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AIDS AND DRUG PRICING: IN SEARCH OF A POLICY

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In the early 1980s, doctors observed a pattern of medical symptoms that would later be diagnosed as Acquired Immune Deficiency Syndrome (AIDS).[1] A virus causes the disease, which results in a general weakening of the immune system and susceptibility to different kinds of physical illness. The symptoms have proved fatal for hundreds of thousands of people with AIDS (PWAs). By 1990, AIDS was the tenth leading killer of Americans and the third most prevalent cause of death among young Americans.[2] As of September 1992, approximately 242,000 Americans have been diagnosed as having AIDS, and the Centers for Disease Control (CDC) estimate that over half a million Americans will be diagnosed with AIDS by 1995.[3] Of those diagnosed, a disproportionate incidence occurs among blacks[4] and Hispanics.[5] The CDC projects that at least 330,000 Americans will die from AIDS by 1995.[6]

For over a decade, scientists have attempted to find both a vaccination and a cure for AIDS through research and development. Most research activity occurs in private laboratories, typically located within pharmaceutical firms, and in university and government-supported facilities. Because federal and state[7] funding supports a significant amount of both

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1. The recognition of symptoms of AIDS can be traced back at least to 1979, when an increase was observed in reported cases of Kaposi's sarcoma. The acknowledgement of AIDS as a disease is generally considered to have occurred in 1981.

2. *AIDS 10th Leading Killer of Americans in 1990*, REUTER LIB. RPT., Jan. 7, 1993, Financial Report.

3. *AIDS Deaths Mount More Slowly*, WASH. TIMES, Jan. 15, 1993, at A2.

4. *More Casualties of AIDS*, BOS. GLOBE, Jan. 2, 1993, at 10.

5. *See* Richard A. Knox, *Burden for Puerto Ricans Reaches Crisis Stage—The Changing Face of AIDS*, BOS. GLOBE, June 18, 1990, at 1 ("AIDS incidence among Hispanics has consistently run more than double than among whites.").

6. Amanda Husted, *Health Watch CDC: 330,000 Americans Will Die From AIDS by 1995*, ALT. CONST., Jan. 15, 1993, at D3.

7. AIDS funding has been cut recently in some states, including Texas. The trend is likely to

academic and corporate AIDS research,[8] the line between public and private initiatives is ambiguous.

To date, research has had limited applicable success, resulting in the development of a few drugs that are used to treat patients with AIDS or those who have been diagnosed as HIV positive but are asymptomatic. None of the drugs approved by the Food and Drug Administration are unambiguously effective or without serious potential side effects. For this reason, members of the medical community have questioned the advisability of using several of the drugs.[9]

The most highly publicized controversy over AIDS drug pricing[10] began in 1987, when the British pharmaceutical company Wellcome introduced azidothymidine (AZT) to the American market. Wellcome originally priced its AZT product, branded as Retrovir, at $10,000 for annual treatment.[11] Industry representatives estimated Wellcome's cost of bringing the product to market at approximately $80 million.[12] Sales of AZT quickly surpassed $220 million per year.[13] Largely as a result of public criticism, Wellcome reduced the annual price to approximately $3,000 per year by 1990, still receiving a margin some have estimated to

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continue, given current budgetary shortfalls. *See* Cindy Rugeley, *Funding Cuts Over AIDS Anger Official*, HOUS. CHRON., Jan. 8, 1993, at A19.

8. *See infra* notes 75-81, 103-105 and accompanying text.

9. For discussion of the therapeutic benefits and disadvantages of AZT, see Margaret A. Fischl et al., *The Efficacy of Azidothymidine (AZT) in the Treatment of Patients with AIDS and AIDS-Related Complex: A Double-Blind, Placebo-Controlled Trial*, 317 N. ENG. J. MED. 185 (1987); Douglas D. Richman et al., *The Toxicity of Azidothymidine (AZT) in the Treatment of Patients with AIDS and AIDS-Related Complex: A Double-Blind, Placebo-Controlled Trial*, 317 N. ENG. J. MED. 192 (1987).

10. The author refers here to controversies regarding pricing of drugs for the treatment of AIDS, but many of the observations made in this Article have obvious, broader implications regarding drug pricing in general. The pharmaceutical industry is currently under congressional scrutiny for alleged abuses. *See* Elyse Tanouye & Michael Waldholz, *Senate Study of Drug Prices Could Prove a Bitter Pill for Pharmaceutical Makers*, WALL ST. J., Feb. 3, 1993, at B1 (citing a forthcoming senate study "expected to show that major drug companies broke public promises to hold price increases below the inflation rate in 1992.").

11. Stephen D. Moore, *CEO Robb Adds Spice to Mix of Drugs at Wellcome*, WALL ST. J., Jan. 4, 1993, at B4, col. 3.

12. See BRUCE NUSSBAUM, GOOD INTENTIONS: HOW BIG BUSINESS AND THE MEDICAL ESTABLISHMENT ARE CORRUPTING THE FIGHT AGAINST AIDS 176-179 (1990). The author states that under early congressional scrutiny, Wellcome itself estimated these costs at $80 million, but refused to supply documentation. Nussbaum also observes that a Wellcome representative later stated that only $30 million of that $80 million represented past expenditures. The remaining $50 million ostensibly represented future expenditure towards the marketing of AZT.

13. THOMAS L. BEAUCHAMP, *AIDS and the Availability of AZT*, *in* THOMAS L. BEAUCHAMP, CASE STUDIES IN BUSINESS, SOCIETY AND ETHICS 207, 209 (3d ed. 1993).

equal 70 percent of production and marketing costs.[14] According to Wellcome's 1992 annual report, sale of AZT, under the trademark Retrovir, generated approximately $388 million in revenues,[15] notwithstanding successive price adjustments.[16] In tandem with a 50 percent reduction in dosage, the annual cost of Retrovir treatment was approximately $2,500 by early 1993.[17]

Attempts to divest Wellcome of its patent rights to AZT have come from several sources, including the National Institutes of Health (NIH), competing pharmaceutical companies, and public interest groups. In July 1991, Bernadine Healy, Director of the NIH, issued a press release stating her belief that NIH investigators played a role in the development of AZT as an AIDS treatment, which merited their inclusion as inventors on the patent.[18] That same year, Barr Laboratories filed an abbreviated new drug application with the Food and Drug Administration (FDA) seeking approval to manufacture a generic drug containing AZT.[19] Wellcome retaliated by suing Barr Laboratories for patent infringement.[20] In 1992, a judge in the District of Columbia dismissed a case initiated against Wellcome by the People With AIDS Health Group for lack of subject matter jurisdiction.[21] Most recently, Wellcome's competitor Novopharm announced its plan to sell AZT without seeking a FDA license, citing as justification its ability to reduce costs to consumers.[22]

The case of AZT is only one example of a pattern that has developed throughout the pharmaceutical industry in the marketing and pricing of AIDS treatments. In 1992, seven drugs prescribed for AIDS-related ill-

14. *Profiting From Disease*, ECONOMIST, Jan. 27, 1990, at 17.

15. THE WELLCOME PLC, ANNUAL REPORT 60 (1992).

16. Moore, *supra* note 11. Two twenty-percent price reductions followed outcry by AIDS activists.

17. Moore, *supra* note 11.

18. Statement of Bernadine Healy, July 17, 1991.

19. John A. Jones, *Barr Labs Boosts Earnings While Awaiting AZT Decision*, INV. BUS. DAILY, Sept. 19, 1991, at 34; *Barr Labs Hopes NIH Was Co-Inventor of AZT*, 12 INSTITUTIONAL INV., INC., Portfolio Letter, July 29, 1991, at 3.

20. Burroughs Wellcome Co. v. Barr Laboratories, 143 F.R.D. 611 (E.D.N.C. 1992). The district court granted in part and denied in part Barr's motion seeking the production by Wellcome of 357 documents.

21. People With AIDS Health Group v. Burroughs Wellcome, No. 91-0574, 1992 U.S. Dist. LEXIS 578 (D.C.D.C. Jan. 17, 1992).

22. John Crewdson, *Documents May Hurt U.S. Efforts to Share Patent, Cut AZT Price*, CHI. TRIB., Oct. 4, 1992, at C3.

nesses varied in average monthly price from $160 to $1,740.[23] In terms of annual costs to consumers, these drugs range from $1,920 to $20,882.88. In a typical instance, a Swedish pharmaceutical company, Astra, has faced activist accusations of price gouging for its $21,000 annual charge for a supply of Foscavir, which is used to prevent CMV retinitis.[24] The company defended its pricing decision, asserting the need to recoup high research and development costs.[25] These prices, like the price of AZT, are likely to surpass the means of many Americans, especially the uninsured. Because current prices of potentially life-sustaining drugs are unacceptable to most consumers, the same scenario is likely to repeat itself with each new product entry: steep prices followed by activist outcry that eventually leads to moderate price concessions.

Critics have argued throughout the 1980s and into the 1990s that both governmental and private research efforts are unsatisfactory.[26] They contend that federal funding is far below the levels needed to expedite the search for prevention and cure, resulting in past and future suffering and mortality which could be avoided if AIDS were given greater budgetary priority.[27] This line of criticism often states or implies that governmental restriction of AIDS spending is a result of social devaluation of two classes of persons categorized as high-risk: male homosexuals and intravenous drug users.[28] Critics contend that sluggish governmental response results from the attitude that: (1) PWAs in these categories are responsible for their illnesses; (2) people develop AIDS because of engagement in immoral activity; and, (3) the loss of health and life among persons in these categories is less costly than the loss of persons in classes

23. *See* Michael Waldholz, *Astra Faces Fight Over Cost of AIDS Drug*, WALL ST. J., January 21, 1992, at B1 (citing New York City pharmacies as the source for the following list of monthly AIDS drug prices: Retrovir (AZT), $220-440; Videx (DDI), $220-320; Diflucan, $1,000; Pentam, $160; Zovirax, $520; Cytovene, $1,100; Foscavir, $1,740).

24. *Id.*

25. *Id.*

26. *See, e.g.*, DANIEL M. FOX, *AIDS and the American Health Polity: The History and Prospects of a Crisis of Authority, in* AIDS: THE BURDENS OF HISTORY 316 (Elizabeth Fee & Daniel M. Fox eds., 1988) (suggesting that strong leadership in the form of a centrist coalition is vital to the expedient handling of the AIDS crisis, and that such leadership, absent from federal sources, has been supplied to some degree by local sources).

27. *See, e.g.*, ROBERT M. WACHTER, THE FRAGILE COALITION: SCIENTISTS, ACTIVISTS, AND AIDS (1991) (discussing the fight over AIDS funding and other political AIDS issues during the 1989 International Conference on AIDS).

28. For a discussion of the marginalization and devaluation of high-risk groups, see Liz McMillen, *Research Council's Report on AIDS Draws Fire for 'Insensitivity,'* CHRON. HIGHER ED., Feb. 24, 1993, at A9.

less socially marginalized.[29]

These and other critics[30] have also attacked corporations, particularly private pharmaceutical companies engaged in AIDS and cancer research, for what they consider unconscionable pricing of drugs approved by the FDA for AIDS and cancer treatments under protection of federal patent monopoly grants.[31] These critics argue that market incentives that encourage research and development expenditure, while desirable, do not justify pricing so exorbitant as to deny access to potentially life-saving drugs.[32] In addition, they suggest that the ostensible need for incentives may be exaggerated, given governmental subsidization of research and development costs.[33]

Activists have demanded the creation of public policies that promote AIDS research without establishing unfettered monopoly power.[34] For example, the prices of some drugs are regulated in Great Britain, where the cost of one month's supply of aerosol pentamidine, a drug for the prevention of AIDS-related pneumocystis carinii pneumonia, was $26 in 1990, compared to the unregulated price of $150 in the United States.[35]

Supporters of current levels of governmental spending, as well as those who prescribe a decrease in spending, emphasize that current budget levels for AIDS research are more generous than amounts spent, per patient, to study other diseases.[36] Some also assert that AIDS, unlike most

29. For discussion of various perspectives from the gay and lesbian communities regarding AIDS policy, see Scott Harris, *Gay Militancy—The Last Civil Rights Move?*, L.A. TIMES, Oct. 11, 1991, at A1.

