rules*].

129. *See* Peter A. Vignuolo, *The Herbal Street Drug Crisis: An Examination of the Dietary Supplement Health and Education Act of 1994*, 21 SETON HALL LEGIS. J. 200, 212 (1997); *Labeling Rules*, *supra* note 128 (arguing that consumers must have a solid understanding and basic knowledge to make informed decisions about dietary supplements).

130. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353, 21 U.S.C. § 343-1 (1994).

131. Jennifer J. Spokes, Note, *Confusion in Dietary Supplement Regulation: The Sports Products Irony*, 77 B.U. L. REV. 181, 189 (1997).

132. National Council for Improved Health v. Shalala, 122 F.3d 878, 880 (10th Cir. 1997).

133. *See* Vignuolo, *supra* note 129, at 212.

134. Spokes, *supra* note 131, at 189.

available supplements.[135] In fact, the FDA sought to regulate claims on the labels, not the number of supplements on the shelves.[136]

In response to the conflict and a persuasive lobbying effort, the Dietary Supplement Act (DSA)[137] put a one year moratorium on the enforcement of the NLEA.[138] Further lobbying efforts eventually led to the enactment of the Dietary Supplement Health and Education Act of 1994 (DSHEA).[139] The DSHEA shifted the burden of proof to the FDA to rebut the presumption that the product is presumed safe.[140]

The FDA requires that dietary supplement labels offer a disclaimer, explaining that certain claims have not been evaluated by the FDA and that the supplement "is not intended to treat, cure or prevent any disease."[141] Ironically, this allows manufacturers to make multiple claims about their product on the dietary supplement without actual proof, provided they include the disclaimer on the label.[142] The DSHEA aided the vitamin and mineral supplement manufacturers by establishing that the FDA would not interfere unless something went wrong.[143]

The DSHEA also requires that the FDA develop standards for supplement labels.[144] Consistent information about vitamins and minerals is lacking because qualitative long-range studies have never been conducted, making conclusive determinations difficult.[145] In response to the need for more information about supplements, Congress requested the establishment of the Office of Dietary Supplements in 1995.[146] In addition, the Presidential Commission on Dietary Supplements is authorized to advise the FDA on the most effective methods of monitoring claims

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135. *See* Vignuolo, *supra* note 129, at 204.

136. *Id.* at 213-16.

137. Dietary Supplement Act of 1992, Pub. L. No. 102-571, 106 Stat. 4491.

138. *See* Vignuolo, *supra* note 129, at 216-17.

139. Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325. The DSHEA was an amendment to the Federal Food, Drug, and Cosmetic Act. *See* Vignuolo, *supra* note 129, at 204-06. Prior to the DSHEA, supplements were regulated as food or drugs. The FDA approved for sale as food many ordinary vitamins and minerals while less common products like herbs and hormones were withheld from sale. Marie McCullough, *Americans Swallow the All-Purpose Pills; Herbs: Debate Brewing Over Health Claims*, SALT LAKE TRIB., Sept. 11, 1997, at B1. Currently, however, as a result of the DHEA, the FDA considers vitamins and minerals as dietary supplements. Brody, *supra* note 123 (stating that the dietary supplement industry's lobbying was coupled with a "letter-writing campaign by consumers who feared that government rules would limit their access to supplements of all kinds").

140. *See* McCullough, *supra* note 124; Vignuolo, *supra* note 129, at 205.

141. McCullough, *supra* note 124.

142. *Id.* (stating that such claims are that a dietary supplement benefits "bodily 'structures,' such as bone, or 'functions,' such as digestion").

143. Brody, *supra* note 123, at A25.

144. Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 343-2 (1994).

145. Brody, *supra* note 123, at A25.

146. *Id.*

on dietary supplements.[147] The FDA approves the dietary supplement labels based on the "significant scientific agreement" standard.[148]

The FDA's long range goals include changing the regulations of nutrient claims by modifying the classifications of dietary supplements, providing percentage levels of dietary ingredients that have not been already classified, and allowing manufacturers of vitamins and mineral dietary supplements to display ingredients other than a vitamin or mineral on their labels.[149]

B. National Council for Improved Health v. Shalala[150]

1. Facts

In *National Council for Improved Health v. Shalala*,[151] the plaintiffs brought an action challenging the constitutionality of a regulation that mandates that prior to placing a dietary supplement with a health claim label on the market, the FDA must issue an authorization to the seller of the supplement.[152] The FDA will authorize the health claims if it determines,

> based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.[153]

After this evaluation, the FDA may determine that the health claim is not supported by the "publicly available evidence" and, therefore, refuse to authorize the health claim label.[154]

The plaintiffs claimed that this regulation violated their right to free speech under the First Amendment.[155] The defendants argued that the plaintiffs lacked standing because the plaintiffs had not alleged an

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147. *Government Mulls Tougher Scrutiny of Supplements*, ENVTL. NUTRITION, Aug. 1, 1997, at 3 (stating that the Commission recently encouraged "swift enforcement action" by the FDA to monitor the safety of dietary supplements and this process will not increase the responsibility of the manufacturer to prove the safety of the supplement).

