

**PATERNALISM VS. PATIENT AUTONOMY:
IS THE FDA'S "MOTHERING"
SMOTHERING GRANDMA'S AND
GRANDPA'S CHOICE OF PRESCRIPTION
DRUGS?**

Thad Brady

In 1994, the Access to Medical Treatment Act was introduced in Congress to expand an individual's ability to use medical treatments that have not been approved by the Food and Drug Administration (FDA). Although this proposed legislation was not successful, similar versions have been introduced as recently as 2005, that continue to offer the promise of cutting-edge medical treatment to millions of sick elderly people. Mr. Brady explores the current prescription drug regulatory system administered by the FDA and illustrates the access barriers and delays in drug approval that affect the elderly population. Balancing the risks and benefits of allowing access to drugs not approved by the FDA, the author proposes a solution that focuses on meeting the needs of the elderly and the terminally ill. This resolution opens access to test drugs in certain situations, limits the FDA's paternalistic control, and focuses on patient autonomy and informed consent.

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I. Introduction

At age sixty-one, former U.S. Representative W.J. “Billy” Tauzin (R-La.) faced a challenge far too common for seniors: he was diagnosed with cancer.¹ Tauzin nearly bled to death from an ulcer in his intestine before his intestinal cancer was even discovered.² Despite undergoing surgery and chemotherapy, a tumor remained in Tauzin’s spine.³ Tauzin considered a new drug, Avastin, with his doctor,⁴ but Avastin had risks of serious side effects, including death, and it had never been used to treat someone who had already undergone surgery.⁵ After discussing the risks and benefits of the new drug with his doctor, Tauzin elected to use Avastin.⁶ Tauzin claims he “made the right choice”⁷ because “[he] wouldn’t be [alive] without Avastin.”⁸ Billy Tauzin lives today, a cancer survivor who is now head of Pharmaceutical Research Manufacturers of America (PhRMA), the trade association and lobbyist group for the drug industry based in Washington, D.C.⁹

Thirty-five-year-old Alita Randazzo was diagnosed with colorectal cancer in 2000.¹⁰ Her doctors recommended the drug Eloxatin to combat her cancer, but Randazzo had to travel to France to get the drug.¹¹ At the time, Eloxatin was not available in the United States and would not be approved by the Food and Drug Administration (FDA) until May 2003.¹² After eight months, Eloxatin no longer helped Randazzo, so her doctors recommended a different drug, Erbi-

1. See William M. Welch, *Tauzin Switches Sides from Drug Industry Overseer to Lobbyist*, USA TODAY, Dec. 16, 2004, at 4B.

2. Martha Brant, *A Politician’s New Cause*, NEWSWEEK, June 28, 2005, <http://www.msnbc.msn.com/id/7963313/site/newsweek/from/RL2/>.

3. *Id.*

4. See *id.* Avastin was approved by the FDA on February 26, 2004. Press Release, U.S. Food & Drug Admin., FDA Approves First Angiogenesis Inhibitor to Treat Colorectal Cancer (Feb. 26, 2004), <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01027.html>.

5. *Id.*

6. *Id.*; see also PHARM. RESEARCH & MFRS. OF AM., PRESIDENT’S MESSAGE, ANNUAL REPORT 2005–2006, at 6 (2005), available at <http://www.phrma.org/files/AnnualReport20052006.pdf> [hereinafter ANNUAL REPORT].

7. ANNUAL REPORT, *supra* note 6.

8. Brant, *supra* note 2.

9. *Id.*

10. Complaint at 7, Abigail Alliance for Better Access to Dev. Drugs v. McClellan, No. 03-1601 (D.D.C. July 28, 2003) [hereinafter Complaint].

11. *Id.* at 7–8.

12. *Id.* at 8.

tux.¹³ Like Eloxatin, Erbitux was not yet approved by the FDA,¹⁴ though many cancer patients had hoped it would be available on the market by the spring of 2002.¹⁵ Erbitux's FDA approval, however, was delayed until February 12, 2004,¹⁶ far too late for Alita Randazzo¹⁷ and other cancer patients.

Billy Tauzin considers himself one of the fortunate few because many Americans, like Alita Randazzo, are unable to access potentially life-saving or life-prolonging drugs.¹⁸ This note explores the FDA's regulation and approval of drugs, analyzes how regulation affects drug access for seniors and the seriously ill, and proposes changes to make prescription drugs more accessible to seniors.

In Part II, this note outlines the FDA's drug regulation and approval process and explores a congressional bill, the Access to Medical Treatment Act (AMTA), which responds to the weaknesses of FDA regulation.¹⁹ Part III analyzes the costs and benefits of drug regulation under the FDA versus regulation under AMTA, including how each approach affects access to alternative medicine; Part IV makes recommendations that achieve a compromise solution between the two regulatory approaches that would enable the elderly and terminally ill to have greater access to alternative medicine.

II. Background

A. Disease, Drugs, and the Elderly

According to the Administration on Aging, more than forty-nine million Americans are age sixty or older, including more than five million older than eighty-five.²⁰ Those numbers are expected to rise as

13. *Id.*

14. See Press Release, U.S. Food & Drug Admin., FDA Approves Erbitux for Colorectal Cancer (Feb. 12, 2004), <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01024.html> [hereinafter Press Release].

15. *An Inquiry into the ImClone Cancer Drug Story: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 107th Cong. 9 (2002) (statement of Rep. W.J. "Billy" Tauzin, Chairman, H. Comm. on Energy and Commerce).

16. Press Release, *supra* note 14.

17. Alita Randazzo died on July 20, 2002, unable to obtain Erbitux for her treatment. See Complaint, *supra* note 10, at 8.

18. See Brant, *supra* note 2.

19. Access to Medical Treatment Act, H.R. 2792, 109th Cong. (2005).

20. ADMIN. ON AGING, DEP'T OF HEALTH & HUMAN SERVS., AOA FY 2007 BUDGET PROVIDES SUPPORT FOR KEY SYSTEMS CHANGES NEEDED TO PREPARE FOR AGING AND LONG TERM CARE NEEDS OF THE BABY BOOMERS, <http://www.aoa>.

the baby boomer generation ages, with projections as high as seventy million Americans older than sixty by the year 2030.²¹ In addition, a 2004 report by the Merck Institute of Aging & Health shows that among Americans sixty-five and older, 20.4% had coronary heart disease, 49.2% suffered from hypertension, 19.9% had a type of cancer, 15.2% were diabetic, and 35.9% had arthritic symptoms.²² The report further reveals that heart disease and cancer caused more than half of the deaths for this same age group.²³ These statistics demonstrate the considerable role disease plays in the lives of elderly people and the substantial need among seniors for drugs to treat these diseases.

Due to an increased susceptibility to disease, seniors use far more medicine than younger people, filling their prescriptions an average of twenty-five times per year compared to only seven times per year for people age sixty-four and younger.²⁴ Consequently, the drug market has responded to this greater demand for prescription drugs among the elderly: approximately 700 of 1000 drugs undergoing clinical testing in 2003 were targeted at diseases or medical conditions related to aging.²⁵ However, largely due to the length and cost of the FDA approval process, only one in five of these drugs is likely to receive approval.²⁶

B. FDA Regulation of Drugs

The Food, Drug, and Cosmetic Act of 1938 (FDCA)²⁷ prohibits introduction of any new drug into interstate commerce unless the drug

dhhs.gov/ABOUT/legbudg/current_budg/docs/FY07%20Budget%20Statement%20Revised.doc (last visited Aug. 24, 2006).

21. NADINE R. SAHYOUN ET AL., CTRS. FOR DISEASE CONTROL & PREVENTION, AGING TRENDS NO. 1, TRENDS IN CAUSES OF DEATH AMONG THE ELDERLY 8 (2001), available at <http://www.cdc.gov/nchs/data/ahcd/agingtrends/01death.pdf>.

22. MERCK INST. OF AGING & HEALTH, THE STATE OF AGING AND HEALTH IN AMERICA 3 tbl.f.3 (2004), available at http://www.cdc.gov/aging/pdf/state_of_aging_and_Health_in_America_2004.pdf.

23. *Id.* at 2 tbl.f.2.

24. PHARM. RESEARCH & MFRS. OF AM., WHAT GOES INTO THE COST OF PRESCRIPTION DRUGS? . . . AND OTHER QUESTIONS ABOUT YOUR MEDICINES 7 (2005), available at http://www.phrma.org/files/Cost_of_Prescription_Drugs.pdf [hereinafter PHRMA].