30. The pharmaceutical industry is under increasing pressure to curb spiraling prices of all kinds of drugs, applicable to a wide variety of diseases other than AIDS. For a discussion of the general public dissatisfaction with drug prices, see Joseph Weber, *For Drugmakers, The Sky's No Longer the Limit*, BUS. WK., Jan. 27, 1992, at 68.

31. *See, e.g.*, Harvey F. Wachsman, *Regulate the Drug Monopolies*, N.Y. TIMES, Jan. 16. 1993, § 1, at 21 (observing pricing abuses under drug patent monopolies and suggesting regulatory action to curb excesses).

32. *See* Brian O'Reilly, *The Inside Story of the AIDS Drug*, FORTUNE, Nov. 5, 1990, at 112, 116 (discussing the Wellcome pricing decisions regarding AZT in light of the notion that "government research saved so much money that the high price of AZT was unwarranted.").

33. *See infra* note 103 and accompanying text.

34. *See* Michael Parrish & Jane Applegate, *Hope grows for Generic AIDS Drug*, L.A. TIMES, May 30, 1991, at D1 (discussing efforts to expedite the availability of a generic form of AZT).

35. Christine Gorman, *The Price Isn't Right: Drug Firms Start to Feel the Heat as the Cost of Medication Spirals*, TIME, Jan. 8, 1990, at 56.

36. For a discussion of competition for health spending dollars among various diseases, see Robert Pear, *AIDS Spending Debate*, CHI. TRIB., Feb. 18, 1993, at C7. For a discussion of the cost of AIDS in comparison with other diseases, see William A. Mundell & Jack Friedman, *Financing to Meet AIDS's True Costs*, N.Y. TIMES, Nov. 22, 1992, § 3, at 11.

diseases, can be controlled by individual responsibility and altered behavior. Therefore, they contend, AIDS research should have a lower priority than investigation of cancer or other illnesses perceived to have a more tenuous behavioral nexus.[37] Others have noted that limitations in AIDS research budgets reflect the compromise that exists among the tensions of competing areas of needs, particularly when the government is seeking to balance the budget by reducing federal spending.[38]

Drug companies defend their pricing decisions as unavoidable, given the high cost of finding, testing, and gaining FDA approval of new drugs[39] and the expenses related to doing business in a heavily regulated industry.[40] The companies cite the economic view, incorporated in the conferral of monopoly rights associated with patent grants, that heavy private spending on research and development is generated by prospects of large profits.[41] Taken to its logical conclusion, this perspective suggests that pressures to deny private corporations monopoly profits will act as a disincentive to pursue research and ultimately impede progress in finding preventative and curative treatments.[42]

37. *See* Michael Mason, *AIDS, God and Uncle Sam: Don't Begrudge Money to Fight Deadly Disease*, ATL. CONST., Nov. 25, 1991, at A11 (quoting then-President Bush as defending moderate spending on AIDS because it "is a disease where you can control its spread by our [sic] own personal behavior." *Id.* The article quotes an anonymous Louisiana woman, "It really burns me up that [(gays')] own moral conduct brings AIDS on them, but they still get all that federal money. None of these other diseases are self induced. The rest of us are being shortchanged."

38. SANDRA PANEM, THE AIDS BUREAUCRACY 81 (1988).

39. Milt Freudenheim, *The Drug Makers' Defense on Costs*, N.Y. TIMES, May 4, 1991, at D2.

40. These expenses are a function of the large number of legal concerns facing pharmaceutical companies. For a detailed documentation of legal issues facing AIDS drug manufacturers, see Alison Joy Arnold, Comment, *Developing, Testing, and Marketing an AIDS Vaccine: Legal Concerns for Manufacturers*, 139 U. PA. L. REV. 1077 (1991). Although the author focuses on legal issues within the context of developing an AIDS vaccination, most of her observations are relevant to the development of all AIDS treatments.

41. *Id.*

42. The regulatory climate of the American pharmaceutical industry in the 1960s and 1970s was blamed by some for the erosion of competitiveness in world markets. *See, e.g.*, Harold A. Clymer, *The Economic and Regulatory Climate: U.S. and Overseas Trends, in* DRUG DEVELOPMENT AND MARKETING 137 (Robert B. Helms ed., 1975) (blaming regulation for an inability to obtain reasonable returns on research and development investments).

Notwithstanding industry criticism of the ostensibly harmful effects of regulation on the profitability of American firms, the pharmaceutical industry was the nation's most profitable industry between 1960 and 1990. *See* Brian O'Reilly, *Drugmakers Under Attack*, FORTUNE, July 29, 1991, at 48 (providing comparative profitability data for the period between 1960 and 1990).

This trend may be reversing in the 1990s. *See* Craig Torres & Michael Waldholz, *Battered Drug Stocks Dive; Bargain Hunters are Leery*, WALL ST. J., Feb. 17, 1993 at C1 (discussing the slump in pharmaceutical stock prices which has resulted from Clinton administration criticism of the industry's practices).

Recently, drug companies have initiated research projects exploring the economic effects of various treatments. The studies supply data revealing the extent to which particular pharmaceutical treatments reduce costs of untreated illness, thereby yielding a net economic benefit to consumers.[43] For example, Amgen has justified its cost of $1,000 per treatment for the drug Neupogen by demonstrating potential savings of $7,000 in avoided hospitalization costs.[44]

Pricing of drugs under monopoly status need not always provoke antagonisms between corporate and activist interests. P. Roy Vagelos, chairman of Merck & Company, suggests that drug companies engage in responsible drug pricing by monitoring themselves to avoid levels of profits that deny access to crucial drugs.[45] Vagelos contends, "If the price is too high and the patient cannot afford the medicine, we have not fulfilled our reason for existence."[46] This attitude, which reflects a vision of the pharmaceutical industry as coupled with an obligation of public service, may lead to voluntary resolution of the tension that often exists between corporate and consumer interests.

Vagelos has recently recommended to the Clinton administration a voluntary system of corporate responsibility, under which companies would limit price increases to the rate of inflation.[47] Under particularly heavy public criticism during the early months of 1993, some pharmaceutical industry officials have even supported proposed regulations for monitoring and enforcing nominally "voluntary" price controls.[48] Yet, managers at other drug companies have appeared angered by these proposals and have suggested that they will not comply with any price control measures that remain truly voluntary.[49]

Given the recent history of heated conflict between private, governmental and consumer groups over AIDS treatment, questions of corporate accountability must be addressed in the absence of pervasive

43. Joan O'C. Hamilton, *Sure the Drug Works, But Is It Worth It?*, BUS. WK., Aug. 26, 1991, at 62. This kind of study is called "outcomes research." *Id.*

44. *Id.*

45. *Merck's View on Prices*, N.Y. TIMES, May 24, 1991, at D3.

46. *Id.*

47. Jeffrey H. Birnbaum & Michael Waldholz, *Harsh Medicine Prices*, WALL ST. J., Feb. 16, 1993, at A1, A6.

48. Michael Waldholz, *Drug Executives Yield Ground to White House*, WALL ST. J., Mar. 10, 1993, at A3.

49. *See supra* note 47.

corporate responsibility.[50] A study of the normative questions that arise regarding the pricing of drugs for AIDS treatment is a prerequisite to the development of intelligent and effective public policy. Much has been written about the FDA approval process of drugs[51] and its effect on access to AIDS treatment.[52] No comprehensive analysis exists, however, regarding the legal, economic and ethical issues concerning the pricing of products once they become legally available to patients.[53] The efficacy of humane liberalization of drug access laws, in deference to individual choice in the assessment of personal risks, is tempered to the extent that

50. With criticism of the pharmaceutical industry reaching a peak at the start of the Clinton administration's new term, industry representatives who do not share Vagelos's conception of mission may still consider some concession strategically superior to resisting price concessions. Mitch Daniels, an executive at Eli Lilly, labels this approach "pre-emptive surrender," and notes that it may be the best industry stance in the current political climate. Rich Jaroslovsky, *Washington Wire*, WALL ST. J., Feb. 19, 1993, at A1.

51. *See, e.g.*, George J. Annas, *Faith (Healing), Hope and Charity at the FDA: The Politics of AIDS Drug Trials*, 34 VILL. L. REV. 771 (1989) (defending FDA requirement of rigorous standards in AIDS drug testing); Marsha N. Cohen, *Getting New Drugs to People With AIDS: A Public Policy Response to Lansdale*, 18 HASTINGS CONST. L.Q. 471 (1991) (observing that patient needs for therapy should be considered in designing drug approval mechanisms, on public policy grounds rather than Constitutional grounds); John Patrick Dillman, Note, *Prescription Drug Approval and Terminal Diseases: Desperate Times Require Desperate Measures*, 44 VAND. L. REV. 925 (1991) (surveying and comparing American and British drug approval systems, and critiqing the American system); *Ill Treatment*, WALL ST. J., Aug. 7, 1985, at 16 (discussing increased delays in FDA approval during the mid 1980s); Susan Okie, *AIDS Sufferers Buying Hope*, WASH. POST, Apr. 2, 1988, at A1, A6 (citing FDA commissioner Frank Young's sympathy with pressures to expedite the processes of approving or making available experimental AIDS treatments).

In 1988, the FDA responded to mounting pressures to expedite the approval process for new drugs by promulgating a regulation establishing a fast-track for the approval of drugs intended for the treatment of diseases considered either severely debilitating or life-threatening. Investigational New Drug, Antibiotic and Biological Drug Product Regulations: Procedures for Drugs Intended to Treat Life-Threatening and Severely Debilitating Illnesses, 53 Fed. Reg. 41,516 (1988). For discussion of the requirements and conditions of fast-track approval under the regulation, see Richard J. Nelson, Note, *Regulation of Investigational New Drugs: "Giant Step for the Sick and Dying"?*, 77 GEO. L.J. 463, 473-475 (1988).

52. Pressures to expedite AIDS drug approvals led in 1987 to regulatory changes that liberalized access to experimental treatments. *See* Title, 21 C.F.R. § 312.34(b)(1)(i)-(iv) (1988) (allowing treatment through the use of "investigational new drugs" during the clinical investigation stage to those suffering from life-threatening disease as long as no comparable drug or therapy is available, and the sponsor of the drug is seeking FDA marketing approval with due diligence).

53. For a good historical/legal analysis of policy issues related to drug pricing, including a brief examination of pricing controls in other countries, see Mary T. Griffin, *AIDS Drugs and the Pharmaceutical Industry: A Need for Reform*, 17 AM. J.L. & MED. 363 (1991).

While Griffin's work provides a detailed account of drug regulation in general and AIDS drug regulation in particular, the approach is historical. My analysis departs from Griffin's approach by examining normative policy questions from an ethical perspective.

drug pricing places treatment beyond the reach of the intended beneficiaries of reform.

This Article presents a comprehensive analysis of the policy considerations regarding the pricing of new AIDS drugs. Part I discusses the two countervailing interests that dominate the debate: the effect of patent monopoly policy on the speed and extent of research and development initiatives and the effect of monopoly pricing on drug accessibility. Part II addresses legal, economic, and ethical concerns that are crucial to the formulation of a sound drug pricing policy, including the principles of monopoly theory, the relationship between monopoly and regulation, the proper allocation of price concessions that reduce profits from normal monopoly levels, and the determination of how much profit is necessary to optimize research and development efforts. Part III examines a "negotiated drug pricing" proposal, aimed at creating and maintaining a fair, effective, and efficient response to the AIDS crisis. Part IV contains concluding remarks and suggests further areas of research and inquiry helpful to the thoughtful resolution of the public policy challenges raised herein.

I. PUBLIC POLICY, PATENTS, AND MONOPOLIES

A. Patent Law

Under U.S. patent law, an inventor who holds a patent is granted the exclusive right to make, use and sell the invention for seventeen years.[54] One can only receive a patent for novel,[55] useful[56] and nonobvious[57] inventions.

Patent monopoly rights represent an effort to balance largely incompatible incentives that can never be perfectly reconciled.[58] The prospective granting of a seventeen-year monopoly to a patent recipient, as potentially extended under the Drug Price Competition and Patent Term Restoration Act of 1984,[59] encourages expensive research and develop-

54. Patent Act of 1952, as revised in 35 U.S.C. § 154 (1988).

55. *Id.* at §§ 101, 102.

56. *Id.* at §§ 101, 112.