148. *See* Food Labeling; General Requirements for Health Claims for Foods, 58 Fed. Reg. 2478, 2504 (1993) (discussing the "significant scientific agreement" standard).

149. *Food Labeling; Requirements for Nutrient Content Claims, Health Claims, and Statements of Nutritional Support for Dietary Supplements*, CHEMICAL BUS. NEWSBASE, Sept. 26, 1997, *available in* 1997 WL 13725210.

150. 122 F.3d 878 (10th Cir. 1997).

151. *National Council*, 122 F.3d at 878.

152. *Id.* at 880.

153. 21 C.F.R. § 101.14(c) (1997).

154. *National Council*, 122 F.3d at 881.

155. *Id.*

injury.[156] Although the district court determined that the plaintiffs had standing, the court found that there was no First Amendment violation.[157]

2. Decision

The Tenth Circuit court vacated the lower court's decision as to the constitutionality of the regulations and dismissed the case on the grounds that the plaintiffs lacked standing.[158] The Tenth Circuit reiterated the three requirements for standing established by the Supreme Court.[159] The court focused on the requirement that the plaintiff suffer an "injury in fact." The court determined that in this case the plaintiffs challenged the health claims regulations without demonstrating that the regulations caused them a specific harm.[160]

A plaintiff may only assert his or her own constitutional rights. The overbreadth doctrine, however, allows a plaintiff to assert First Amendment rights of someone not before the court, but whose rights may be infringed upon by an overly broad regulation.[161] The overbreadth doctrine requires that the plaintiff suffer an injury as well.[162] Assertions of a general nature are inadequate to constitute a specific and concrete harm.[163] The court concluded that since "no potentially prohibited claim ha[d] been made, there [was] no possible violation of the health claims regulations and thus no possibility of prosecution."[164] The court then determined that the lower court inaccurately applied the "overbreadth doctrine," incorrectly expanding the notion of standing.[165]

C. *Analysis*

The decision in *National Council* did not apply the NLEA or the statute at issue. Although the court vacated the district court's determination that the regulation was constitutional, the court protected the ability of the Secretary of Health and Human Services to create and implement regulations by requiring that plaintiffs challenging these regulations assert an injury in fact.

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156. *Id.*

157. National Council for Improved Health v. Shalala, 893 F. Supp. 1512, 1516, 1520 (D. Utah 1995).

158. *National Council*, 122 F.3d at 883.

159. *Id.* at 881 (citing Lujan v. Defenders of Wildlife, 504 U.S. 555 (1992)). First, the plaintiffs must claim "an injury in fact." In addition, plaintiffs must show causation. Finally, the plaintiffs must show that a favorable decision will likely cure the plaintiff's injury. *Defenders of Wildlife*, 504 U.S. at 555.

160. *National Council*, 122 F.3d at 883.

161. *Id.* at 881 (citing Village of Schaumburg v. Citizens for a Better Environment, 444 U.S. 620, 634 (1980)).

162. *Id.* at 882 (citing Phelps v. Hamilton, 122 F.3d 1309 (10th Cir. 1997)).

163. *Id.* at 884.

164. *Id.*

165. *Id.*

Targeting the nutritional supplement industry, the FDA recently established final regulations for labeling which will take effect in April 1999.[166] Furthermore, the Food and Nutrition Board[167] recently revised the Recommended Daily Allowances.[168] The new regulations are not ironclad like regulations in other industries.[169] Despite progress, dietary supplements may still be sold without necessarily providing proof of safety or effectiveness,[170] which could jeopardize the public's need to safeguard itself against fraudulent claims.[171]

V. THE PHYSICIAN/HOSPITAL RELATIONSHIP

A. *Background*

Before Medieval times in Europe, hospitals were viewed as charitable (and often religious) resting places for the sick, rather than a place in which one would be cured.[172] When Europeans settled in the Colonies, they brought this "tradition of charitable giving."[173] The modern hospital evolved in the eighteenth century, and over time has become more available to serve varied medical concerns.[174]

At the beginning of this century, hospitals catered to the poor because the wealthier patients preferred to have private doctors care for them in their homes.[175] As hospitals acquired more advanced technology, medical education improved and surgery became more centralized in the hospitals. As hospitals became more respectable, more individuals elected to be cared for in a hospital, increasing the need for more sophisticated regulation of hospitals.[176]

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166. *Labeling Rules*, *supra* note 128, at 16.