25. Beth Baker, *Assessing the Risks, Benefits of Clinical Trials*, AARP BULLETIN ONLINE, June 2003, <http://www.aarp.org/bulletin/yourhealth/a2003-07-11-clinicaltrials.html>.

26. DALE E. WIERENGA & C. ROBERT EATON, ALLIANCE PHARM. CORP., PHASES OF PRODUCT DEVELOPMENT, http://www.allp.com/drug_dev.htm (last visited Aug. 18, 2006).

27. 21 U.S.C. §§ 301–392 (2005).

has been approved by the Secretary of Health and Human Services.²⁸ The FDCA established the FDA²⁹ and authorizes the Secretary, through the Commissioner of Food and Drugs, to use the FDA to carry out drug regulation.³⁰ Under the FDCA, drugs are broadly defined as “articles (other than food) intended to affect the structure or any function of the [human] body” and are “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease.”³¹ Penalties for using drugs in violation of the FDCA include the seizure and destruction of the drugs,³² injunctions against further use of the drugs,³³ fines, or imprisonment.³⁴

Obtaining FDA approval to sell and distribute a drug is a two-stage process: the Investigational New Drug (IND) application followed by the New Drug Application (NDA).³⁵ In special circumstances, the FDA offers “expanded access” protocols to hasten drug approval and patient access. These protocols include accelerated approval, parallel track mechanisms, and Treatment IND.³⁶ Besides these protocols, patient participation in FDA-required clinical testing³⁷ also enhances drug access to the public, but only in a limited manner.

1. INVESTIGATIONAL NEW DRUG (IND) APPLICATION

Prior to filing an IND application with the FDA, the drug manufacturer must extensively screen its drug to determine pharmacological value and toxicity in animals.³⁸

The IND application must contain information about the manufacturer’s ability to produce and consistently supply the drug, the drug’s toxicity in humans (including data from the animal testing and

28. *Id.* § 355(a).

29. *Id.* § 393.

30. *Id.* § 379(d).

31. *Id.* § 321(g)(1).

32. *Id.* § 334.

33. *Id.* § 332.

34. *Id.* § 333(a)–(b).

35. Ctr. for Drug Evaluation & Research, U.S. Food and Drug Admin., Drug Approval Application Process, <http://www.fda.gov/cder/regulatory/applications/default.htm> (last visited Aug. 18, 2006).

36. Christopher Mills, Comment, *Mainstreaming the Alternatives When Complementary and Alternative Medicines Become Westernized*, 13 ALB. L.J. SCI. & TECH. 775, 791 (2003).

37. Clinical trials are performed in order to receive approval for a New Drug Application. See discussion *infra* Part II.B.1–2.

38. Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., Investigational New Drug (IND) Application Process, http://www.fda.gov/cder/regulatory/applications/ind_page_1.htm (last visited Aug. 18, 2006).

any previous use of the drug in humans in foreign jurisdictions), and detailed protocols for proposed clinical tests for the trial phase of human testing.³⁹ The primary purpose of the IND application is to establish that a drug “will not expose humans to unreasonable risks” if it is tested on humans.⁴⁰ After submitting the application, the manufacturer must wait thirty days before conducting any clinical trials on humans.⁴¹ During that time, the FDA reviews the application to assess the safety of the drug.⁴² If at any time prior to or during the clinical trials the FDA believes that the studies cannot be conducted without unreasonable risk to the human subjects, the FDA can place a “clinical hold” to delay or even interrupt the testing.⁴³

2. NEW DRUG APPLICATION (NDA)

Once the drug passes through clinical testing successfully, the next step in the FDA approval process is for the manufacturer to file an NDA. The NDA is meant “to tell the drug’s whole story, including what happened during the clinical tests, what the ingredients of the drug are, the results of the animal studies, how the drug behaves in the body, and how it is manufactured, processed and packaged.”⁴⁴ The NDA’s purpose is to allow the FDA to determine (1) “[w]hether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks,”⁴⁵ (2) “[w]hether the drug’s proposed labeling (package insert) is appropriate, and what it should contain,”⁴⁶ (3) “[w]hether the methods used in manufacturing the drug and the controls used to maintain the drug’s quality are adequate to preserve the drug’s identity, strength, quality, and purity.”⁴⁷ If the FDA finds that the drug is safe, the labeling appropriate, and the

39. *Id.*

40. *Id.*

41. *Id.*

42. *Id.*

43. Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., Clinical Hold Decision, <http://www.fda.gov/cder/handbook/clinhold.htm> (last visited Aug. 18, 2006).

44. Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., New Drug Application (NDA) Process, <http://www.fda.gov/cder/regulatory/applications/NDA.htm> (last visited Aug. 18, 2006) [hereinafter NDA Process].

45. *Id.*

46. *Id.*

47. *Id.*

manufacturing controls and methods adequate, it approves the drug for sale and marketing in the United States.⁴⁸

3. ACCELERATED APPROVAL AND PARALLEL TRACK MECHANISMS

For serious or life-threatening diseases, the FDA can grant accelerated approval for a drug when it determines that a drug can be used safely under controlled distribution or use⁴⁹ or when there is reliable evidence of the drug's effect at a "surrogate endpoint."⁵⁰ A surrogate endpoint is indirect evidence that, by itself, is not conclusive of a drug's benefit, but rather is "likely to predict therapeutic benefit" of the drug.⁵¹ It is an indicator of the drug's benefit when clinical testing has not yet produced a conclusive result. Nevertheless, to qualify for accelerated approval, the drug must demonstrate a significant benefit over the existing therapy for a serious and life-threatening disease.⁵²

The parallel track mechanism, meanwhile, allows investigational drugs that have shown promise during clinical testing to be made available in special circumstances before the drug completes the FDA approval process.⁵³ However, because the U.S. Public Health Service developed this policy in response to the AIDS epidemic,⁵⁴ the parallel track mechanism is limited to drugs that treat HIV disease.⁵⁵ Even then, eligible patients must have no therapeutic alternatives and have a medical condition that prevents their participation in clinical testing in order to receive the investigational drugs through the parallel track mechanism.⁵⁶

4. TREATMENT INVESTIGATIONAL NEW DRUG (IND)

Treatment INDs are drugs the FDA makes available to patients prior to approval and general marketing of the drugs, but only in spe-

48. *Id.*

49. U.S. Food & Drug Admin., A Drug Review Glossary, <http://www.fda.gov/fdac/special/newdrug/bengloss.html> (last visited Aug. 18, 2006) [hereinafter Glossary].

50. *Id.*

51. *Id.* For example, CD4 cell counts are used by doctors to measure the strength of the immune system. *Id.*

52. *Id.*

53. *Id.*; see also Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., CDER Handbook, Parallel Track, <http://www.fda.gov/cder/handbook/parallel.htm> (last visited Aug. 18, 2006) [hereinafter Parallel Track].

54. See Parallel Track, *supra* note 53.

55. Glossary, *supra* note 49.

56. *Id.*; see also Parallel Track, *supra* note 53.

cial circumstances.⁵⁷ There must either be “preliminary evidence of drug efficacy” for a drug used “to treat a serious or life-threatening disease,” or there must be “no comparable alternative drug or therapy available” to treat that disease.⁵⁸ Thus, the drug must be currently undergoing or have already completed clinical testing.⁵⁹ As with the parallel track mechanism, only patients who do not qualify for the clinical trials of the drug are eligible to receive treatment INDs.⁶⁰ A treatment IND differs from parallel track because it is not limited to drugs that treat HIV-related disease.

5. CLINICAL TRIALS

Clinical trials involve the study of human volunteers to assess the risks and benefits of an IND.⁶¹ For patients seeking preapproved experimental drugs, clinical trials can be a practical alternative. Clinical trials are conducted by the U.S. National Institutes of Health and other federal agencies, as well as private entities, including pharmaceutical companies and private universities.⁶² An IND undergoes clinical trials following the approval of an IND application and prior to the filing of an NDA for marketing and distribution approval.⁶³ The FDA itself does not conduct clinical trials, but it supervises them to help protect the participants and verify the efficacy of the data generated in the trials.⁶⁴ Clinical trials have strict guidelines limiting who may participate in the trial based on factors such as the participant’s gender, age, and medical condition, including type and stage of the participant’s disease.⁶⁵ Researchers use these criteria to create a rela-

57. Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., CDER Handbook, Treatment IND, <http://www.fda.gov/cder/handbook/treatind.htm> (last visited Aug. 18, 2006) [hereinafter Treatment IND].