57. *Id.* at § 103.

58. For an exhaustive examination of patent policy and its effects on scientific progress, see Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989); for a detailed discussion of public policy tradeoffs inherent in different theoretical patent approaches, see Mark F. Grady & Jay I. Alexander, *Patent Law and Rent Dissipation*, 78 VA. L. REV. 305 (1992).

59. The normal patent life of seventeen years, conferred under the Patent Act, can potentially

ment.[60] A pharmaceutical company can only justify the cost of groundbreaking applied science when the expected value of profits resulting from monopoly pricing power, including evaluation of all risks, exceeds the hurdle rates established by the company for its new research projects.[61] Absent artificially inflated monopoly profits, incentives for innovation are dramatically reduced.[62] Moreover, the monopoly granted to a groundbreaker ideally allows for early diffusion of information by virtue of the property protection it affords.

The monopoly granted for patented products must be robust in order to provide an incentive to innovate—it must confer an inducement sufficient to encourage the project under initially risky conditions. Yet, a sphere of monopoly protection that is too strong can undermine the policy goals of patent law in several ways.

First, post-monopoly research aimed at refining and improving the product or inventing similar products must also be encouraged.[63] This activity has numerous potential beneficial effects, including increases in

be extended under the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 21 U.S.C. and 35 U.S.C.) [hereinafter Restoration Act]. The purpose of the Restoration Act is, *inter alia*, to encourage pharmaceutical research and development through the extension of drug patent terms in compensation for time expended on FDA approval processes. H.R. REP. No. 857, 98th Cong., 2d Sess., pt. 1, at 15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648. Extension periods are determined as a function of F.D.A. review time spent on assessing safety and effectiveness, as well as approval of marketing plans. For discussion of the Restoration Act, see ALLEN M. FOX & ALAN BENNETT, THE LEGISLATIVE HISTORY OF THE DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT OF 1984 (1987); Susan Kopp Keyack, Note, *The Drug Price Competition and Patent Term Restoration Act of 1984: Is it a Healthy Long Term Solution?*, 21 RUTGERS L.J. 147 (1989).

60. For discussion of patent policy and incentives to innovate, see Robert P. Merges, *Commercial Success and Patent Standards: Economic Perspectives on Innovation*, 76 CAL. L. REV. 805 (1988); A. Samuel Oddi, *Beyond Obviousness: Invention Protection in the Twenty-First Century*, 38 AM. U. L. REV. 1097 (1989).

61. For a thorough discussion of high-technology project selection, see BRIAN C. TWISS, MANAGING TECHNOLOGICAL INNOVATION at 119-147 (1974). Generally, capital intensive projects are evaluated using some method of discounted cash flow analysis. For a good introduction to this concept, see ALFRED RAPPAPORT, CREATING SHAREHOLDER VALUE: THE NEW STANDARD FOR BUSINESS PERFORMANCE (1986).

62. Under this line of reasoning, drug patenting has traditionally been justified as a regulatory necessity arising from market failure. *See, e.g.*, HENRY G. GRABOWSKI, DRUG REGULATION AND INNOVATION: EMPIRICAL EVIDENCE AND POLICY OPTIONS 11-14 (1976) (discussing the market failure rationale for drug regulation).

63. For discussion of patent law and innovations that "design around" or improve existing patents, see Jordan P. Karp, Note, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169 (1991).

product quality and manufacturing efficiencies, as well as the inducement of competition which should ideally act as a natural moderator of price. Moreover, incentives to refine patented products should expedite the development and improvement of those products. The tension between groundbreaker, early-entrant monopoly interests and late entrant interests is unavoidable: the more inviolate and all-encompassing the sphere of the groundbreaker's monopoly, the greater the groundbreaker's incentive to engage in pioneering work, but the lesser the followers' incentive for refinement.[64]

Second, commentators argue that the protection of individual property rights in the patent-granting process may inadvertently encourage a culture that eschews optimally efficient cooperative efforts.[65] Yet, the possibility of joint-venture activity and contracts that establish prospective shares in potential innovations suggests that impediments to cooperation resulting from prospective monopoly grants are somewhat illusory. While the patent process fosters a competitive environment in which laboratories are involved in a race for discovery,[66] patenting does not foreclose a wide scope of possible cooperative arrangements for the mutual enhancement of advantage.

Still, as clusters of cooperating entities engage in isolated research, the potential for inefficient duplication of effort increases.[67] Moreover, potential team discoveries may remain forever unrealized.[68] Coordination of AIDS research, aimed at the sharing of scientific information, is therefore important.[69]

Nevertheless, the benefits of centrally managed research programs

64. For an examination of the relationship between patents and market entry of close substitutes, see Michael Waterson, *The Economics of Product Patents*, 80 AMER. ECON. REV. 860 (1990).

65. *See* Richard C. Levin et al., *Appropriating the Returns from Industrial Research and Development*, 3 BROOKINGS PAPERS ON ECON. ACTIV. 783, 788 (1987) ("Because technological advance is often an interactive, cumulative process, strong protection of individual achievements may slow the general advance.").

66. For a discussion of patent races, see Jennifer Reinganum, *The Timing of Innovation: Research, Development, and Diffusion*, *in* 1 HANDBOOK OF INDUSTRIAL ORGANIZATION 849 (Richard Schmalensee & Robert D. Willig eds., 1989).

67. Levin et al., *supra* note 65, at 787-788.

68. The author refers here to a synergistic phenomenon familiar to all who have engaged in collaborative efforts, wherein the contributions of two persons, of no value in isolation, provide a solution to the puzzle when mixed in a collaborative process. Often the contributions of collaborator B would not be triggered without an off-hand suggestion made by Collaborator A. Likewise, Collaborator A would not make the jump from her own suggestion to the contribution of Collaborator B in isolation.

69. *See* Edward N. Brandt, Jr., *Government Involvement and the Development of Public Policy*

may be incompatible with the open marketplace of scientific competition. Incentives of both potential property rights and potential glory are central to both academic and commercial research in the United States. At some level, the contest to achieve these prizes must become competitive. Implicit in the patent monopoly is a faith that the impetus to innovation conferred by possible monopoly rents outweighs competitive inefficiencies, redundancies, and lost opportunities for synergy, especially given the collaborative opportunities that remain within an essentially competitive milieu.[70]

Third, the "winner-take-all" mentality of patent law, which denies any return to late finishers, may serve to discourage some valuable research. Companies assessing risks and predicting rewards are likely to abandon potentially fruitful projects because the patent for a product recognizes only the efforts of one technical inventor.[71] Because patent law magnifies the risks faced by smaller companies and late entrants,[72] one group of researchers has argued in favor of a system that awards multiple prizes.[73] The one-winner approach of patent law may also indirectly discourage cooperation, by reducing the incidence of overlapping or synergistic research. As patent law directs laboratories to seek their own unique ground and concomitant early-entrant advantages, the pool of potential collaborators is likely to diminish.

Finally, a natural tension exists between monopoly pricing power, which encourages the initial discovery or invention, and the actual diffusion of both the technology and the product, which is the ultimate policy goal behind the monopoly grant.[74] While the prospect of inflated rents

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in AIDS Research and Reporting, *in* AIDS AND PATIENT MANAGEMENT: LEGAL, ETHICAL AND SOCIAL ISSUES 36, 40 (Michael D. Witt ed., 1986).

70. Because collaboration is bounded by the limitations of group dynamics and individual cognitive confines, losses attributable to replication of efforts across labs and collaborative opportunity costs may be inevitable. In a free marketplace and under the incentives created by patent law, the best functionally sized entities may naturally develop, unavoidably replicating some efforts as a natural by-product of the competitive process.

71. For an examination of probability assessment in the race for new discoveries, see Steven A. Lippman & Kevin F. McCardle, *Preemption in R&D Races*, 32 EURO. ECON. REV. 1661 (1988).

72. While size may be an advantage in the pursuit of a patent, management capabilities such as research skills, development skills, and marketing quality may supersede size as a strategic variable. For discussion of managerial considerations that may challenge the "bigger is better" view regarding pharmaceutical development, see *Management Focus: The Big Pill*, ECONOMIST, Mar. 6, 1993, at 67.

73. Manfredi La Manna, et al., *The Case for Permissive Patents*, 33 EURO. ECON. REV. 1427 (1989).

74. This tension is part of a larger conflict: what is the appropriate allocation of available resources between research and treatment? In 1986, approximately $542 million went to AIDS pre-

should expedite research and development efforts, the assessment of those rents during the seventeen-year duration of the patent impairs the immediate distribution of and access to protected products. In the balance, impediments to the immediate distribution of new products are usually outweighed by the very development of the product itself, which may have been enabled solely by the granting of the patent. If the choice is between invention followed by impaired distribution for several years and no invention at all, the delay in diffusion that inevitably results from monopoly pricing appears to be justified.

The model under which unlimited monopoly pricing potential is believed to induce optimal research and development is sound. There are some potential drawbacks, such as negative efficiencies that may accompany competitive as opposed to cooperative exploration. Yet, the effectiveness and fairness of unbridled monopoly power are even more substantially limited by another factor: the significant amount of public subsidization which currently exists to encourage and support private AIDS treatment research. Subpart I(B) examines the nature and degree of federal and state spending on AIDS research and the manner in which the existence of these subsidies erodes both the size of the corporate stake in the ultimate product, and the motivational legitimacy of monopoly expectations as an inducement for private research efforts.

B. The Orphan Drug Act

Private pharmaceutical companies that are involved in AIDS research are the beneficiaries of direct federal funds as well as significant regulatory and tax benefits under the Orphan Drug Act (Act).[75] The Act was created to provide private pharmaceutical companies with incentives to conduct research to find treatments for rare diseases and conditions.[76] Congress was persuaded to pass the Act because the rarity of certain diseases so limited the pool of potential consumers that even patent-conferred monopoly rents would create insufficient research and development incentives.[77]

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vention activities and programs, with 43% of this figure going to AIDS research. That same year, approximately $1 billion was spent on AIDS treatment. Jane E. Sisk, *The Cost of AIDS: A Review of the Estimates*, 6 HEALTH AFF. 5 (Summer, 1987).

75. Pub. L. No. 97-414, 96 Stat. 2049 (1983).

76. *Id.* at 2049; *see also* H.R. REP. No. 840(I), 97th Cong., 1st Sess. (1982), *reprinted in* 1982 U.S.C.C.A.N. 3577.

77. *Id.*

To encourage research on treatment of rare diseases, the Act in its most current form[78] provides a tax credit equal to 50 percent of the cost of clinical trials.[79] In addition, the Act offers research and development grants for clinical testing by independent researchers.[80] The Act also provides grantees exclusive marketing rights, for a period of seven years, on certified new orphan drug applications.[81]

To qualify for these benefits, pharmaceutical companies must apply to the FDA for Orphan Drug status. A drug with a target population of less than 200,000 automatically qualifies for Orphan Drug status.[82] In addition, a drug may receive Orphan Drug protection if one can convince the FDA that without Orphan Drug status the development of the drug would be unprofitable, and thus infeasible.[83] Automatic Orphan Drug status, once granted, is not currently revocable in the event that the target population eventually exceeds 200,000.[84] Pharmaceutical companies developing drugs for the treatment of AIDS have received Orphan Drug benefits for many of these products. As of August 31, 1991, half of the drugs approved by the FDA for AIDS-related illnesses were designated as Orphans.[85]

Li-Hsien Rin-Laures and Diane Janofsky have argued persuasively that the non-revocability of Orphan Drug status may work against the original intent of the legislation.[86] Drugs that initially qualify as Orphans, particularly under the automatic "200,000 or less" clause, may later become highly profitable for several reasons. Target populations

78. Since its inception in 1983, the Orphan Drug Act has been amended in 1984, 1985, and 1988. *See* Health Promotion and Disease Prevention Amendments, Pub. L. No. 98-551, 98 Stat. 2817 (1984); Orphan Drug Amendments of 1985, Pub. L. No. 99-91, 99 Stat. 387 (1985); Orphan Drug Amendments of 1988, Pub. L. No. 100-290, 102 Stat. 90 (1988). For a history of the Orphan Drug Act, see Carolyn H. Ashbury, *The Orphan Drug Act: The First Seven Years*, 265 JAMA 893 (1991).