167. The Food and Nutrition Board makes recommendations about intake levels of vitamins and minerals. *See* Brody, *supra* note 123, at A25.

168. *Id.*

169. *See Labeling Rules*, *supra* note 128, at 16 (stating that regulations like the Good Manufacturing Practices or monographs are more concrete).

170. Sabatini, *supra* note 126, at 68.

171. FTC, *supra* note 126 (providing measures to better inform the public). The public needs to be aware of products that "advertis[e] as a quick and effective cure-all for a wide range of ailments or for an undiagnosed pain . . . [or] . . . use key words, such as 'scientific breakthrough,' 'miraculous cure,' 'exclusive product,' and 'secret ingredient.'" *Id.*

172. *See* Helena G. Rubinstein, Note, *Nonprofit Hospitals and the Federal Tax Exemption: A Fresh Prescription*, 7 HEALTH MATRIX 381, 390 (1997). The sick were usually cared for by clerics or knights, rather than doctors. *Id.*

173. *See id.* at 391. "As in Europe, almshouses, the forerunners of American hospitals, 'serv[ed] general welfare functions and only incidentally car[ed] for the sick,' housing them together with the elderly, the insane, and the orphaned." *Id.* (quoting PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 149 (1982)) (alterations in original).

174. *See id.*

175. *See* Dallet, *supra* note 25, at 331.

176. *See id.* at 331-32.

The Joint Commission on Accreditation of Hospitals (JCAHO) was created in 1952 to combat the lack of standards among hospitals.[177] The JCAHO increased the standards necessary for hospital accreditation and, since that time, has primarily set the standards for hospital, medical staff, and physicians.[178] The JCAHO determined that each hospital must adopt medical bylaws, to which the hospital and practicing physicians agree.[179] These bylaws have been described as "a contract between the hospital and the physician."[180] The immunity provisions in the bylaws were intended to protect the hospital and its personnel from suits alleging defamation or another claim arising from determinations made in the peer review process.[181]

Responding to the need to create a higher standard of medical care and to the increasing instances of medical malpractice, Congress passed the Health Care Quality Improvement Act[182] in 1986.[183] Congress recognized that "[t]he threat of private money damage liability . . . unreasonably discourages physicians from participating in effective professional peer review."[184] Congress sought to provide an ideal environment for professional peer review in the medical community which required ensuring immunity from damage actions to all those who qualify.[185] A member of a peer review board is considered immune if the action meets four requirements, including that the action must be taken

> (1) in the reasonable belief that the action was in the furtherance of quality health care, (2) after a reasonable effort to obtain the facts of the matter, (3) after adequate notice and hearing procedures are afforded to the physician involved or after such other procedures as are fair to the physician under the circumstances, and (4) in the reasonable belief that the action was warranted by the facts known after such reasonable effort to obtain facts and after meeting the requirement [regarding the conduct of the hearing].[186]

As hospitals' liability has increased, hospitals have focused on improving the quality of care within their facilities.[187] The peer review process is the primary means by which hospitals guarantee that the quality of care remains high by establishing a mandatory level of performance for the physicians as a prerequisite to obtaining hospital privileges.[188]

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177. *See id.* at 332.
178. *See id.*
179. *See* MILLER, *supra* note 5, at 161.
180. Rees v. Intermountain Health Care, Inc., 808 P.2d 1069, 1073 (Utah 1991).
181. *Rees*, 808 P.2d at 1076.
182. 42 U.S.C. §§ 11101, 11111-11115, 11131-11137, 11151-11152 (1994).
183. Brown v. Presbyterian Healthcare Servs., 101 F.3d 1324, 1333 (10th Cir. 1996).
184. *Brown*, 101 F.3d at 1333 (quoting 42 U.S.C. § 11101(4)).
185. *Id.*
186. 42 U.S.C. § 11112(a).
187. *See* Dallet, *supra* note 25, at 326-37.
188. *See id.* at 327.