58. *Id.*

59. Ken Flieger, *FDA Finds New Ways to Speed Treatments to Patients*, in FDA CONSUMER SPECIAL REPORT ON NEW DRUG DEVELOPMENT IN THE UNITED STATES (1995), available at <http://www.fda.gov/fdac/special/newdrug/speeding.html>.

60. Treatment IND, *supra* note 57.

61. U.S. Food & Drug Admin., Basic Questions and Answers About Clinical Trials, <http://www.fda.gov/oashi/clinicaltrials/clintrialdoc.html> (last visited Aug. 18, 2006) [hereinafter Basic Questions].

62. See Baker, *supra* note 25; WebMD, 12 Answers to Common Questions, <http://www.webmd.com/content/pages/13/65814.html> (last visited Aug. 18, 2006) [hereinafter WebMD].

63. See *supra* Part II.B.1–2.

64. See Basic Questions, *supra* note 61.

65. U.S. Nat’l Inst. of Health, An Introduction to Clinical Trials, <http://clinicaltrials.gov/ct/info/whatis> (last visited Aug. 18, 2006) [hereinafter Clinical Trials].

tively uniform test group to reduce variation in the results.⁶⁶ Thus, many volunteers who do not meet eligibility requirements cannot participate in research studies and are, therefore, precluded from accessing investigational drugs.⁶⁷

An estimated one million Americans participate in clinical trials each year, approximately 15% to 20% of whom are older than sixty-five.⁶⁸ This percentage is puzzling, considering that 700 of 1000 drugs in clinical trials conducted in 2003 were targeted at age-related diseases.⁶⁹ However, older patients are often excluded from trials because researchers prefer participants who do not take other medications or have no other medical conditions.⁷⁰ For example, a 2001 study found that only 9% of trials for heart disease medicines included patients older than seventy-five,⁷¹ even though this age group accounts for 37% of all heart attack victims.⁷² The study also showed that 60% of clinical trials did not include any patients older than seventy-five and more than a third specifically excluded older people.⁷³

C. Alternative Medicine and the Access to Medical Treatment Act (AMTA)

Almost half of Americans use some type of alternative therapy,⁷⁴ and in 1997 alone, Americans spent \$27 billion on such treatments.⁷⁵ Surprisingly, one study showed that in 1990, Americans made more visits to alternative health care providers than to primary care physi-

66. See Basic Questions, *supra* note 61; see also WebMD, *supra* note 62 (“Researchers establish these guidelines [for clinical trial participation] to ensure that their study will provide useful, reliable results.”).

67. See Basic Questions, *supra* note 61.

68. Baker, *supra* note 25.

69. See *supra* Part II.A. This argument assumes that the proportion of age-related drugs in 2003 is roughly representative of other years.

70. Baker, *supra* note 25; see also WebMD, *supra* note 62 (“For instance, in a study of a medication to prevent heart attacks, people who have already had a heart attack might be excluded.”).

71. Patrick Lee et al., *Representation of Elderly Persons and Women in Published Randomized Trials of Acute Coronary Syndromes*, 286 JAMA 708, 710 (2001).

72. *Id.* at 708.

73. *Id.* at 711.

74. 145 CONG. REC. S14806 (daily ed. Nov. 18, 1999) (statement of Sen. Daschle); see also David M. Eisenberg et al., *Trends in Alternative Medicine Use in the United States, 1990–97*, 280 JAMA 1569, 1575 (1998) [hereinafter *Trends in Alternative Medicine*].

75. 145 CONG. REC. S14806 (daily ed. Nov. 18, 1999) (statement of Sen. Daschle).

cians.⁷⁶ Based on trends in the 1990s, these numbers are likely to increase.⁷⁷

The goal of AMTA is to increase access to alternative medicine. AMTA allows a health care practitioner (HCP) the flexibility to tailor a treatment regimen to a patient's beliefs and desires, even if a treatment is not approved by the FDA, subject to certain disclosure and reporting requirements as well as penalties for failure to comply with those requirements.⁷⁸ AMTA provides that an HCP "who knowingly violates any provision of this Act shall not be covered by the protections under this Act and shall be subject to all other applicable laws,"⁷⁹ including the FDCA and its penalties.⁸⁰

The AMTA was the brainchild of U.S. Representative Berkley Bedell (D-Iowa) and U.S. Senators Tom Harkin (D-Iowa) and Tom Daschle (D-S.D.).⁸¹ Representative Bedell and Senator Harkin are themselves recipients of alternative medical treatments.⁸² Together, Bedell, Harkin, and Daschle drafted AMTA, and the bill was first introduced in the Senate on May 19, 1994, with Senator Daschle as the sponsor and Senators Harkin, Claiborne de Borda Pell (D-Iowa), Charles Grassley (R-Iowa), Mark Hatfield (R-Or.), and Dennis DeConcini (D-Ariz.) as cosponsors.⁸³ Representative Eleanor Norton (D-D.C.) introduced the bill six days later in the House of Representatives.⁸⁴ AMTA did not make it beyond the committee stage of legislation in either the Senate or the House.⁸⁵ Since then, other versions of

76. In 1990, Americans visited alternative care practitioners 425 million times, compared to 388 million visits to conventional care physicians. See David M. Eisenberg et al., *Unconventional Medicine in the United States: Prevalence, Costs, and Patterns of Use*, 328 *NEW ENG. J. MED.* 246, 246 (1993).

77. *Trends in Alternative Medicine*, *supra* note 74, at 1573-74. Total visits by patients to alternative practitioners increased from 427 million in 1990 to 629 million in 1997. *Id.* at 1572.

78. Access to Medical Treatment Act, H.R. 2792, 109th Cong. § 3(a) (2005).

79. *Id.* § 8.

80. See *supra* Part II.B.

81. Mills, *supra* note 36, at 781.

82. *Id.* at 780-81. Bedell was cured of Lyme disease through a treatment involving injecting a cow's colostrums into his body and was later cured of prostate cancer using an experimental drug, 714-X, provided by a doctor in Quebec, Canada. *Id.* at 780. Harkin was cured of allergies through a treatment involving bee pollen. *Id.* at 781.

83. Access to Medical Treatment Act, S. 2140, 103d Cong. (1994).

84. Access to Medical Treatment Act, H.R. 4499, 103d Cong. (1994).

85. See *id.*; S. 2140.

the bill have been introduced in Congress, most recently on June 8, 2005,⁸⁶ with no more success than the original bill.⁸⁷

1. DISCLOSURE REQUIREMENTS UNDER AMTA

Before administering alternative medical treatments to patients, the HCP must conclude, based on current information and accepted practices, that the treatment is safe.⁸⁸ The HCP must then follow certain disclosure requirements: (1) informing the patient in writing that the treatment is not approved by the FDA and that the patient's use of the treatment is at his or her own risk; (2) informing the patient in writing of the treatment's "contents and methods," "anticipated benefits," and "reasonably foreseeable side effects," as well as the treatment's effects on others in the past; (3) giving the patient a recommendation for the treatment that provides "sufficient opportunity to consider whether or not to use" the treatment; and (4) requiring the patient to sign an agreement stating that he or she has been fully informed of the treatment and the risks involved.⁸⁹

2. REPORTING REQUIREMENTS UNDER AMTA

If the HCP discovers that an alternative treatment poses a danger to the patient receiving the treatment, the HCP must (1) cease use of the treatment, (2) cease recommending the drug or medical device that was part of the treatment, and (3) report his or her findings to both the manufacturer and the Director of the Centers for Disease Control and Prevention (CDC).⁹⁰ The Secretary of Health and Human Services (HHS), upon confirmation that the treatment is dangerous, is to inform the public of the danger and prohibit further use of the treatment.⁹¹

Conversely, if the HCP discovers that the treatment yields beneficial effects for the patient that are significantly greater than expected, the HCP must report the findings to the National Center for Complementary and Alternative Medicine at the National Institutes of Health (NIH).⁹²

86. Access to Medical Treatment Act, H.R. 2792, 109th Cong. (2005).

87. *See id.*

88. *See id.* § 3(b).

89. *Id.*

90. *Id.* § 4(a).

91. *Id.* § 4(b).

92. *Id.* § 5.