79. Orphan Drug Amendments of 1988, *supra* note 78.

80. Orphan Drug Amendments of 1988, *supra* note 78.

81. 21 U.S.C. § 360cc(a) (1988). The effect of this seven-year grant of market exclusivity for qualifying new drug applications is to extend the normal monopoly protection granted under federal patent law.

82. Pub. L. No. 98-551, 98 Stat. 2817 (1984).

83. *Id.*

84. An amendment was proposed in 1990 to alter this situation, so that market exclusivity would end once an Orphan Drug's target exceeded 200,000. H.R. 4638, 101st Cong., 2d Sess., 136 CONG. REC. H5799 (daily ed. July 30, 1990). President Bush pocket vetoed the amendment.

85. OFFICE OF ORPHAN PRODUCTS DEVELOPMENT, ORPHAN DESIGNATIONS THROUGH AUGUST 31, 1991 (1991).

86. Li-Hsien Rin-Laures & Diane Janofsky, Note, *Recent Developments Concerning the Orphan Drug Act*, 4 HARV. J.L. & TECH. 269 (1991).

may quickly exceed 200,000, dramatically increasing demand, and hence profit potential.[87] Indications for treatment through a particular drug may expand over the course of its development, creating a surge or jolt in demand.[88] Profits may also increase more than originally anticipated if the market bears higher prices than initially predicted.[89] Moreover, demand may increase as a result of drug companies successfully and artificially squeezing their products into Orphan categories by "creating artificial [target] subsets."[90]

Because the Act's market insulation continues to grant incentives to develop drugs even after such incentives become unnecessary, efforts were made during the 1991-92 congressional year to amend the Act.[91] Among the changes proposed by the amendments was the application of a "sales trigger." If Congress had passed the amendments, the trigger would have worked as follows: If an Orphan Drug was on the market for two years and sales exceeded $200 million, the FDA would approve marketing of the drug by competitors, unless exceptionally high development costs could be demonstrated.[92] Under a "transition rule," Orphan Drugs already on the market at the time of the amendments would be grandfathered, such that the sales trigger would be applied only after five years, instead of two years.[93] For those drugs the sales of which never exceed $200 million, exclusive marketing rights would have been extended under the proposed amendments from seven to nine years.[94] In addition, awards of Orphan Drug status would have required a determination that, based on three-year projections, the patient population is unlikely to exceed 200,000.[95]

The 1992 Amendments were defeated.[96] Although the bill's sponsors, Senators Kassebaum and Metzenbaum, intend to bring another proposal before the 103rd Congress,[97] the Act currently provides drug companies with publicly subsidized windfall profits. Drugs for the treatment of

87. *Id.* at 280.
88. *Id.* at 282.
89. *Id.* at 282-283.
90. *Id.* at 288.
91. Orphan Drug Act Amendments of 1992, S. REP. No. 358, 102nd Cong., 2d Sess. (1992).
92. *Id.* at 22.
93. *Id.* at 3.
94. *Id.* at 21.
95. *Id.* at 21.
96. Reginald Rhein, *Five Biotech Bills Signed into Law, New Congress Ponders Many More*, BIOTECHNOLOGY NEWSWATCH, Jan. 4, 1993, at 1.
97. *Id.*

AIDS are prime candidates for Orphan Drug protection that extends beyond the Act's original and intended justifications. The number of PWAs in the U.S. already exceeds 200,000[98] and demand for treatment is expected to continue to rise dramatically.[99] Moreover, treatment indication for AZT expanded during the 1980s to include not only PWAs, but also many asymptomatic people who are HIV-positive.[100] This expanded treatment indication creates precisely the kind of demand surge suggested by Rin-Laures and Janofsky.[101] Both PWAs and those who are HIV-positive/asymptomatic are likely to spend significant amounts of discretionary capital on encouraging treatments. The imperfections in the Act's achievement of its mission suggest that drug companies may receive more than adequate, government sponsored incentives to conduct otherwise infeasible research.[102] In tandem, the Act and the Patent Act underwrite risk and provide research subsidies, while conferring and even extending proprietary rights to supernormal monopoly profits. In effect, the public pays twice.[103]

Governmental subsidies to AIDS research affect the discussion of monopoly pricing in several ways. First, significant public underwriting of research and development weakens corporate contentions that high prices are necessary to recoup investments.[104] Second, public subsidies

98. *See* Jeffrey Schmalz, *Gay Politics Goes Mainstream*, N.Y. TIMES, Oct. 11, 1992, § 6, at 18.

99. *See supra* notes 3, 6 and accompanying text.

100. Jean McCann, *Giving AZT Early May Prevent Progression to AIDS*, 134 DRUG TOPICS, Aug. 6, 1990, No. 15, at 14.

101. *See supra* note 86.

102. For further discussion of and critique of the Orphan Drug Act, see John J. Flynn, *The Orphan Drug Act: An Unconstitutional Exercise of Patent Power*, 1992 UTAH L. REV. 389 (1992) (questioning the constitutionality of the Act); Patricia J. Kenney, *The Orphan Drug Act—Is It a Barrier to Innovation? Does It Create Unintended Windfalls?*, 43 FOOD DRUG COSM. L.J. 667 (1988) (answering "yes" to both title questions, and recommending fine tuning of the Act to improve implementation of intended policies); Abbey S. Meyers, *The Impact of Orphan Drug Regulation on Patients and Availability*, 47 FOOD & DRUG J. 9 (1992) (suggesting changes in FDA Orphan Drug policy to improve the Act's value to patients); Cynthia A. Thomas, *Re-Assessing the Orphan Drug Act*, 23 COLUM. J.L. & SOC. PROB. 413 (1990) (supporting market exclusivity of Orphan Drugs in general, but observing the need for Congress to modify administration of the Act to mitigate abuse).

103. *See* David Dahl, *Drug Prices Rising Despite Federal Aid*, ST. PETERSBURG TIMES, Feb. 25, 1993, at A1 (quoting Senator David Pryor, D-Ark., "Americans subsidize the development of medications, then they are forced to pay high prices for the drugs they already helped bring to market. . . . In essence, we have given the drug manufacturers a legally sanctioned license to price gouge the American public.").

104. Thus, one commentator suggests that Wellcome's initial claim of the necessity to recoup $80 million dollars in costs to develop AZT was grossly inflated. *See* NUSSBAUM, *supra* note 12, at 176-181.

operate as an artificial inducement to enter into AIDS research, providing both financial incentives and governmental underwriting of risk. Public sponsorship of AIDS research replaces some portion of the patent-conferred incentives that are necessary to encourage companies to undertake privately financed research. Last, government spending on AIDS treatment research justifies a view of resulting products as quasi-public goods.[105] Because the public has a stake in AIDS research, the unmitigated license of private companies to assess prices in a vacuum cannot be justified. Through its subsidy, the public obtains both a say in the pricing process and the right to some concessions of normal monopoly prices.

C. *Are Monopoly Principles of Patent and Orphan Drug Policy Inviolate?*

The granting of a seventeen-year patent monopoly and extensions under the Orphan Drug Act serves at least two functions: the encouragement of research and development and the rewarding of successful innovations that lead to marketable products and processes.[106] The application of the force of law to grant artificially inflated profits provides the super rewards necessary to justify expenditure on potential innovations which, by their nature, are highly speculative. Because most projects in search of new products and processes will ultimately fail, incremental laboratory projects often can be rationalized only by the prospect of supernormal profits.

The most basic of financial axioms is that great risk must be justified by the potential for great reward. Yet, complete monopoly power for patentable innovations does not affect all product-market segments identically. This is because a monopoly grant is a supply-side phenomenon, which is affected differentially by levels of demand that can vary dramatically. Consider, for example, a monopoly for a new kind of mouse trap. Demand for the trap is moderate because the utility of superior pest control is of moderate importance to most people. People are willing to pay somewhat more, but not much more, for a better mousetrap. Compare this mousetrap with a hypothetical cure for AIDS. Demand for the latter product is enormous because most PWAs are willing, if necessary, to devote virtually all existing assets to gaining access to the product. If

105. For detailed discussion of this contention, see *infra* notes 160-84 and accompanying text.

106. *See* Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979) (reviewing the purposes of the federal patent system and stating that patent law "seeks to foster and reward innovation.").

identical monopolies are awarded for both of these products, the mouse trap will be moderately profitable, whereas the AIDS cure will be wildly profitable.

Are these disparities in potential monopoly profitability justified by differentiated demand among varying product-market segments? Those defending supernormal profits for an AIDS cure would contend that fluctuations in demand, and therefore in potential demand curves for product innovations, efficiently allocate research and development efforts to the most desired products. Companies will invest more in search of a cure for AIDS than in search of a better mousetrap because potential profit for the former innovation is greater than for the latter. The prospect of heavily inflated profits based on magnitude of predicted demand provides the impetus for increased and expedited spending among a greater number of competitors, which should speed the process of finding the desired product.

Notwithstanding the essential soundness of patent monopolies, principles of patent policy are not inviolate. They are a creation of public policy, an attempt to rectify a market failure that results in inadequate incentives to innovate. Because patent monopolies are created as policy and not a component of some natural economic law, they are somewhat arbitrary and reflect only one of many possible choices available to address a market imperfection. There is nothing sacrosanct about the seventeen-year grant. Moreover, regulatory innovations may prove more economically effective than the current system.

I emphasize the human creation of the existing system in order to address more dispassionately the idea of "managed competition," the latest rhetoric of the Clinton administration as it faces the challenge of providing health care to all while protecting legitimate private interests.[107] While the term "managed competition" seems peculiarly fashioned to raise the hackles of all true believers in the free market, the patent monopoly system is already a human contrivance. In other words, the granting of an exclusive marketing privilege under requisite circumstances is already a form of managed competition. Because it is a familiar form, there is a misguided temptation to confer the system with virtues of natural economic law. Accordingly, when we frame the best solution to the public policy challenges regarding drug prices, it is impor-

107. *See* Hilary Stout & Rick Wartzman, *White House Considers Taxes to Cover Health-Care Costs of Up to $90 Billion*, WALL ST. J., Feb. 16, 1993, at A3.

tant to remember that managed competition is inevitable. The question, then, becomes how best to manage competition.[108]

D. Politics, Emotions, and Statistics: The Need for Rational Analysis Based on the Best Available Data

In industries that are either non-politicized or operating outside the sphere of crisis, both current law and custom embrace the creation of unfettered monopoly rights attendant to the granting of a patent.[109] These rights find their theoretical justification in the incentives they create for the investment of time and money in risky and expensive research and development.[110] When the patent is for a desirable but unnecessary consumer product, the public tacitly supports the monopoly patent system by declining to object. In other words, for most products and under most circumstances, patent monopolies are not controversial. Because demand for luxury products is a function of taste, consumer freedom appears to remain relatively unimpaired by prices that can only rise so far, given the normal elasticity of demand limitations that exist for non-essential products.[111]

In an atmosphere of tolerance toward monopoly patent pricing in the abstract, outrage regarding monopoly pricing of patented AIDS drugs results from the obvious difference between discretionary and essential goods. Elasticity of demand for life-saving products is virtually non-existent, particularly under crisis conditions in which no alternatives or substitutes have been formulated. Society naturally desires reductions in highly inflated prices of patented drugs which can extend life or dramatically enhance quality of life. When prices are so prohibitive that access to crucial treatments is denied, society has difficulty rationalizing death and suffering on the basis of abstract economic concepts. The call arises

108. The policy recommendation in which this Article culminates—negotiated drug pricing—is therefore not viewed as the regulation of a previously unregulated area. Rather, it is a change in the nature of regulation, aimed at more accurately recognizing economic and ethical interests of all parties concerned.

109. *See supra* notes 54-57 and accompanying text.

110. *See supra* note 60 and accompanying text.

111. For example, consumers are unlikely to be outraged by substantially supernormal, unregulated profits related to the patent on NutraSweet low-calorie sweetener. The ability of the patent holder to exploit its monopoly is limited by the public's ability to abstain from purchasing the product should the price become outrageous. While consumers may desire the product, they do not need it. Manufacturers know that individuals curb the price they are willing to pay to indulge their discretionary preferences and tastes.

for either voluntary price concessions or mandatory governmental regulation.