Hospital privileges entitle a physician to admit his patients to a hospital for treatment.[189] Without those privileges, the physician cannot have access to the hospital's equipment, staff, and supplies.[190] Whether or not a physician will be granted hospital privileges depends on the peer review process.[191] The peer review board may reject the physician applicant's initial application to obtain hospital privileges, or the board may not renew privileges, or may even limit the physician's hospital privileges.[192]

B. Brown v. Presbyterian Healthcare Services[193]

1. Facts

Dr. Brown was a physician with Lincoln County Medical Center (Medical Center).[194] The Medical Center, managed by Presbyterian Healthcare Services, revoked her hospital privileges, after Dr. Williams, an economic competitor of Dr. Brown, conducted an initial peer review proceeding.[195] Later, formal peer review revealed that Brown breached a consultation agreement with the hospital by not obtaining proper consultation with other doctors.[196] As a result, the peer review board recommended that the hospital terminate Brown's privileges, an approach which the Medical Center adopted.[197]

Following the disciplinary action, the Medical Center filed a report regarding the revocation of Brown's privileges with the National Practitioner Data Bank (Data Bank).[198] It was determined that Brown's performance would be classified as "Incompetence/Malpractice/-Negligence."[199] Brown submitted her own report to the Data Bank, claiming that the Medical Center never found her incompetent, guilty of malpractice, or negligent.[200] Although the Medical Center was notified that Brown had submitted a report, the Medical Center did not take the opportunity to revise its report.[201]

At trial, the jury found for Dr. Brown on her claims for defamation, tortious interference with a contract, and some of Brown's antitrust

189. *See id.* at 329.
190. *Id.*
191. *Id.*
192. *See* 40 AM. JUR. 2D *Hospitals and Asylums* § 10. A difference exists in the process whether a physician seeks hospital privileges at a public or private hospital. *Id.*
193. 101 F.3d 1324 (10th Cir. 1996).
194. *Brown*, 101 F.3d at 1327.
195. *Id.* at 1327-28.
196. *Id.* at 1328.
197. *Id.*
198. *Id.*
199. *Id.*
200. *Id.*
201. *Id.*

claims. The judge set aside the jury's award of damages for tortious interference with a contract claim and the award of punitive damages against Dr. Williams on the antitrust claim.[202] Both Brown and Presbyterian Healthcare Services appealed the amended decision of the trial court.[203]

2. Decision

The Tenth Circuit concluded that the district court committed no error, but determined that the court should not have set aside the jury award of damages for Brown's claim of intentional interference with a contract.[204] In its analysis of Brown's issues on appeal, the court considered that a jury's award of damages should not be disturbed unless "clearly erroneous or there is no evidence to support the award."[205] After reviewing the financial analysis of two witnesses, the court concluded that Presbyterian's interference caused financial harm to Brown's practice and would provide a "reasonable basis for estimating the plaintiff's loss."[206] In addition, the court concluded that Dr. Brown presented enough evidence such that a jury could reasonably determine the amount of loss to the plaintiff.[207] Therefore, the court determined that the evidence was sufficient for the jury to have made an accurate determination of compensatory damages.[208] The court reversed the district court's order vacating the award.[209] The court also concluded that the punitive damages must be reinstated.[210] The court determined, however, that the award of punitive damages against Dr. Williams would be duplicative and improper and therefore, affirmed the district court's decision to set aside those damages.[211]

In addition, the court concluded that the hospital was not immune from damages resulting from the revocation of Dr. Brown's privileges pursuant to the Health Care Quality Improvement Act.[212] Dr. Brown proved that reasonable efforts were not taken by the peer review board to gather the facts about her,[213] failing to meet one of the requirements under the Act.[214]

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202. *Id.* at 1327.
203. *Id.* at 1329.
204. *Id.*
205. *Id.* at 1330.
206. *Id.*
207. *Id.* at 1331.
208. *Id.*
209. *Id.*
210. *Id.*
211. *Id.* at 1332.
212. *Id.* at 1333-34 (citing 42 U.S.C. § 11101(1), (2) (1994)).
213. *Id.* at 1333.
214. *Id.* at 1334.

The court also rejected Miller's immunity claim.[215] The court asserted that immunity would apply to Miller if she did not have "knowledge of the falsity of the information contained in the report [to the Data Bank]."[216] Because Miller assisted in the preparation of the report which stated that Dr. Brown was negligent, incompetent, and guilty of malpractice, the court concluded that there was sufficient evidence for the jury to have reasonably concluded that this report was false and that Ms. Miller was aware of that fact.[217]

The court also responded to the Medical Center's claim that the trial court committed error in failing to enter judgment as a matter of law in their favor with regards to Brown's antitrust claim.[218] The court concluded that both Ms. Miller and Dr. Williams were very involved in the decision making process that revoked Brown's privileges.[219] A jury could reasonably have concluded that Dr. Williams and Ms. Miller "controlled, coerced or unduly influenced the decisionmaking process."[220]