III. Analysis

A. Costs of FDA Regulation

The mission of the FDA's Center for Drug Evaluation and Research (CDER) is "to assure that safe and effective drugs are available to the American people."⁹³ Most people are unable to understand the complexities of a drug's chemical makeup and assess its potential risks.⁹⁴ People rely upon the FDA to monitor the safety of drugs and protect them from "uncounted numbers of drugs, elective procedures, and medical devices [sic] that have had little or no scientific testing."⁹⁵ All drugs have some risk of adverse reaction, and the FDA generally ensures that a drug's benefits outweigh its risks to the public, but the FDA's regulatory scheme imposes many costs, both tangible and intangible.⁹⁶

1. FDA PATERNALISM

One significant cost to the elderly is that FDA regulation of drugs restricts personal liberty.⁹⁷ While FDA regulation restricts freedom of choice for all age groups, it is of greater consequence to the elderly because members of this demographic group fill prescriptions about 3.5 times more per year than their younger counterparts.⁹⁸ By having access to only FDA-approved prescription drugs, the elderly are deprived of their ability to choose desirable medical treatments that fall outside this limited class of drugs. In 1914, Justice Cardozo

93. Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., New Drug Development and Review Process, http://www.fda.gov/cder/handbook/dev_rev.htm (last visited Aug. 18, 2006).

94. See Yonni D. Fushman, Comment, *Perez v. Wyeth Labs, Inc.: Toward Creating a Direct-to-Consumer Advertisement Exception to the Learned Intermediary Doctrine*, 80 B.U. L. REV. 1161, 1166 (2000); see also Michael D. Greenberg, *AIDS, Experimental Drug Approval, and the FDA New Drug Screening Process*, 3 N.Y.U. J. LEGIS. & PUB. POL'Y 295, 298 (2000).

95. Mills, *supra* note 36, at 794.

96. See U.S. Food & Drug Admin., Think It Through: Managing the Benefits and Risks of Medicines, <http://www.fda.gov/fdac/special/testtubetopatient/benefits-risks.html> [hereinafter Think It Through]; see also *United States v. Rutherford*, 442 U.S. 544, 555 (1979); NDA Process, *supra* note 44.

97. See Greenberg, *supra* note 94. For a more detailed discussion on medical patients' liberties and the effect of FDA regulation on those liberties, see Bret L. Lansdale, *A Procedural Due Process Attack on FDA Regulations: Getting New Drugs to People with AIDS*, 18 HASTINGS CONST. L.Q. 417, 424-27 (1991), and Steven R. Salbu, *Regulation of Drug Treatments for HIV and AIDS: A Contractarian Model of Access*, 11 YALE J. ON REG. 401, 423-28 (1994).

98. See PHRMA, *supra* note 24.

asserted that “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body.”⁹⁹ The FDA limits this right by restricting access to all but a few select prescription drugs. It is ironic that many of the people subject to the FDA’s “mothering” are themselves parents and grandparents.

Presumably, “[p]atients have the right to control their medical treatment.”¹⁰⁰ This right is based in the doctrine of informed consent, under which the patient can choose his or her medical care if given sufficient information to understand the consequences, risks and benefits, and alternatives to the chosen medical treatment.¹⁰¹ Because prescription drugs are a type of medical treatment, why should the doctrine of informed consent not also allow patients to choose their preferred prescription drugs without FDA interference? The doctors and researchers who conduct clinical testing of experimental drugs for FDA approval require a participant’s informed consent,¹⁰² yet informed consent is insufficient to allow distributing an experimental drug outside the clinical testing context. Patients can choose to end medical treatment, even if doing so would result in death,¹⁰³ but they cannot choose to take a potentially life-saving drug, despite being fully informed of the consequences, risks, and alternatives, simply because the FDA has not approved the drug.

The FDA’s apparent response to this paradox is that it regulates drugs for protective purposes.¹⁰⁴ Essentially, the FDA takes a paternalistic role,¹⁰⁵ vicariously choosing for patients whether the benefits sufficiently outweigh the risks to justify accessibility to the drug. This paternalistic approach severely limits patient autonomy for patients of all ages, but the FDA’s risk-benefit analysis is particularly unfair to the elderly¹⁰⁶ because an elderly patient’s risk-benefit analysis is very different from that of a younger patient. In comparison to younger

99. *Schloendorff v. Soc’y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914).

100. LAWRENCE A. FROLIK & RICHARD L. KAPLAN, *ELDER LAW IN A NUTSHELL* 18 (3d ed. 2003).

101. *Id.* at 18–19.

102. *Clinical Trials*, *supra* note 65. The patient gives consent after having been informed of the “details about the study, such as its purpose, duration, [and] required procedures” *Id.*

103. *See Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 281 (1990).

104. *See United States v. Rutherford*, 442 U.S. 544, 555 (1979); *Think It Through*, *supra* note 96; *see also NDA Process*, *supra* note 44.

105. *See Greenberg*, *supra* note 94.

106. For a more detailed discussion of the risk-benefit analysis for the elderly, *see infra* Part IV.

generations, an elderly person has lived longer, has fewer years to live, and is more likely to be in poor health.¹⁰⁷ Therefore, an elderly person has less to lose and more to gain from an experimental drug than younger people and may be more willing to face adverse effects if there is even a small possibility of being cured or of prolonging life. Conversely, younger people are more likely to take an FDA drug that is less risky but also produces lower benefits.¹⁰⁸ FDA regulation caters to the younger generation by ensuring that drug benefits far outweigh the risks.

Some commentators think the FDA goes too far in its efforts to err on the side of safety. One critic explains the FDA's extremely risk-averse behavior:

If [FDA officials] approve a drug and one person in a million dies of it, they get the blame. But if they keep [the drug] off the market and a thousand people die for lack of it, they will still be seen as just doing their job, and groups . . . will still hail them for "protecting Americans from unsafe and ineffective drugs."¹⁰⁹

For this reason, the FDA has little incentive to allow patients to take their chances with prescription drugs, but it has every incentive to deny patient access to unknown or risky medicine, even when the potential benefits are great.

2. FINANCIAL COSTS AND THE EFFECT ON DRUG ACCESSIBILITY

Turning to more concrete costs, completing the FDA drug approval process costs an average of \$500 million.¹¹⁰ However, PhRMA claims that the total cost to drug companies, including research and development before the drug approval process, can range from \$800 million¹¹¹ to \$1 billion.¹¹² In comparison, the average cost of drug development was \$138 million in 1975, and \$318 million in 1987.¹¹³

These high research and development costs have at least two important effects on the drug market for the elderly. First, expensive

107. See discussion *supra* Part II.A.

108. For a more detailed discussion of the risk-benefit analysis for people under the age of sixty-five, see *infra* Part IV.

109. David Wagner, *Friend or Enemy?*, INSIGHT ON THE NEWS, Aug. 17, 1998, at 8.

110. U.S. Food & Drug Admin., FDA and the Drug Development Process: How the Agency Ensures That Drugs Are Safe and Effective, <http://www.fda.gov/opacom/factsheets/justthefacts/17drgdev.html> (last visited Aug. 18, 2006) [hereinafter Drug Development Process].

111. PhRMA, *supra* note 24, at 2.

112. Brant, *supra* note 2.

113. PhRMA, *supra* note 24, at 2.

drug development increases the price of prescription drugs so that manufacturers can cover their costs.¹¹⁴ These high drug prices limit drug availability to those who can afford them or have insurance sufficient to cover a substantial portion of the cost.¹¹⁵ Many elderly people lack such coverage and are unable to afford beneficial drugs.¹¹⁶ The total cost of drugs for elderly patients is staggering. In 2003 alone, Americans spent \$179 billion on prescription drugs.¹¹⁷ Elderly patients fill prescriptions at a ratio of twenty-five to seven in comparison to patients under the age of sixty-five,¹¹⁸ thus shouldering more than three-quarters of those costs, or about \$135 billion.¹¹⁹

The second effect of the high cost of FDA approval is that it keeps out of the market many beneficial drugs that would not be profitable enough to cover the costs of approval.¹²⁰ However, PhRMA claims that only three out of ten prescription drugs available in the United States generate enough revenue to meet or exceed the average costs for research and development,¹²¹ thus bolstering their argument that drug companies develop drugs for the primary purpose of treating patients rather than increasing their own profits.¹²² Even if this is true, the drug industry still earned profits of \$550 billion in 2004,¹²³ and made returns on investments hundreds of times greater than the cost of research and development on some drugs.¹²⁴ Nevertheless, the

114. See Sarah E. Eurek, *Hatch-Waxman Reform and Accelerated Market Entry of Generic Drugs: Is Faster Necessarily Better?*, 2003 DUKE L. & TECH. REV. 18, ¶ 2 (2003), <http://www.law.duke.edu/journals/dltr/articles/PDF/2003DLTR0018.pdf>.