Nonetheless, regulation of AIDS drug pricing should be predicated upon studies indicating the degree to which research and development incentives are likely to be impaired. It is understood that investment incentives are positively correlated with expected returns.[112] Indeed, deterioration of economic expectations is commonly viewed by economists as a determinant of declining innovation.[113] Still, the marginal utility of each added dollar of expected return is likely to decline. If this is the case, each incremental windfall profit dollar yields a research incentive of decreasing significance. Price increments that become increasingly ineffectual at encouraging innovation for future use also impede the dispersion of the already existing drug. At some point, questionable or insignificant gains in incentive are realized at a cost of access that society will consider unjustifiable.

Because declines in marginal utility and drug access associated with price increases will be gradual, the point at which the tradeoff between incentives and access becomes unacceptable exists on a slippery slope. The determination regarding the value of an increment of research incentive versus the value of an additional immediate treatment is subjective. It is impossible to quantifiably compare the value of an existing life with the value a future life. Furthermore, the suggestion that sacrifice of current treatment will expedite gains in innovation, resulting in a net saving of lives, is undoubtedly speculative. Some would likely consider the idea barbaric. Yet given all these limitations, it is necessary to determine the point at which insignificant gains in research and development incentives cannot justify additional monopoly price increases.[114] This determination should be made using the best available data under obviously imperfect conditions of speculation while regarding the elasticity of research expenditure as a function of marginal gains in expected profit.

As groups representing PWAs seek access to vital treatments while corporations seek maximization of profits for their shareholders, emo-

112. For this reason, weaknesses in patent policy have been shown under various circumstances to impede innovation. *See, e.g.*, Elizabeth A. Hall, *The Impact of a Weakened Patent Policy on Development Incentives*, 31 Q. REV. ECON. & BUS. 79 (1991).

113. *See, e.g.*, Zvi Griliches, *Patents: Recent Trends and Puzzles, in* WORKING PAPERS ON ECONOMIC ACTIVITY: MICROECONOMICS 291, 303 (Martin N. Baily and Clifford Winston eds., 1989).

114. The policy issues raised in this regard are normative issues of patent scope. For a detailed discussion of the considerations and tradeoffs regarding patent scope policies, see Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839 (1990).

tions can obfuscate the economic and ethical analysis of the most crucial question: what policies are best suited to the most expedient saving of lives and amelioration of sickness and suffering? The following discussion is intended to address this question, taking into account both economic realities and ethical obligations.

II. WHO SHOULD PAY FOR EXPENSIVE NEW DRUGS: AN ANALYSIS OF RIGHTS AND DUTIES

In the best of worlds, all needs would be met. Under conditions of scarcity, questions of resource allocation are invariably questions of normative philosophy and political economy. In an attempt to determine sound policies that encourage optimization of access to those in need, it is necessary to explore the nature of rights and duties in the provision of basic human needs. This Part examines the question, Who should pay for expensive new drugs, given finite resources?

A. Classical Rights and Duties Analysis

Under traditional rights and duties analysis, the creation of duties can be justified only when: (1) the party to whom the suggested duty is owed has a correlative right; and, (2) that right comprises an entitlement from the particular party to whom the duty attaches.[115] The creation of a right on the part of terminally ill patients to receive treatment depends upon and is shaped by the correlative duties that society imposes either upon ourselves or others. AIDS patients can only obtain such a right if the rights and duties equation is balanced by assessing the cost of the entitlement to a paying entity.

Some may argue that the rendering of any potential rights as contingent on the location of a justifiable duty-holder degrades the nature of rights. If a right is viewed as inalienable, natural, or God-given, then that right is protected by virtue of its sanctification and is thus fundamental. Under this view, an inalienable right is sufficient in itself to establish correlative duties to meet the needs it creates. Thus, Alan Gewirth notes, "burdens are for the sake of benefits, and not vice

115. For a discussion of the relationship between rights and duties from which this statement is derived, see Joel Feinberg, *Duties, Rights, and Claims*, 3 AMER. PHIL. Q. 137 (1966) (defining a right as the "justified entitlement to something from someone"). For discussion of the correlativity of rights and duties in general, see Marcus G. Singer, *The Basis of Rights and Duties*, 23 PHIL. STUD. 48 (1972); David Lyons, *Rights, Claimants and Beneficiaries*, 6 AMER. PHIL. Q. 173 (1969).

versa."[116] As a result, "Respondents have correlative obligations because subjects have certain rights."[117] If rights create duties, and not vice versa, then balancing the rights-duties equation involves finding places to locate the burdens created by duties and assessing related costs at those sites.

I respond to those who recommend the assessment of duties sufficient to meet the demands of rights as follows: It is true that the conception of a fundamental right is intolerably denigrated if the very existence of the right becomes dependent on the previous and overriding discovery of driving duties. To state that a right is truly inalienable, as all rights are lest they become mere desires or goals, is to stipulate its preeminence in determining how to flesh out the rights-duties equation. While I concede that true rights are the source of duties and not vice versa, this concession must require a conservative circumscription of the sphere in which rights are identified.

Specifically, true rights, which create duties under Gewirth's reasoning, should be limited to what philosophers label "negative rights," or rights to be left alone.[118] The "rights" which philosophers call "positive rights" are those that require positive action rather than omission.[119] Because "positive rights" call on the limited resources of a potential cadre of duty holders, they are more complex and controversial than negative rights. What some philosophers call positive rights, such as the right to receive treatment regardless of ability to pay, are not actually rights, but rather hopes and expectations that are contingent upon the charity of those who have the resources to pay.[120] Those maintaining these hopes and expectations wish to be beneficiaries of charitable compassion felt by a donor. Thus, John Kleinig observes, "Where people do love and care for each other, there is no need for rights-talk, since what is due to the other will be encompassed within the loving or caring relationship."[121]

116. Alan Gewirth, *Why Rights Are Indispensable*, 95 MIND 329, 333 (1986).

117. *Id.*

118. For a more elaborate discussion distinguishing negative and positive rights, see MAURICE W. CRANSTON, WHAT ARE HUMAN RIGHTS? (1973).

119. *Id.*

120. For the argument against this statement, see Gewirth, *supra* note 116, at 341. Gewirth argues that provision of basic human sustenance, such as food or other life-preserving care, is not merely charity. Accordingly, because the right drives the duty, "assurance of the fulfillment of [the] right requires governmental provision."

121. John Kleinig, *Human Rights, Legal Rights and Social Change*, *in* HUMAN RIGHTS 46 (Eugene Kamenka & Alice Ehr-soon Tay eds. 1978). It seems ironic that Kleinig discusses what is "due" to another in the process of supplanting adversarial rights analysis with love and care.

While true rights, i.e., negative rights, are the compelling force behind mandatory duties, precatory moral action is the precursor to charitable donation.

At least three possible types of correlative duties[122] exist to meet the obligations created in fashioning a right: (1) not depriving another; (2) assisting to protect another from deprivation; and, (3) helping one who is deprived.[123] A duty to subsidize AIDS drug treatments to make them more affordable comprises the third variety of duty, a duty to help others. Duties to provide assistance to those in need can be justified under respectable tenets of normative philosophy,[124] but such duties are limited in nature.

Immanuel Kant suggests that defendable duties arise under a categorical imperative, such that the duty can be made universal, respects individuals as ends rather than means, and respects human autonomy.[125] Richard DeGeorge believes that the duty to assist those in need meets Kant's standards. However, DeGeorge also believes that this duty is limited or imperfect because it is directed to all the world and limited by society's ability to meet many such needs with finite resources.[126] Imperfect duties are bounded by conditions of fairness and affordability, such that "the obligations or burdens imposed by a right must be affordable in relation to resources, other obligations, and fairness in distribution of burdens."[127] Society's determination of who should subsidize drug company concessions of normal monopoly profits must consider the validity and scope of a fair duty, as well as a recognition that competing needs for assistance may circumscribe the degree of subsidization.

Clearly, few people in a capitalist society truly believe that all unmet needs have a right to be met, such that the needs should exhaust all discretionary expenditure by property holders in their own behalf.[128] One

122. Edwin M. Hartman, for example, has argued in favor of a fourth possible type of correlative duty, which he calls "avoiding helping to deprive." Edwin M. Hartman, *Donaldson on Rights and Corporate Obligations, in* BUSINESS ETHICS: THE STATE OF THE ART 163, 165 (R. Edward Freeman ed., 1991).

123. HENRY SHUE, BASIC RIGHTS 20 (1980).

124. For a discussion of the duty to help others, see Peter Singer, *The Obligation to Help, in* RALPH W. CLARK, INTRODUCTION TO MORAL REASONING 100 (1986).

125. For detailed discussion of these tenets, see IMMANUEL KANT, FOUNDATIONS OF THE METAPHYSICS OF MORALS (Robert Paul Wolff ed., Lewis W. Beck Trans., 1969).

126. RICHARD J. DE GEORGE, BUSINESS ETHICS 75 (3d ed. 1990).

127. Thomas J. Donaldson, *Rights in a Global Market, in* BUSINESS ETHICS: THE STATE OF THE ART 139, 149 (R. Edward Freeman, ed., 1991).

128. To the contrary, the idea that the needs of all must be met before the wants of others can be

also hopes that few persons in capitalist society feel no desire to meet some level of need experienced by those less fortunate than themselves. This desire to aid, highly individualized and personal, has traditionally formed the realm of charity. Charity is a word that has become somewhat pejorative in connotation in recent years, but which perhaps has been given short shrift in the process. Because those in need comprise a seemingly insatiable source of demand, which greatly exceeds society's limited ability and willingness to meet that demand, need alone cannot create rights. Rather, it depends upon the generosity of those whose compelling sense of charity ensures that the demand is not entirely unmet.[129] The reality then is this: PWAs seeking subsidization[130] of drug costs, like all others in need of outside help, can and will receive that subsidization to an extent defined by the sense of altruism experienced by such entities as private donors, government, and corporate benefactors, potentially including pharmaceutical companies.

B. Theories in Support of Corporate Pricing Concessions

Society recognizes a duty to provide health care under limited circumstances. Programs that provide subsidization of medical care in the United States exist, but they are generally linked to age, income, and employment status rather than residence and need.[131] Richard E. Merritt summarizes the American approach to health care financing as three-dimensional: health care is "a fringe benefit for most of the employed. . ., an entitlement conditioned by categorical eligibility for many, e.g., Medicaid and Medicare. . ., and it is a matter of chance and charity for all the rest."[132]

One can make compelling arguments in favor of recognizing a right to

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met is clearly Marxist rather than Capitalist in nature. *See* generally Karl Marx & Friedrich Engels, *The German Ideology, in* THE MARX-ENGELS READER 146 (Robert C. Tucker ed., 1972).

129. For discussion of the nature of charity as opposed to regulatory public support by edict, see Laura Brown Chisolm & Dennis R. Young, *Symposium Introduction: What is Charity? Implications for Law and Policy*, 39 CASE W. RES. L. REV. 653 (1989).

130. As the Article argues later, PWAs in the present system of government-supported research and development are not actually seeking subsidization of drug costs. Because tax dollars go toward the development of new pharmaceutical products, consumers and other citizens have an investment in these products, such that reductions in price may represent return on investment rather than private corporate subsidization. *See infra* notes 174-84 and accompanying text.

131. Daniel M. Fox & Emily H. Thomas, *The Cost of AIDS: Exaggeration, Entitlement, And Economics, in* AIDS AND THE HEALTH CARE SYSTEM 197, 205 (Lawrence O. Gostin ed., 1990).

132. Richard E. Merritt, *Focusing on State Roles in Financing Options, in* AIDS AND LONG-TERM CARE 115 (Donna L. Infeld and Richard McK.F. Southby eds., 1989).

publicly subsidized health care, either for all or for those who cannot afford to pay for it themselves.[133] These include the value of a compassionate society, the notion of public health as a public good, and the need to spread responsibility for charitable subscription equitably across society in order to avert moral free ridership.