Finally, the court resolved Ms. Miller's claim that the district court erroneously failed to award her judgment as a matter of law based on the merits of Dr. Brown's defamation claim.[221] The court concluded that Brown established actual injury because hospitals check the National Data Bank record every time they receive an application for privileges. A negative comment about Dr. Brown would harm her chances to be approved for other privileges.[222]

C. *Other Circuits*

In *Davila-Lopes v. Zapata*,[223] the First Circuit determined that a physician did not a have a property interest in a hospital's grant of privileges.[224] Dr. Davila-Lopes sought re-instatement of his hospital privileges at Puerto Rico regional hospital.[225] Since the hospital was financed by the Commonwealth, all of the hospital bylaws were approved by the Secretary of Health.[226] The bylaws of the hospital were "comprehensive and procedurally detailed"[227] and included a requirement that prior to any hearing the physician must be given notice "contain[ing] a concise statement of the practitioner's alleged acts or omissions, including [pa-

215. *Id.*
216. *Id.*
217. *Id.*
218. *Id.*
219. *Id.* at 1335.
220. *Id.*
221. *Id.* at 1335-36.
222. *Id.* at 1336.
223. 111 F.3d 192 (1st Cir. 1997).
224. *Zapata*, 111 F.3d at 197.
225. *Id.* at 193.
226. *Id.*
227. *Id.* at 194.

tient records] or the other reasons or subject matter forming the basis for the adverse recommendation."[228]

The hospital declined to reinstate the plaintiff's hospital privileges.[229] Prior to a final decision, the plaintiff attempted to obtain a statement describing the reasons for the refusal,[230] however, he never received this notice.[231] The court concluded that the hospital did not follow the procedures established in the bylaws.[232] Although a requirement of adequate process in decisions affecting hospital privileges can create a property interest,[233] the court determined that even though there was a detailed set of procedural rules this did not establish a constitutionally protected property right.[234]

D. *Analysis*

Courts appear to accept regulations that closely monitor physicians' practices. The Tenth Circuit and the First Circuit defined the manner in which hospitals would be monitored. Although the First Circuit did not define the hospital privileges as a physician's property interests, the court determined that the hospital had deviated from its bylaws, infringing on the physician's right. The Tenth Circuit concluded that in addition to hospitals and peers monitoring physicians, the court also must monitor the evaluation process itself.

As more nonprofit hospitals become private hospitals,[235] the peer review process may have a dilatory effect on the hospital services available to patients. The goal of these hospitals has changed from charity to profit.[236] Many of the sales of hospitals or joint ventures that are established are between these nonprofit hospitals and a for-profit company.[237] The for-profit company will make the decisions for the hospital.[238] These decisions, based on the ultimate goal of profit, may result in a trimming of services and responses to community needs.[239] The peer review process may fall victim to the same profit-minded goal.

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228. *Id.*
229. *Id.*
230. *Id.*
231. *Id.*
232. *Id.* at 195.
233. *Id.* (citing Lowe v. Scott, 959 F.2d 323, 338 (1st Cir. 1992)).
234. *Id.*
235. *See* Robert Kuttner, *Columbia/HCA and the Resurgence of the For-Profit Hospital Business*, NEW ENG. J. MED., Aug. 3, 1996, at 446.
236. *See* Harris Meyer, *Selling . . . or Selling Out*, HOSPS. & HEALTH NETWORKS, June 5, 1996, at 22.
237. *See* VOLUNTEER TRUSTEES FOUNDATION FOR RESEARCH AND EDUCATION, WHEN YOUR COMMUNITY HOSPITAL GOES UP FOR SALE 8 (1996).
238. *Id.*
239. *Id.*

CONCLUSION

The multi-faceted health care system combines public federal, state, and local programs, private insurance, charity, and individual payments.[240] Each level of the health care system supports varying needs of the constituents. Tenth Circuit health law reflects the diversity of the overall health care system. It has followed the general trend towards improving conditions for patients. First, hospital and physician regulation has been more clearly defined to increase the quality of care for patients. Second, the Secretary of Health and Human Services continues to clarify health claim regulations, which provide more knowledge to consumers and decrease the chances that consumers will be misled by false claims.

The Tenth Circuit also addressed the issue of a woman's right to an abortion. The term "viability" remains flexible because the Supreme Court recognized its inability to define the term, preferring to allow the medical experts to determine on a pregnancy-by-pregnancy basis. Accordingly, the Tenth Circuit has upheld the "undue burden" standard.

The Tenth Circuit is striving towards better conditions for patients and consumers of the health care system. Although this requires increased regulation, that is a small price to pay to ensure health.

Christyne J. Vachon

240. CUNIFF & MCCARTHY, *supra* note 33, at 4.