115. See *id.*

116. See Jonathan P. Glazier, Note, *The Drug Pricing Controversy: A Review of Actions Taken by the Pharmaceutical Industry and the Federal and State Governments*, 1 J. HEALTH & BIOMEDICAL L. 163, 173 (2004).

117. Press Release, The Henry J. Kaiser Family Found., Americans Value the Health Benefits of Prescription Drugs, But Say Drug Makers Put Profits First, New Survey Shows (Feb. 25, 2005), <http://www.kff.org/kaiserpolls/pomr022505nr.cfm>.

118. PhRMA, *supra* note 24, at 7.

119. This calculation is based on the rough assumption that all patients spent approximately the same amount on each filled prescription regardless of age.

120. See Michael Horwin, *War on Cancer: Why Does the FDA Deny Access to Alternative Cancer Treatments?*, 13 ALB. L.J. SCI. & TECH. 681, 717 (2003).

121. PhRMA, *supra* note 24, at 2; see also Brant, *supra* note 2.

122. See ANNUAL REPORT, *supra* note 6, at 4.

123. Brant, *supra* note 2.

124. For example, pediatric testing of the heartburn drug Prilosec only cost its manufacturer between \$2 million and \$4 million, but the pediatric market for Prilosec generated \$1.2 billion. See Patricia Barry, *Brands v. Generics*, AARP BULLETIN ONLINE, Mar. 2002, <http://www.aarp.org/bulletin/medicare/a2003-06-23-brandsvsgenerics.html/page=2>.

fact that drug companies receive a return on their investment only 30% of the time speaks more to their inability to accurately predict a drug's profitability than to their motive for developing the drug.¹²⁵ From an economic perspective, "pharmaceutical companies have an incentive to finance, test, and market only those drugs they can ultimately patent,"¹²⁶ as well as to protect their investments and to market their products for a profit.¹²⁷

Unlike most drugs developed by pharmaceutical companies, many alternative drugs are composed of natural substances and thus cannot be patented.¹²⁸ Thus, it is almost impossible for an entity that develops an alternative drug to protect its investment long enough to recover its development costs.¹²⁹ This translates into unprofitable drugs that companies have almost no incentive to research and develop. Some of these unprofitable "drugs" are marketed under a different guise, such as an herbal supplement, vitamin, or mineral, but they cannot legally be marketed as a drug.¹³⁰ The FDCA forbids advertising that a substance is "for use in the diagnosis, cure, mitigation, treatment, or prevention of disease"¹³¹ without FDA approval.¹³² Therefore, the high costs of FDA approval often make beneficial alternative drugs either unavailable to the elderly or available but with their potential benefits and risks unknown to the general population.

125. See Horwin, *supra* note 120, at 716–17.

126. See *id.* at 717. Because patents provide protection from the unauthorized use of a drug for seventeen years, pharmaceutical companies will seek patents prior to FDA approval to protect their investment into research and development of the drug. See James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 CATH. U. L. REV. 433, 435–36 (1986). Otherwise, competitors could develop a generic "copy" of the drug without incurring the costs of research and development. See *id.* at 440–41 (stating that, once a patent expires, "a manufacturer may secure FDA approval of a generic copy of an approved drug by showing that the generic product contains the identical active ingredients as, and is bioequivalent to and bioavailable with, the original drug.").

127. See *id.*; see also Mary T. Griffin, *AIDS Drugs & the Pharmaceutical Industry: A Need for Reform*, 17 AM. J.L. & MED. 363, 365–71 (1991) (discussing the use of patents by pharmaceutical companies to monopolize the market for a particular drug and maintain high prices while driving up profits).

128. Tiffany Danitz, *Consumer Protection vs. Market Freedom*, INSIGHT ON THE NEWS, July 7, 1997, at 16.

129. See *id.*

130. See Peter J. Cohen, *Science, Politics and the Regulation of Dietary Supplements: It's Time to Repeal DSHEA*, 31 AM. J.L. & MED. 175, 210 (2005); see also Suzan Onel, *Dietary Supplements: A Definition That Is Black, White, and Gray*, 31 AM. J.L. & MED. 341, 347 (2005).

131. 21 U.S.C. § 321(g)(1) (2005).

132. See *supra* Part II.B.

3. THE DISINCENTIVE TO DEVELOP DRUGS THAT CURE

Another less obvious effect of the high cost of drug approval is that manufacturers have little incentive to produce a drug or medical treatment that *cures* rather than *treats* a particular disease.¹³³ Pharmaceutical companies profess that their goal is “the health of patients”¹³⁴ and that the “industry is squarely on the side of patients.”¹³⁵ However, with potential FDA approval costs of hundreds of millions of dollars, a manufacturer has more incentive to research and develop drugs that merely mask symptoms or slow down a disease,¹³⁶ thus creating long-term consumers of the drug and providing a steady flow of revenue. Conversely, developing a drug that cures creates demand and generates sales only in the short-term.¹³⁷ With Americans filling three billion prescriptions per year¹³⁸ and drug companies earning \$550 billion in annual profits,¹³⁹ the drug industry has little, if any, incentive to produce treatments that cure patients.

4. THE COST OF WAITING FOR FDA APPROVAL

For many patients, waiting for the FDA to approve a drug is a significant cost of the FDA approval process. Due to extensive clinical testing, the average drug takes 8.5 years to receive FDA approval and become available to the public.¹⁴⁰ Some pharmaceutical companies claim it can take up to fifteen years to develop a drug.¹⁴¹ During that time, patients suffer and die from diseases that drugs awaiting FDA approval could potentially treat.¹⁴² To expedite drug availability, the

133. See Morton Kondracke, Editorial, *Medical Research Spending an Investment in Nation's Health*, CHI. SUN-TIMES, Jan. 28, 2006, at 14.

134. ANNUAL REPORT, *supra* note 6, at 4.

135. *Id.* at 6.

136. See Kondracke, *supra* note 133.

137. See Marcia Angell, *The Truth About the Drug Companies*, N.Y. REVIEW OF BOOKS, July 15, 2004, at 52, 58 (discussing the many ways in which pharmaceutical companies manipulate the market in order to increase profits, and noting that although the companies often emphasize innovative new drugs, the amount of actual innovation is questionable, especially considering the lack of economic incentive to develop drugs that cure and the secretive nature of the industry).

138. David R. Francis, *Medicare Reform Carries Huge Fiscal Toll*, CHRISTIAN SCI. MONITOR, Oct. 17, 2003, at 5.

139. TRANSPARENCY INT'L, SUMMARY SHEET: CORRUPTION IN THE PHARMACEUTICAL SECTOR 1 (2006), available at [http://www.globalaging.org/health/world/2006/World%20HE%20Feb1%20Pharma%20Corruption%20\(phcorrupt\).pdf](http://www.globalaging.org/health/world/2006/World%20HE%20Feb1%20Pharma%20Corruption%20(phcorrupt).pdf).

140. Drug Development Process, *supra* note 110.

141. Kondracke, *supra* note 133.

142. See discussion *supra* Part I.

FDA instituted its “expanded access” protocols: accelerated approval, parallel track mechanisms, and treatment INDs. While these protocols seem to be effective remedies for those waiting for drug approval, in reality they increase access for only a limited number of patients and fail to promote broad access to promising drugs.¹⁴³

Some expanded access protocols appear to be the FDA’s response to the HIV epidemic, which pressured the FDA to expedite drug approval so that HIV patients could have access to new treatments.¹⁴⁴ For instance, parallel track mechanisms to introduce drugs to the market are limited to treatments for HIV disease¹⁴⁵ and are therefore not beneficial for elderly patients with other diseases.