A right to treatment that arises from the idea of a compassionate society is necessarily a limited or circumscribed right. This right is restricted by the claims of other rights that may arise from competing needs and make demands on limited resources. From this standpoint, the right may be defined as encompassing a reasonable amount of financial support. The slippery concept of reasonableness is defined by balancing the many needs for compassion in light of the scarcity of available funds.[134] Existence of a right to receive care is dependent, of course, on the recognition of a correlative duty for society to make reasonable provision for the unmet needs of those in exigency or poverty. Recognition of such rights and duties is extremely controversial.[135] The rights at issue in this Article are best justified by virtue theories of ethics and feminist ethics of care.[136]

Virtue theories extend at least as far back as Aristotle,[137] who encouraged the development of traits considered good unto themselves, apart from the analysis of rights and duties. Among the virtues commonly recognized in Judeo-Christian cultures are selflessness, mercy and compassion. These attributes are virtuous precisely because they extend beyond the classically recognized negative rights and corresponding duties.[138]

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133. In the case of expensive new drug treatments for AIDS, the public subsidy could help all recipients by a profit underwriting grant to the proprietor, reducing the market price charged to all. The subsidy could also be granted to purchasers on the basis of proven need, thereby focusing subsidization on persons who cannot afford to pay monopoly rents themselves.

134. In other words, random generosity should be tempered with distributive justice. *See* Leonard M. Fleck, *Just Health Care Rationing: A Democratic Decision-Making Approach*, 140 U. PA. L. REV. 1597, 1598 (1992) (recognizing the opportunity costs associated with donations to meet one human need rather than to a competing need, and observing, "Generosity is morally praiseworthy only if the more basic demands of health care justice have been satisfied.").

135. *See infra* notes 148-59 and accompanying text for a discussion of libertarian criticism.

136. The ethics of care has been labelled "feminist" as well as "feminine." Susan Sherwin suggests caring is a direct component of feminine ethics, which can also contribute to a feminist ethics, which is directly concerned with questions of oppression. SUSAN SHERWIN, NO LONGER PATIENT: FEMINIST ETHICS AND HEALTH CARE 49 (1992).

137. Aristotle, Nichomachean Ethics, Bk. II.4, *in* THE COMPLETE WORKS OF ARISTOTLE 1745 (Jonathan Barnes ed., 1984) (original publication date).

138. *See supra* note 118 and accompanying text.

1. Ethics of Care

An ethics of care suggests that purportedly rational goals of freedom, autonomy and the recognition of related rights[139] are inadequate normative targets under conditions of inequality.[140] Carol Gilligan notes,

> The experiences of inequality and interconnection, inherent in the relationship of parent and child, . . . give rise to the ethics of justice and care, the ideals of human relationship—the vision that self and other will be treated as of equal worth, that despite differences in power, things will be fair; the vision that everyone will be responded to and included, that no one will be left alone and hurt.[141]

From one feminist perspective, the activity of "doing for others" has been assigned and segregated to women, and therefore largely omitted from conceptions of human nature that undergird much philosophical and economic theory.[142] As a result, contractarian models of ethics are built on an understanding of humans as self-seeking and competitive[143] and only likely to provide social good inadvertently when allowed to pursue self-interest freely. Annette Baier observes that selfless human behavior, particularly among parents and health professionals, arises from a recognition of responsibility in relationships characterized by dependency and inequality.[144] Nel Noddings suggests that the realm of ethics should concern caring rather than abstract ideas of justice.[145]

An ethics of care may provide intellectual footing for an intuitive sense that society is morally bound to shift resources away from discretionary, luxury spending toward health care for the very sick and the dying.[146]

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139. For a discussion of the relationship between feminist jurisprudence and rights, see Deborah L. Rhode, *Feminist Critical Theories*, 42 STAN. L. REV. 617 (1990).

140. The ethics of care has developed out of "relational" feminism, which acknowledges differences between men and women, and extols undervalued, relationship-oriented, humanistic attributes often associated with women. For a discussion of the development of ethics of care from relational feminism, see Joan C. Williams, *Deconstructing Gender*, 87 MICH. L. REV. 797 (1989).

141. CAROL GILLIGAN, IN A DIFFERENT VOICE: PSYCHOLOGICAL THEORY AND WOMEN'S DEVELOPMENT 62-63 (1982).

142. JEAN BAKER MILLER, TOWARD A NEW PSYCHOLOGY OF WOMEN 70 (2d ed. 1986).

143. *Id.*

144. *See generally* ANNETTE BAIER, POSTURES OF THE MIND (1985).

145. *See generally* NEL NODDINGS, CARING: A FEMININE APPROACH TO ETHICS AND MORAL EDUCATION (1984).

146. This moral obligation can be conceived as either a duty to subsidize individual categories of need, or more broadly as a social obligation to provide adequate health care to all persons as a public service. For a discussion of the argument against privately financed health care and in favor of equal distribution of medical care, *see generally* THEODORE R. MARMOR & JON B. CHRISTIANSEN, HEALTH CARE POLICY: A POLITICAL ECONOMY APPROACH (1982).

More broadly conceived, universal health care through compulsory sickness insurance is institutionalized in a number of countries, including Germany, Austria, Norway, Britain, and the Netherlands. These health care programs reflect the recognition of a duty to provide basic treatment to all.[147] Whether conceived as a specific duty to provide subsidies to the sick and dying, or as a broader duty to provide governmentally supported health care for all, the ostensible obligation encompasses the tax-base subsidization of expensive new drug treatments for AIDS.

While an ethics of care is an important impetus to private generosity, it cannot stand on its own merits against classical rights and duties criticism. Libertarian theory, for example, disfavors imposing a public duty to subsidize expensive pharmaceutical treatment. Libertarian arguments generally focus on the relationship between individual freedom from coercion and private property rights and the distinction between public use and private interest.

Robert Nozick's theory of entitlement suggests property is justly held only if the acquisition and transfer of that property are just.[148] Entitlement in acquisition is derived from making a product or mixing one's labor with an object.[149] Transfer of a justly acquired product is legitimate only if voluntary.[150] Involuntary redistribution of property is not justified, because it coercively violates individual and authentic property entitlement.[151]

Charles L. Schultze likewise criticizes "the public use of private interest."[152] Schultze observes that "the collective-coercion component of intervention should be treated as a scarce resource."[153] He suggests that social intervention that expropriates private interests for the public good should be substantially curtailed in order to preserve economic efficiency and individual choice.[154] Milton Friedman takes the argument to its logical conclusion by stating that the appropriation of government funds for charitable purposes should be constrained, so that individual freedoms are preserved in making ethical decisions and choosing which public

147. DENNIS J. PALUMBO, PUBLIC POLICY IN AMERICA 179 (1988).
148. ROBERT NOZICK, ANARCHY, STATE, AND UTOPIA 149-54 (1974).
149. *Id.*
150. *Id.*
151. *Id.*
152. *See* CHARLES L. SCHULTZE, THE PUBLIC USE OF PRIVATE INTEREST (1977).
153. *Id.* at 6.
154. *Id.* at 6-7.

needs, if any, to subsidize.[155]

How, if at all, can one reconcile feminist ethical theory with the classical liberal foundations of capitalist society? When the ethics of care collide with the interests of private property and autonomy, it is appropriate that the former should be subsumed within the latter. Several considerations suggest that freedom and autonomy are, and should be, dominant values over care.

Most importantly, reasonable minds differ considerably in the particular behaviors that constitute care. Because individuals have varying notions regarding the nature of the commonwealth, ideas of care would diverge even if unlimited resources existed. Given the reality of severely limited funds, there is no single, unassailable definition of the most caring policies.

Because consensus on the nature of the "public interest" in a pluralistic society cannot exist, governmental spending in the name of "caring" must ultimately force dissenters to fund causes not preeminent among their own personal priorities.[156] Milton Friedman's call for minimal regulation focuses on the decentralization of, rather than the annihilation of, modes of caring.[157] Minimizing compulsory subsidization of an official version of the "public interest"[158] preserves discretionary funds for each individual's charitable vote. Freedom to choose the causes one supports is not inherently incompatible with caring, which in fact is an individual, emotional phenomenon that can and should be left to personal choice.

Perhaps most importantly, caring thrives best within a free society in which the responsibility for caring is not bureaucratized, politicized, and thereby sanitized beyond ordinary human contact. Yet the converse is not true—freedom is not preserved by compulsory caring and centralized determination of the nature of compassion and the public welfare.

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155. MILTON FRIEDMAN, CAPITALISM AND FREEDOM 7-21 (1982).

156. Thus, one commentator has observed that arbitrary, trivial or authoritarian regulation will tend to be perceived as bureaucratic imperialism and may encourage disrespect for the law. *See* George A. Steiner, *New Patterns in Government Regulation of Business, in* BUSINESS ETHICS 518, 522-23 (W. Michael Hoffman & Jennifer Mills Moore eds., 2d ed. 1990).

157. *See supra* note 155.

158. The "official version" of the public interest represented by many forms of regulation is often discussed in terms of paternalism. *See, e.g.*, Steven Kelman, *Regulation and Paternalism, in* RIGHTS AND REGULATIONS 241 (M. Bruce Johnson & Tibor R. Machan eds., 1983).

For a discussion of the difficulties associated with determining what is the substance of the public interest, see FRIEDMAN, *supra* note 155, at 133-136.

Rather, each effort to institutionalize care further erodes the values of autonomy and freedom.

Thus, while there is room for an ethics of care within a free society, there is no place for freedom in a society that coerces a particular political doctrine of care. Laws that preserve our individual autonomy also maintain our potential to follow the ethical voices that lead us to care in differing ways. Maximization of individual freedom preserves the fundamental right of all persons to pursue their own ethics of care, free from the coercive, governmental version of right and wrong. Because meaningful ethics are derived from personal thought, investigation and discovery, the most legitimate ethics of care are those that focus moral decision-making on the individual.[159] It is both possible and desirable to promote the social welfare by allowing individuals to consider and assess privately their responsibility to care for others.

2. *New Drugs as a "Quasi-Public Good"*

I have argued that an ethics of care cannot legitimately be institutionalized through governmental action without serious degradation of fundamental personal rights. Any regulatory initiative to subsidize consumer purchases of new AIDS drugs must rely, if at all, on a determination that effective, universally accessible AIDS treatment is a public good supported by tax dollars. A good is generally considered public if: (1) no individual's consumption of the good diminishes its consumption by others; and, (2) a private-market pricing system cannot be used to assess fees according to individual usage.[160] Because of these attributes, public goods are not readily adaptable to the private market. It is therefore appropriate for the government to finance necessary public goods for the welfare of all.

Is public health, including the application of expensive pharmaceutical treatments, a public good? Certainly it is not, in the pure, classical sense derived from the definition above. Drug treatment is finite and divisible, so that the consumption by one individual diminishes the pool of goods. For many years, private market pricing has charged individuals separately for their usage of pharmaceutical products.

Classical, exemplary varieties of public goods, such as military protec-

159. For greater elaboration of the idea that ethics should be personal and not compulsory, see Steven R. Salbu, *Law and Conformity, Ethics and Conflict: The Trouble With Law-Based Conceptions of Ethics*, 68 IND. L.J. 101 (1992).

160. EDWIN MANSFIELD & NARIMAN BEHRAVESH, ECONOMICS U.S.A. 512 (1986).

tion, must be indivisible in order to be removed from the private market.[161] National defense redounds equally to the benefit of all[162] and is distributed as a whole rather than allocated in different portions to different consumers. Pharmaceutical treatment is finite and directed selectively in differing portions to individual consumers. In this sense, it is not a classical public good and not immune from incorporation into the private market mechanism.

Yet, several factors regarding AIDS treatment may recommend against facile classification efforts. Perhaps most significantly, numerous goods are treated in the United States as public or quasi-public goods, notwithstanding their divisibility or partial divisibility among beneficiaries. Services such as public education are certainly not entirely indivisible, but rather confer both private and public benefit: the individual educated at public expense receives a benefit that is individually appropriable in a capitalist society and, at the same time, a part of the larger work force infrastructure that is essential to social and economic prosperity.[163] These "quasi-public goods" are not the purest examples of the need for government to participate in a vacuum left by private market failures. Still, the largely indivisible public welfare component of institutions like education is sufficiently compelling to require substantial public support.

Health care is in many ways like education and thus qualifies as a quasi-public good in the United States. Like education, medical care confers both private and public benefit: the individual who receives the treatment is personally assisted, while the work force and consumer base are kept able-bodied and productive. For this reason, while health care is not a classical public good, it is viewed as a vital part of our social and economic infrastructure and our tax dollars, therefore, support it.

As a quasi-public good, health care is precariously balanced between two competing and irreconcilable considerations. On the one hand, society is reluctant to coerce individuals to underwrite causes which they

161. *Id.*

162. This is true despite the controversy that often surrounds the degree to which any particular act of war is considered beneficial or detrimental. National defense is a public good because of its universal application, notwithstanding disagreements regarding how good the good actually is.

163. The example of public school education reveals the complexity of the public goods/private goods distinction. In particular, the movement to provide individual choice regarding personal consumption of educational services suggests that market mechanisms will be utilized more frequently in the future to allocate public goods. For discussion of this trend, see JOHN E. CHUBB & TERRY M. MOE, POLITICS, MARKETS, AND AMERICA'S SCHOOLS (1990).

may not personally support.[164] Yet, if a substantial majority of society does support the public financing of health care under certain circumstances,[165] implementation of such a policy may only be possible via a centralized, compulsory process. This need for a uniform policy to execute the public will arises from the problem of moral free ridership. In essence, individuals cannot effectively vote their support for subsidized health care solely through charitable subscription. One person's voluntary donation reflects that individual's acceptance of a widely recognized duty to provide care to all in need, while others who choose not to provide charitable support gain a moral free ride.[166] Of course, much real need will remain unmet under voluntary, noncoercive systems because many members of society will decline to devote their own dollars to the cause. Even those of the best faith may withdraw their support and refuse to carry a disproportionate share of the load that is widely believed to be the responsibility of all.[167] As a result of the free ridership problem, good-faith efforts to preserve individual freedoms may result in the gross underfunding of products and services uniformly considered to deserve much more significant attention. The only way to assure that these projects receive appropriate recognition is to compel all taxpayers to support them, removing the phenomenon of attrition associated with incentives to ride free in a system of voluntary support.

As noted earlier, free ridership and the associated underfunding of vital projects come at the inevitable cost of coercion. It is thus essential

164. *See supra* notes 152-53 and accompanying text.

165. This is probably a reasonable assumption. *See* Hilary Stout, *Seeking a Cure*, WALL ST. J., Mar. 12, 1993, at A1 (discussing a Wall Street Journal/NBC News Poll, according to which "78% of the public believe that the current health-care system doesn't meet the needs of most Americans," and "66% say they would be willing to pay higher taxes so that everyone could get health insurance.").

166. *But see supra* notes 148-53 and accompanying text (positing libertarian arguments of distributive justice, which suggest that what this Article labels "moral free ridership" may in fact be moral coercion). In reality, moral free ridership and moral coercion are flip sides of the same coin. Moral free ridership is the risk attendant to choosing completely free markets, while moral coercion is the risk that accompanies a denial of compulsory subsidization of public welfare benefits which a substantial majority of citizens believe should be provided to all.

167. Even classically liberal economist Milton Friedman is sympathetic to this line of reasoning. He suggests that "we cannot rule out the possibility that. . . charitable activities will be inadequate, if only because of the neighborhood effect involved in the fact that I benefit if another man contributes to the care of the insane." FRIEDMAN, *supra* note 155, at 33. Although Friedman is speaking of free ridership related to a recognized duty to care for the insane, his observation applies as well to free ridership problems associated with health care provision, assuming society recognizes the relevant duty.

that funding gains are balanced against this consideration, particularly by determining the degree of social consensus in support of the public subsidy. If the public unanimously supports the funding, the level of coercion approaches zero while the amelioration of free ridership is significant. On the other hand, if there is a narrow majority of support for the public subsidy, coercion is great and amelioration of free ridership is reduced. In this latter scenario, dissenters would argue that they are not receiving a free ride at all because the "ride" leads to a destination they have no desire to reach. Accordingly, compulsion to support a quasi-public good, justified on the basis of averting moral free ridership, must be based upon reliable data indicating widely held public support of the beneficial use of public funds.

A substantial majority of the American public supports the idea of increased access to health care through some level of tax subsidization.[168] In the area of AIDS research and treatment, this consensus has been recognized in the form of substantial governmental spending. Both public and private medical researchers are beneficiaries of significant amounts of NIH subsidy, estimated by Bruce Nussbaum to equal $9 billion for 1991 alone.[169] Ten percent of this expenditure currently goes to AIDS research.[170] President Clinton's most recent proposals recommend increases in governmental spending on AIDS, including an additional $8.2 billion for prevention, immunization, and women's health research.[171] This public spending reflects, implicitly, a degree of political consensus that Americans have an aggregate public duty to allocate tax dollars to AIDS research and care. This spending also indicates that such care is considered a public or quasi-public good, deserving of public subsidy and otherwise susceptible to moral free ridership.

I have attempted to persuade readers to take care against recklessly recognizing rights without due consideration of the entire rights-duties equation.[172] I have also suggested that subsidization of AIDS drugs is justified under a quasi-public goods theory.[173] Even those who question the legitimacy of the quasi-public goods rationale must recognize the

168. *See supra* note 165.

169. NUSSBAUM, *supra* note 12, at 330.

170. Dick T. Washington, *Your Money or Their Lives: Patient Advocates Are Learning from AIDS Activists How to Work the System*, TIME, Oct. 12, 1992, at 66.

171. Hilary Stout, *Clinton's Economic Package: Health Care Goals Take a Back Seat to Driving Down the Deficit for Now*, WALL ST. J., Feb. 18, 1993, at A10.

172. *See supra* notes 115-30 and accompanying text.

173. *See supra* notes 160-71 and accompanying text.

public's proprietary stake in the products that arise from such publicly funded research as currently exists, as long as the support of tax dollars remains. While critics may choose to challenge the appropriateness of any funding, the reality of funding under current policy should confer upon the public, including potential consumers, a voice in questions such as pricing, which is currently relegated under patent law to unilateral corporate determination.

Some may also argue that much governmental spending on research and development consists of grants to public rather than private institutions and that this diminishes the magnitude of actual private appropriation of quasi-public goods. Yet, while much governmental funding goes to basic research or university research ostensibly "not-for-profit," private patent holders are currently able to appropriate individual benefit from this source.[174] Upon receipt of their patents, patent holders get a subsidized ride consisting of the public research groundwork on which they build their own research.[175] This benefit does not account, of course, for the more direct governmental support the pharmaceutical companies themselves receive in order to help finance their own research efforts.

For example, the National Institutes of Health have spent $30 million dollars to develop the cancer drug Taxol.[176] In 1991, Bristol-Myers received government research findings as well as exclusive rights to Taxol in order to expedite its public dispersion.[177] Exploiting its monopoly advantage, Bristol-Myers charges $6,000 for four months of treatment.[178] As one critic observes, " 'cancer patients already have financed the inven-

174. For a discussion of the reciprocity of academic and industrial laboratory research, see DAVID SCHWARTZMAN, THE EXPECTED RETURN FROM PHARMACEUTICAL RESEARCH: SOURCES OF NEW DRUGS AND THE PROFITABILITY OF R&D INVESTMENT 15-19 (1975) (discussing the interaction and cross-exploitation of information between the public and private research and development sectors).

175. The concept of information as a valuable asset that can be appropriated at no charge is often cited as a crucial market failure necessitating incentives such as patent monopolies in order to encourage research and development. *See, e.g.*, Richard E. Romano, *Aspects of R&D Subsidization*, 1989 Q.J. ECON. 863 (observing that "the market fails to provide the socially optimal level of R&D expenditure because of the public properties of information.").

This Article suggests that the appropriability of information, which requires patent protection as an incentive to innovation, also provides private industry with windfall contributions to investment, as they receive free rides on publicly funded research, yet are able under patent law to appropriate all profits for themselves.

176. John Carey, *How Many Times Must a Patient Pay?*, BUS. WK., Feb. 1, 1993, at 30.

177. *Id.*

178. *Id.*

tion of Taxol once as taxpayers. . . . Why should they be forced to pay Bristol-Myers a second time as consumers?' "[179]

This example may be extreme, perhaps reflecting an inordinate amount of governmental spending. Even so, the company cannot be expected to market a product for free, or at a loss, simply because the government incurred development costs. Still, criticism of Taxol's marketing history highlights a valid principle: Patent-related monopoly authorization should be tempered and limited to the extent that taxpayer dollars have conferred a public property interest in the relevant product.

In the case of Taxol, Bristol-Myers is justified in seeking a reasonable profit in return for its marketing efforts. Yet, because much of the financial risk associated with preliminary research and development was borne by the public, Bristol-Myers' appropriation of extraordinary gains cannot be explained by the usual "incentives" rationale for conferring patent monopolies.[180] The company has not incurred all of the risky development expenses that, admittedly, need and deserve to be highly rewarded. Moreover, because much of the research expenditure was public rather than private, a monopoly grant was not a necessary incentive upon which private efforts are typically considered to be conditioned. Because it is estimated that as many as one half of the promising AIDS drugs are developed in government or university laboratories,[181] the issues raised by Taxol are very much applicable to the public policy questions related to the pricing of new AIDS treatments.

The reality of government spending on both public and private medical research, as a component of our view of health care as a quasi-public good, suggests that the public is justified in expecting to benefit from its investment. In particular, the public becomes a stakeholder in the property produced by all funded research.

I observed earlier that purely private property claims can confer no justifiable duty of charitable subsidization.[182] Yet, given the realities of federal spending on medical and health care research, purely private property claims encompassed in private patents for products such as

179. *Id.* (quoting James P. Love, director of the Taxpayer Assets Project, founded by Ralph Nader).

180. For discussion of the incentives rationale for the granting of patent monopolies, see *supra* notes 58-74 and accompanying text.

181. *See* Carey, *supra* note 176 (observation attributed to Dr. Bruce A. Chabner, director of cancer treatment at the National Institutes of Health).

182. *See supra* notes 148-59 and accompanying text.

AZT are a legal fiction. Because governmental funding of medical research is substantial and ubiquitous,[183] potential public beneficiaries, including prospective patients, have a stake in new products sufficient to justify, at the very least, a voice in decisions regarding the sale and marketing of those products. In other words, public support of quasi-public goods must be balanced by some degree of public sharing in the fruits of the investment, as well as input into the nature of that sharing. As we cannot justify the expropriation of purely private property based simply on the needs of others, so we cannot relegate to purely private benefit the profits of endeavors that, by virtue of tax-base support, have become to some degree public property.

I have argued that public support of AIDS research should give the public a voice regarding the use of products developed through that research based on a legitimate property stake. It does not necessarily follow that the public will use its voice to plead for price concessions in pharmaceutical sales. While the entire tax base supports the research itself, only a small proportion of that tax base utilizes drugs developed in the process. We cannot presume, without evidence, that the return sought by all taxpayers is comprised, even in part, of price concessions which will directly benefit only a relative few. Instead, it is incumbent upon the government to listen to the public voice in a hearing process, which would balance the just interests of both public and private stakes in deciding how to utilize the assets at issue. The public's property interest in the research and product development it has helped finance forms a substantial part of the theoretical justification of negotiated pricing discussed in Part III. The negotiation process gives due recognition to all legitimate interests in determining the extent to which public investment should be repaid in the form of corporate pricing concessions.[184]

183. Even if a private company were to refuse any direct federal aid, its work is indirectly financed by the funded research findings of university investigators and other laboratory scientists, whose work is published and then exploited by all.

184. The public's stake in patented products can also be used to understand calls for unilateral responsible pricing practices in lieu of regulation. Voluntary responsible pricing proposals have arisen largely in response to price increases for existing drugs that exceed the rate of inflation. These proposals typically suggest that drug companies might seek to avoid new regulation by volunteering to hold price increases for existing drugs to the inflation rate. Because these proposals are more relevant to drugs already on the market than to newly discovered drugs, I do not emphasize voluntary responsible pricing proposals in this Article. For further discussion of these proposals, see *supra* notes 45-49 and accompanying text.

III. IN SEARCH OF THE BEST POLICY: NEGOTIATED DRUG PRICING—A MODEL FOR BALANCING DRUG ACCESSIBILITY CONSIDERATIONS WITH RESEARCH AND DEVELOPMENT INCENTIVES

Recent public pressure regarding containment of health care costs has raised old questions concerning regulation of the pharmaceutical industry. As both AIDS activists and groups, such as the elderly, press Congress to find ways of moderating the cost of necessary treatments, the prospect of a regulated drug industry in the United States seems likely.[185] Regulatory possibilities include the development of governmental caps or pricing schedules and a system of price negotiation similar to arbitration proceedings.