On average, accelerated approval reduces the approval process by 3.3 years,¹⁴⁶ but it is still not fast enough for patients who are enduring severe pain or nearing death.¹⁴⁷ Similarly, treatment INDs permit “the FDA substantial leeway in determining when . . . a new drug might become available.”¹⁴⁸ The FDA’s discretion to decide which drugs are appropriate for the IND and accelerated processes thus helps to maintain its paternalistic control that denies full patient autonomy. In 2004 and 2005, thirteen and ten drugs respectively were approved through a fast-track mechanism each year.¹⁴⁹ Through June 2006, only five drugs have been approved for a fast track.¹⁵⁰

As for accessing drugs by participating in clinical trials, the elderly seem to receive minimal benefit from this option. While clinical testing is a viable option for many patients, the elderly are excluded from a disproportionately large percentage of these trials, even though most involve drugs treating diseases related to aging.¹⁵¹

143. Cf. Sheila R. Shulman & Jeffrey S. Brown, *The Food and Drug Administration’s Early Access and Fast-Track Approval Initiatives: How Have They Worked?*, 50 FOOD & DRUG L.J. 503 (1995) (arguing that the FDA should expand early access and fast-track programs to encompass more diseases).

144. See Greenberg, *supra* note 94, at 308–15.

145. Glossary, *supra* note 49.

146. See Shulman & Brown, *supra* note 143, at 512–13.

147. One study found that among patients diagnosed with terminal cancer within thirty days of entering the study, two-thirds survived less than six months. See Antonio Vigano et al., *The Relative Accuracy of the Clinical Estimation of the Duration of Life for Patients with End of Life Cancer*, 86 CANCER 170, 175 (1999).

148. Greenberg, *supra* note 94, at 320–21.

149. U.S. Food & Drug Admin., CDER Fast Track Products Approved Since 1998 Through March 31, 2006, <http://www.fda.gov/cder/rdmt/internetftap.htm> (last visited Oct. 12, 2006).

150. *Id.*

151. See discussion *supra* Part II.A.

Moreover, like the FDA's expanded access protocols, clinical trials grant patient access to only a limited number of drugs that are already undergoing the approval process,¹⁵² thus leaving many patients of all ages without access to potentially life-saving drugs that are not being tested on human subjects.

B. Is AMTA the Answer?

In contrast to the FDA's paternalistic, conservative approach to drug regulation, AMTA takes a "liberal" approach with a focus on patient autonomy.¹⁵³ Representative Frank Pallone (D-N.J.) explained the rationale for changing the current system: "I do not see how the FDA is serving the public when, by its actions it prevents a [person] with a brain tumor or . . . non-Hodgkins lymphoma [sic] from getting a treatment these individuals and their families have been informed about and have freely chosen to pursue."¹⁵⁴ AMTA would remove many of the FDA's barriers and allow patients to consult with their doctors to consider a wide array of medical treatments.¹⁵⁵ More significantly, AMTA seems to be the solution for most accessibility problems associated with FDA drug regulation.

First, AMTA would allow drug manufacturers to introduce drugs into the market without the \$500 million price tag attached to FDA approval. The sales price for these prescription drugs would be a fraction of the price for current FDA-approved prescription drugs,¹⁵⁶ reflecting lower development and marketing costs. Under AMTA, substances that cannot obtain patent protection and that are considered "unprofitable" under the FDA regulatory regime could be advertised and sold to consumers as prescription drugs that treat or cure disease.¹⁵⁷ In addition, without the high cost of FDA regulation, drug manufacturing would no longer be limited to large pharmaceutical

152. See discussion *supra* Part II.B.5.

153. Mills, *supra* note 36, at 793.

154. 142 CONG. REC. H4115 (daily ed. Apr. 29, 1996) (statement of Rep. Pallone).

155. See 145 CONG. REC. S14806 (daily ed. Nov. 18, 1999) (statement of Sen. Daschle).

156. See BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS AND PROBLEMS 721–22 (4th ed. 2001) (asserting that market competition can reduce the prices of health care, including prescription drugs).

157. Access to Medical Treatment Act, H.R. 2792, 109th Cong. § 3(b) (2005).

companies.¹⁵⁸ Doctors or scientists who develop revolutionary medical treatments but lack the investment capital to develop the drug would have greater access to the drug market.¹⁵⁹

Second, while manufacturers may still have a low incentive to develop drugs that cure rather than treat disease, at least they would not face the high costs of FDA approval, costs which encourage the development of drugs that merely slow the progression of disease or cover up symptoms, thereby extending the market life and profit for the drug. These lower drug development costs should then *increase* a pharmaceutical company's incentive to develop more effective drugs, even drugs that cure disease. With lower cost barriers to enter the drug market, more competitors would enter the market, driving up innovation and drug development. The increased competition would then encourage drug manufacturers to develop better drugs than their competitors, even drugs that cure.

Finally, AMTA would expedite drug availability by essentially removing the barriers to introducing a drug into the market. Under AMTA, an HCP could use a treatment if he or she had "no reason" to conclude that the treatment was dangerous to the patient.¹⁶⁰ Thus, a treatment could be used in the early stages of development or even before it had undergone any testing, as long as the patient is fully informed and provides consent.¹⁶¹ A patient would have access to any medical treatment that he or she desired if there was a manufacturer willing to produce the drug or treatment, a doctor willing to give the treatment, and written information available about the treatment, including a warning regarding its use.¹⁶²

In summary, AMTA would empower elderly patients to choose the medical treatment they desire. Combining lower prices for prescription drugs, increased options for medical treatments, and expeditious drug availability would allow seniors and all other medical patients to be able to choose the most effective medical treatments, weighing the risks against their own perceived benefits.

Although AMTA would dramatically increase patient autonomy under the FDA as compared to the current status, it would do so "at

158. See 145 CONG. REC. S14806 (daily ed. Nov. 18, 1999) (statement of Sen. Daschle).

159. See *id.*

160. H.R. 2792.

161. *Id.*

162. *Id.*

the expense of the safety of the entire public,"¹⁶³ a sacrifice many people consider to be too great for the benefits to the few.¹⁶⁴ Under the present version of the AMTA, an unsophisticated patient may obtain a prescription for an alternative remedy to treat a relatively minor disease, such as arthritis, with the promise of wonderful results based on limited testing, only to suffer severe debilitation and even death in the long term. Another patient may suffer severe adverse effects from a drug prescribed by a doctor who had allowed a financial interest in the drug's success to affect his or her judgment in suggesting the drug treatment. Still others may find that their doctors based their opinions of a drug on insufficient knowledge that was inadequate for the patients to truly make informed decisions. Where does AMTA leave these unfortunate patients? Out in the cold.

One AMTA critic noted:

In this age of media hype, it is plausible that literally millions of Americans could be persuaded to take a pill every day that they hoped would prevent cancer—especially if it included some natural ingredient or a vitamin. Suppose that long after millions of people were popping this cancer prevention pill, proper, expensive randomized clinical trials were finally conducted to see if the hoped for benefits in fact existed. Now suppose that those clinical trials . . . showed that these anti-cancer pills either didn't work at all—or actually caused lung cancer.¹⁶⁵

As scary as such a situation sounds, it has happened before, even under FDA regulation.¹⁶⁶ Under this general cost-benefit analysis, AMTA would successfully provide some benefit to a small portion of medical patients, but it would also pose a serious risk to the vast majority of other patients, particularly those with minor diseases.

C. Who Will Police Unapproved Drugs

AMTA would allow drug manufacturers to circumvent the FDA approval process and market their drugs to the terminally ill and the

163. Mills, *supra* note 36, at 793.

164. See, e.g., *id.* at 796.

165. *Patient Access to Alternative Treatments: Beyond the FDA: Hearings Before the H. Comm. on Gov't Reform & Oversight*, 105th Cong. 173 (1998) (statement of Thomas J. Moore, Senior Fellow, Health Policy Institute, George Washington University).

166. See G.S. Omenn et al., *Effects of a Combination of Beta Carotene and Vitamin A on Lung Cancer and Cardiovascular Disease*, 334 *NEW ENG. J. MED.* 1150, 1155 (1996) (discussing a study in which FDA-approved beta carotene and vitamin A supplements provided no benefit and may have actually had an adverse effect on the participants contracting lung cancer).

elderly. Nevertheless, these drugs would remain regulated by at least four controls: the health care practitioner, tort liability, the Internet, and market factors.

1. THE HEALTH CARE PRACTITIONER (HCP)

Under AMTA, doctors would take on an increased role in protecting patients from harmful drugs and treatment. Currently, doctors rely upon FDA regulation to protect the public from harmful drugs. AMTA would force doctors to become the protectors—to become more informed of terminally ill or elderly patients' alternatives and act as gatekeepers for their patients, shielding them from harmful drugs.¹⁶⁷

At least some doctors are willing and ready to accept this added responsibility. The American Association for Health Freedom, an interest group representing HCPs who treat patients with alternative and complementary medicine,¹⁶⁸ fully supports AMTA in its present form and is lobbying Congress to have it passed.¹⁶⁹ Nevertheless, a doctor can avoid the responsibility of protecting the patient from potentially harmful unapproved drugs by referring the patient to another doctor.¹⁷⁰

2. TORT LIABILITY

Patients and their families who have been harmed by alternative medical treatments will still be able to avail themselves of the tort system to obtain redress. Drug manufacturers would remain liable for their products, and doctors would continue to face medical malpractice suits if they breach the standard for medical care. At least one AMTA critic has argued that the informed consent requirement of AMTA effectively “engulfs the tort of medical malpractice” because a

167. Kristen J. Josefek, Comment, *Alternative Medicine's Roadmap to Mainstream*, 26 AM. J.L. & MED. 295, 309–10 (2000); see also *Boyd v. Albert Einstein Med. Ctr.*, 377 Pa. Super. 609, 618 (1988).

168. Am. Ass'n for Health Freedom, About AAHF, <http://www.apma.net/aahf/showarticlenew.asp?articleid=6> (last visited Aug. 18, 2006).

169. Am. Ass'n for Health Freedom, AMTA Should Have a Subtitle: Safe and Equal Access to the Best in Health Care, <http://www.apma.net/AMTA/default.asp> (last visited Aug. 18, 2006).

170. But see Sarah Brewer, *Can My GP Say No to Homeopathy? Complementary Medicine on the Health Service—Plus Working Through Painful Memories, Losing Weight and Easing Insomnia*, DAILY TELEGRAPH, July 18, 2001, at 22 (discussing how some doctors refuse to refer their patients to practitioners of alternative or homeopathic remedies).

doctor would be shielded as long as a patient was fully informed of the consequences.¹⁷¹ However, AMTA requires the doctor to use “generally accepted principles” to determine if a treatment would put a patient in danger.¹⁷² Thus a doctor who strays from accepted principles in the medical field would remain liable for medical malpractice.¹⁷³

3. THE INTERNET WATCHDOG AND THE INFORMED CONSUMER

In modern times, the Internet has become a valuable tool in the dissemination of information cheaply and efficiently. An Internet user can conduct an online search for a disease and have access to thousands of Web sites containing helpful information.¹⁷⁴ Thus, a terminally ill or elderly patient could obtain additional information regarding an experimental drug to supplement the doctor’s advice and better evaluate the risks and benefits. In fact, one observer noted that Americans today are willing to take only *advice* from their doctors and are likely to demand more information and control over their medical destiny.¹⁷⁵ The proposed version of AMTA would allow them more control over that destiny.

Furthermore, in the political arena, Internet bloggers¹⁷⁶ have become self-appointed watchdogs for the public, keeping people in-

171. Mills, *supra* note 36, at 798. Surprisingly, a study published in the *Journal of the American Medical Association* found that malpractice claims against providers of alternative medicine were actually less frequent and less severe than claims against providers of conventional medicine. See David M. Studdert et al., *Medical Malpractice Implications of Alternative Medicine*, 280 JAMA 1610, 1612 (1998).

172. Access to Medical Treatment Act, H.R. 2792, 109th Cong. § 3(b)(1)(A) (2005).

173. For example, under Illinois law, a doctor commits medical malpractice by deviating from the medical profession’s standard of care and causing injury to the victim. *Campbell v. United States*, 904 F.2d 1188, 1191 (7th Cir. 1990).

174. See Andrea Petersen, *Home Remedies*, WALL ST. J., Oct. 19, 1998, at R4. Examples of Web sites that provide online health care information for medical patients and their families include the following: <http://www.healthfinder.gov>; <http://www.health-futures.org>; <http://www.altemed.od.nih.gov>; <http://www.nlm.nih.gov>; <http://www.ahcpr.gov>; <http://www.docboard.org>; and <http://www.cancercareinc.org>.

175. Anna Quindlen, *In a Peaceful Frame of Mind*, NEWSWEEK, Feb. 4, 2002, at 64.

176. A blogger is a person who maintains a “blog”—short for “Weblog”—an online Web site that can be used to post a personal daily journal, breaking news stories, photographs, or any other information the blogger desires. See Google.com, *Blogger: Tour: What’s a Blog?*, http://www.blogger.com/tour_start.g (last visited Aug. 18, 2006). In this case, a blogger can use his or her blog to post medical information and news regarding prescription drugs for Internet users. According to Google, “blogs have reshaped the web, impacted politics,

formed of scandals and corruption in the government. These bloggers could also act as watchdogs for the public in the alternative medical treatment arena, informing patients of harmful treatments as well as beneficial drugs.

One problem with relying on the Internet as a regulator, however, is that much of the information comes from self-appointed “experts,” many of whom do not have a medical background. Moreover, some of the elderly may not be technologically savvy enough for the Internet to be a readily available resource. Even for those familiar with the Internet, “the universe of medical information can be a morass and a minefield, [but] savvy patients can find their way to the best doctors, cutting-edge clinical trials and badly needed support from other people who have the same illness.”¹⁷⁷

The Internet is but one of many resources for obtaining medical information. One journalist noted that patients “look for information [regarding their medical conditions] on Web sites, in newspapers and magazines, and in conversations with friends, so that cocktail parties sometimes sound more like hospital waiting rooms than social events.”¹⁷⁸ The rise of this “informed consumer” in the health care market may be sufficient to counter many potential dangers to patients from unknown drugs.

4. REGULATING MARKET FACTORS

Finally, the drug market itself would regulate drug manufacturers. Harmful or ineffective drugs would become unprofitable and would be squeezed out of the market by profitable drugs that are safe and effective. In general, drug manufacturers would continue to test their products despite the absence of any explicit requirement to do so under AMTA, just as a food manufacturer would test its food products before and after placing the final product on the market. New and innovative ideas for treatments would improve the effectiveness and safety of the drug or treatment. In this way, the drug market would essentially regulate itself as do other product markets. In fact, some pharmaceutical companies are already taking steps to regulate themselves. For example, in the summer of 2005, PhRMA and its

shaken up journalism, and enabled millions of people to have a voice and connect with others.” *Id.*

177. Josefek, *supra* note 167, at 308.

178. Quindlen, *supra* note 175.

members adopted a self-imposed code of principles providing guidelines for direct-to-consumer advertising.¹⁷⁹

Critics of deregulation point to examples of historical quackery and ineffective or even harmful medicines that have been marketed directly to the public.¹⁸⁰ However, following the recent Vioxx¹⁸¹ debacle that affected tens of thousands of Americans, even FDA-approved drugs may not be as safe as once thought. Faced with the choice of potentially harmful FDA-approved drugs or unapproved drugs, many elderly patients may take their chances with the latter, particularly when those drugs appear to offer greater benefit and potential.

IV. Resolution

There is no doubt that alternative medicines play an ever-increasing role within our health care system.¹⁸² With the advent of successful alternative medicines, the increased popularity of such medicines among Americans, and “growing acceptance among traditional medical practitioners, it would seem logical to remove some of the access barriers that consumers face when seeking certain alternative therapies.”¹⁸³ However, the dangers that novel or untested alternative treatments could pose to the public necessitates maintaining some of the access barriers removed by AMTA.

The patients who should have access to experimental medicines are the terminally ill and the elderly. Applying a risk-benefit analysis, these patients stand to benefit tremendously from alternative medi-

179. *D-T-C Ads to Emphasize Information Patients Need*, CHAIN DRUG REV., Aug. 29, 2005, at 91 (on file with The Elder Law Journal).

180. Danitz, *supra* note 128; see also *Clinical Trials and Patient Safety: Hearing Before the H. Comm. on Government Reform and Oversight*, 105th Cong. 42 (1998) (statement by Michael A. Friedman, Lead Deputy Comm’r, Food and Drug Administration) (referencing the common practice in the 1940s and 1950s to give babies pure oxygen, which caused blindness in approximately 10,000 babies).

181. Vioxx is a painkiller that was used by twenty million Americans before it was taken off the market when studies revealed that it increased the risk of heart attacks and strokes. See *New Questions About Vioxx Study* (National Public Radio broadcast Feb. 23, 2006) [hereinafter *New Questions*]; see also Aaron Smith, *FDA: Cozy with Drugmakers*, CNN MONEY, Nov. 8, 2005, <http://money.cnn.com/2005/11/08/news/fortune500/pdufa/>. Scientists are accused of having withheld information from the FDA about the drug’s potential dangers in order to get the drug approved. See *New Questions, supra*.

182. For example, between 1990 and 1997, expenditures for professional alternative medicine services increased by 45.2%. 145 CONG. REC. S14806 (daily ed. Nov. 18, 1999) (statement of Sen. Daschle).

183. *Id.*

cine and are more likely to accept the substantial risks these treatments may pose as long as the perceived risks do not outweigh the potential benefits.¹⁸⁴

The reason the terminally ill should have access to alternative treatments is fairly clear: they have been labeled “terminally ill” because no conventional methods exist to treat or cure their disease.¹⁸⁵ A patient who could die at any time would probably be willing to accept an experimental drug or treatment that might carry unknown serious risks because of the possibility that the drug or treatment would successfully cure the disease or prolong the patient’s life.¹⁸⁶

The plight of the elderly may be less dramatic than that of the terminally ill, but it is nonetheless similar. Older patients who have lived full and productive lives and do not have many years left to live may be willing to take a gamble on experimental medicine if they believe the benefits outweigh the risks for them. For example, an Alzheimer’s disease patient may wish to undergo an alternative treatment with the chance to be cured, rather than wait for the debilitating disease to rob him of his memory and ability to function. An elderly patient in the early stages of cancer may wish to try an experimental drug with unknown risks rather than undergo painful and often unsuccessful chemotherapy,¹⁸⁷ particularly when the potential side effects of some chemotherapy drugs consist of organ damage (including

184. See Greenberg, *supra* note 94, at 298; see also *United States v. Rutherford*, 442 U.S. 544, 555–56 (1979) (noting that the same risk-benefit analysis applied by the FDA to the general population also applies to the terminally ill).

185. Mills, *supra* note 36, at 799. But see *Rutherford*, 442 U.S. at 557 (recognizing that “[e]ven critically ill individuals may have unexpected remissions and may respond to conventional treatment.”).

186. See Greenberg, *supra* note 94, at 298.

187. The minimal effect conventional medical treatments have on cancer patients alone is staggering:

It is very rare, currently, to ever get a complete remission or cure in a patient who has a malignant brain tumor using our standard modalities of surgery, radiation and chemotherapy. . . . As a rough estimate, neurosurgeons do well to cure 1 in every 1000 brain cancer patients they operate on. Radiation therapy slows the growth of adult tumors gaining perhaps one month of life and again may result in a cure in only 1 in 500–1000 patients. . . . Similarly, chemotherapy research, despite 30 years of clinical trails, has not resulted in the development of a single drug or drug combination that elicits more than an occasional transient response in primary brain tumors.

Letter from Robert E. Burdick, M.D., to Judge Sim Lake, U.S. Dist. Court for the S. Dist. of Tex. (Feb. 19, 1977), available at <http://www.burzynskipatientgroup.org/burdickreport.htm>.

potential damage to the heart, lungs, and kidneys), nerve damage, blood in the urine, or even another type of cancer.¹⁸⁸

Whether terminally ill or elderly, patients should have an opportunity to assess for themselves the benefits and risks of an alternative medical treatment, after having been fully informed as required under AMTA, and then have the right to choose the treatment they desire. Assessing risks and benefits usually requires a subjective determination that accounts for circumstances unique to each individual and is, therefore, ill-suited for the FDA bureaucracy.¹⁸⁹ The terminally ill and the elderly, with the help of their doctors, are in the best position to make this determination and choose their desired medical treatment.¹⁹⁰

However, for the remainder of medical patients, the risk of serious injury and death probably exceeds the benefits of allowing a completely open and free market for prescription drugs. Young and middle-aged patients who are not terminally ill generally live longer than terminally ill and elderly people and thus have more to lose by taking experimental drugs. Besides living longer than the terminally ill and the elderly, younger patients may have families, especially small children, who rely on them for support. These patients also tend to have less serious diseases than the terminally ill and even the elderly, who have weaker immune systems and can die from minor diseases.¹⁹¹ In summary, the younger patient generally has less to gain and more to lose from an alternative medicine than the terminally ill or elderly patient.

188. MayoClinic.com, Chemotherapy: Using Chemicals to Treat Cancer, <http://www.mayoclinic.com/health/chemotherapy/CA00029> (last visited Aug. 18, 2006).

189. Cf. Greenberg, *supra* note 94, at 315 (arguing that regulatory risk assessment “may operate to the detriment of smaller groups of people whose risks and benefits differ dramatically from those of an idealized general public”).

190. Horwin, *supra* note 120, at 708; *see also* Greenberg, *supra* note 94, at 296–97 (noting the increased sentiment during the AIDS epidemic that patients whose lives depended on experimental drugs were in a better position to make risk-benefit decisions regarding their own use of these drugs than was the FDA).

191. *See* KATHY POND, WATER RECREATION AND DISEASE. PLAUSIBILITY OF ASSOCIATED INFECTIONS: ACUTE EFFECTS, SEQUELAE AND MORTALITY 28 (2005), available at http://www.who.int/water_sanitation_health/bathing/recreadischap2.pdf.

A. Proposed Modifications to AMTA

AMTA should be limited to terminally ill patients and elderly patients age sixty-five and older. With life expectancies approaching seventy-five years for males and eighty years for females,¹⁹² sixty-five-year-olds should be able to take into account their life expectancy when assessing the potential benefits and risks of an experimental treatment.

Moreover, AMTA should require the terminally ill and the elderly to seek the opinion of a second doctor before proceeding with an alternative treatment or drug. The second opinion would not be binding upon the patient, thus allowing the patient to choose to proceed with the first doctor's recommended treatment even if the second doctor disagrees. The purpose of this requirement is to give the patient an opportunity to hear another doctor's perspective and adequately assess the value of the treatment. The added time involved in seeking a second opinion would also allow a patient to fully evaluate his or her situation before proceeding and discourage hasty decisions. Finally, an opinion from a second doctor would help shield the patient from pressure by the first doctor and help to reveal any false or misleading information the first doctor may have given.

Finally, AMTA should require the doctor suggesting the treatment to disclose any financial interest in the experimental treatment. Whether a doctor has a significant financial interest in the treatment he or she is prescribing can affect the patient's trust in the doctor's opinion. Without knowing the doctor's stake in the success of the medicine, the patient cannot be fully informed and make a responsible decision regarding the use of such medicine.

Along with these proposed AMTA modifications, health care practitioners, tort liability, the Internet, and regulating market factors would help protect elderly and terminally ill patients from dangerous drugs and scams.¹⁹³ As a whole, these safeguards would adequately shield uninformed patients from danger and help insure that those who choose to risk taking an untested drug are fully informed of the possible consequences.

192. CTRS. FOR DISEASE CONTROL & PREVENTION, HEALTH, UNITED STATES, 2004, WITH CHARTBOOK ON TRENDS IN THE HEALTH OF AMERICANS 143 tbl.27 (2004), available at <http://www.cdc.gov/nchs/data/hus/04trend.pdf>.

193. See *supra* Part III.C.

B. Would the FDA Go Down in Flames?

Because AMTA would be limited to the terminally ill and the elderly, the FDA would survive and continue to regulate drugs. Patients younger than sixty-five who do not have terminal illnesses would still need the conventional medical treatments available with FDA approval. For that matter, some elderly patients would still want the safety of FDA-approved drugs, particularly for relatively simple or minor diseases where the risk of serious harm from an experimental drug outweighs the benefits of a potential cure. AMTA or similar legislation would essentially establish a dual system of FDA-approved and unapproved prescription drugs. While its presence in drug regulation would decrease, the FDA would still play a significant role in regulating the drugs available to Americans younger than sixty-five as well as the drugs aimed at treating minor diseases regardless of the patient's age.

V. Conclusion

Whether Congress chooses to pass AMTA or similar legislation, alternative medical treatments need to be accessible to terminally ill and elderly patients. Current means of medical treatment are not doing enough to curb disease.

Until Congress passes legislation to help the terminally ill and elderly, many more patients like Alita Randazzo will die, perhaps needlessly, because the FDA denies them potentially life-saving and life-prolonging medical treatment. Until then, older patients will remain victims to the authoritarian paternalism of the FDA, which displaces a person's judgments with its own bureaucratic analysis. In doing so, the FDA not only denies the elderly access to beneficial drugs, but also the right to decide their own medical destiny.