Any regulatory scheme must address the potential discouragement of research and development that is likely to result from a reduction of monopoly rents. In particular, if the government seeks to increase drug accessibility by limiting profits, it should adjust for resulting market disincentives by increasing subsidies to private corporate research. The obverse of this observation is also true: to the extent that government has subsidized private research efforts and continues to do so into the future, the public has a right to expect a return on its investment, which may include price concessions.

This principle of governmental payment for regulatory monopoly concessions is justified on numerous levels. Economically, the subsidies restore partially forfeited monopoly incentives to the level normally attributable to exceptionally high demand for life-or-death products. Moreover, governmental research allowances spread the cost of underwriting AIDS research to the public at-large, rather than concentrating expense directly upon drug companies and indirectly upon consumers. If public policy demands that crucial product development be underwritten by a broader base than the small minority who use the products, then the public at-large should bear the expense of the subsidy. To charge companies with the entire cost of developing a quasi-public good is inequitable. The entire citizenry should bear at least part of the cost of creating quasi-public goods.[186]

What kind of mechanism will provide for the fair and just pricing of new AIDS drugs, given their status as quasi-public goods financed in

185. *See* Milt Freudenheim, *Drug Makers Face Pressure to Restrain Price Increases*, N.Y. TIMES, May 11, 1991, at 1.

186. *See supra* notes 174-83 and accompanying text.

part by tax dollars? My recommendation is a negotiated drug pricing model, under which industry and public representatives would enter a bargaining process to develop prices. The concept is democratic and would provide voting representation proportionate to the relative investment stakes of public and private interests.[187] Because input would be commensurate with investment, I distinguish negotiated drug pricing from ordinary instances of regulation, supposedly in the public interest, that are not associated with public investment. Negotiated drug pricing is not a form of governmental interference with private interests. Rather, it is a mechanism supported by a substantial respect for property rights. Negotiated drug pricing gives the public a say in the return it receives for its portion of the investment in AIDS treatment research and development. As such, the process is highly compatible with the desire for an unfettered marketplace, wherein property owners are allowed to determine the use of their assets without undue governmental interference.[188]

Several important tasks must be addressed regarding negotiated monopoly pricing. These include: (1) establishing methods for allocating public and private interests in patented drugs; (2) understanding the limited nature of the relationship between research as a quasi-public good and price concessions; (3) avoiding product-to-market delays; and, (4) providing a mechanism for reasonable price increases over the lifespan of the drug. For the purposes of this analysis, I address each of these issues briefly, although their elaboration remains an important challenge for more detailed future analysis.

A. Establishing Methods for Allocating Public and Private Interests in Patented Drugs

I have referred to scientific research findings as a quasi-public good for two reasons: (1) because private research is funded by both public and private sources, private and public interests should jointly own the products and processes obtained from that research;[189] and, (2) the research

187. For discussion of the desirability of democratic rationing of health care in general, see Fleck, *supra* note 134.

188. While negotiated pricing is compatible with a free-market economy, supply-side theory may apply relatively ineffectually to the peculiarities of the drug industry. Regulatory intervention may be justified by a recent report of the Office of Technology Assessment, which indicates that free-market competition is an inadequate moderator of prices in the market for prescription drugs. Office of Technology Assessment Report, *Pharmaceutical R&D: Costs, Risks and Rewards*, Reuter Transcript Rpt., Feb. 25, 1993.

189. *See supra* notes 174-83 and accompanying text.

and the public health interests that research findings serve have divisible and indivisible components. Given the free-market proposition that only indivisible interests are centrally financed and thus regarded as public goods,[190] public health research falls between the categories and has attributes of both public and private goods.[191]

The negotiation process recommended in this Part is meant to serve as ground for mediating public and private interests in public health. If negotiated pricing is implemented, an essential substantive concern which will drive the bargaining process is how to assess the relative investments, and therefore the merited returns, of public and private stakeholders. The creation of methods for assessing proportionate public and private stakes requires economic study, recognizing both direct and indirect forms of investment. For example, the public stake is likely to include both dollars donated to a particular research project and dollars committed to basic university research upon which the particular project is built.

B. Understanding the Limited Nature of the Relationship Between Research as a Quasi-Public Good and Price Concessions

Public support of and the public stake in research productivity justify broad-based input regarding the marketing of patented drugs. While the public voice should be heard and weighed in the proposed negotiations, society may expect return on its investment in forms other than consumer price reductions. One cannot presume that representatives of taxpayers will request exclusively, or even partially, price concessions in exchange for their investment. The public may instead support diversion of monopoly rents toward further research.[192] Likewise, society may prefer that its subsidization of research be rewarded by returning the public's share of the profits to the tax base, in order to reduce the federal deficit.

I raise the very real possibility that the public may not support monopoly drug consumer subsidies because such subsidies disproportionately

190. *See supra* note 160 and accompanying text.

191. *See supra* note 163 and accompanying text.

192. *See supra* notes 112-14 and accompanying text. This Article proposes that regulation of AIDS drug pricing should be predicated upon studies indicating the degree to which research and development incentives are likely to be impaired. In drug pricing negotiations, the public should, and probably will, consider the tradeoff between immediate, inexpensive access to new drugs, and profit incentives that encourage pharmaceutical companies to develop future new drugs.

benefit a small fraction of the taxpayer base which provided the original investment. A majority of citizens may prefer to devote the public portion of monopoly rents to further research or deficit reduction, in order to spread the benefit more evenly. While PWAs benefit disproportionately from monopoly price concessions, all of society shares in future research aimed at eliminating a contagious disease or in reduction of the deficit. From this standpoint, a decision during negotiations to support price reductions is charitable in nature.

Of course, the best way to assess the public will is to provide a hearing during pharmaceutical price negotiations. Survey research will provide an important evidentiary component in this process. As stakeholders and voters, it is incumbent on all citizens to examine carefully the issues relevant to determining how best to contribute to the public good.

Lawyers and scholars should lead in this process. This Article contends that the public should desire significant price concessions as part of the return on its investment, both out of compassion and enlightened self-interest.

1. The Utility of Price Concessions as an Exercise of Compassion

Seriously or terminally ill patients experience great hardship when useful or essential drugs are exorbitantly priced. Even representatives of the drug industry have admitted that a need exists for cost-containment in health care.[193] This need is particularly compelling for consumers of patented drugs for the treatment of deadly diseases.

The public may recognize the virtue of pricing subsidies by thinking of its investment in terms of Rawlsian empathy.[194] From a position of rational and mutually disinterested scrutiny,[195] society has incentives to conclude that the just distribution of life-saving drugs is that which provides universal access. This conclusion is reached by placing oneself in a position that most will never occupy—the position of a person who cannot afford an otherwise available, life-extending drug. In so doing, one may become more receptive to the compassionate emotions suggested

193. Milt Freudenheim, *Future Clouded at Drug Makers and Stocks Fall*, N.Y. TIMES, Feb. 4, 1993, at A1, C15 (quoting a spokesperson of the Pharmaceutical Manufacturers Association).

194. JOHN RAWLS, A THEORY OF JUSTICE (1971). The reference to "Rawlsian empathy" is an extension of Rawls's philosophy, rather than a direct application. Whereas Rawls refers to the original condition, in which a veil of ignorance is employed in order to determine principles of distributive justice, this Article refers to that same condition more generically as a locus from which we may be able to realize most fully our potential for compassion.

195. *Id.* at 13.

earlier within the context of feminist ethics of care.[196]

This Article has suggested, in regard to legally coerced public price subsidies, that the ethics of care could be subsumed within a free society, but not vice versa.[197] The result of this line of reasoning was the rejection of mandatory, regulated care. Yet, when society votes to choose a payoff for its public investment in private research as part of a process of negotiated pricing, a vote of compassion is empathically rational without being coercive.

2. *The Utility of Price Concessions as an Exercise of Enlightened Self-interest*

While everyone enters the decision-making process with vested interests and relative advantages or disadvantages reflecting extant fortune, no one is entirely secured of a harmless future. Even the healthiest, most advantaged and optimistic view health insurance as a basic and desirable product of fundamental utility. Tomorrow, one who has been most blessed by good fortune may be faced with a crisis.

For this reason, it behooves all of society to enter into a social contract in which the risk of vulnerability to exorbitantly priced drug treatments is shared. It is rational, even from the standpoint of self-interest and apart from considerations of compassion, to allocate to price subsidies some portion of the return on public investment in research. By dividing the public return between immediate price concessions and future investment in research, it is possible to strike a balance that benefits both the short- and long-term interests of society at-large. Each person receives the equivalent of public insurance against high prices in the event of illness, as well as the prospect of expunging AIDS.[198]

196. *See* SHERWIN, *supra* note 136, at 75, and accompanying text. Sherwin observes, "A feminist moral relativism demands that we consider who controls moral decision-making within a community and what effect that control has on the least privileged members of that community."

197. *See supra* notes 158-59 and accompanying text.

198. While I have proposed compassion and the social contract as two compelling reasons to vote for price concessions during negotiations, theoretical purists may not accept the arguments posed by both simultaneously. This is because at some point, the feminist ethics of caring may come into conflict with the presuppositions of social contract theory. In particular, formulation of a social contract is predicated on acceptance of and respect for disparities of advantage and power. A possible middle ground, wherein compassion and social contract justifications may become more consistent, is contained in the idea of "contractualism," which emphasizes moral consensus over the more classical social contractarian seeking of self-interest. For a discussion of contractualism, see T.M. Scanlon, *Contractualism and Utilitarianism, in* UTILITARIANISM AND BEYOND (Amartya K. Sen & Bernard Williams eds., 1982).

C. *Avoiding Product-to-Market Delays*

In seeking to expedite the equitable distribution of new drugs consistent with valid private and public expectations and property interests, it is necessary to avoid establishing impediments to bringing products to market as quickly as possible. In particular, when the legitimate public voice is added to the decision-making process by negotiation or otherwise, improvement in the quality of decision substance may come at the price of delay.[199] Because the life-and-death nature of AIDS treatment exacerbates the harm associated with sluggish marketing, the avoidance of bureaucratic obstacles is especially crucial.[200] Yet easy agreement regarding price will be difficult to reach, given the divergent interests of private corporations seeking to maximize profit and consumers attempting to minimize price.

Despite these inevitable difficulties, negotiated drug pricing must not be discarded by lumping it into the category of unjustifiable governmental regulation or interference with private interests. As emphasized earlier, the public's financial stake in AIDS research is direct and so substantial that it justifies significant public ownership of resulting products. Unlike regulation that may be viewed by governmental minimalists as intrusive, or as creating untenable public interests in private property, public rights in AIDS drugs are supported by the numbers.

The difficult task, then, is to recognize the irrefutable public stake in helping to determine new drug prices without creating unnecessary product-to-market delay. In some ways, the interests of public and private representatives are aligned in favor of expedient marketing. Potential consumers want access to the product as soon as possible, and private purveyors want to expedite profitable sales. Congruence of mission at this level will temper, but not remove, conflicting interests over price.[201]

199. Delay is likely to result from goal conflict, when numbers of decision makers with divergent interests increase. For discussion of the phenomenon and effects of goal conflict on decision-making, see RICHARD M. CYERT & JAMES G. MARCH, A BEHAVIORAL THEORY OF THE FIRM 117-25 (1963).

200. For discussion of the potential pitfalls of bureaucratic decision-making regarding public policy and scientific research, see Harold P. Green, *The Law-Science Interface in Public Policy Decisionmaking*, 51 OHIO ST. L.J. 375, 400-402 (1990).

201. Analogously, labor disputes should be shortened because management wants a work force to continue production while labor wants jobs to continue income flows. While this limited goal congruence between management and labor should logically reduce the length of negotiation impasses, contract disputes and strikes still may linger longer than either side desires. Likewise, it must be assumed that reductions in negotiation time for AIDS drug pricing will be limited by the intransigence of sellers, buyers, or both, in regard to terms viewed as non-negotiable.

In fashioning a workable system of negotiated drug pricing, it is necessary to exploit incentive alignments and minimize dysfunctional adversarial delay.

D. Providing a Mechanism for Reasonable Price Changes Over the Lifespan of the Drug

Negotiated drug pricing is a solution to some of the conflicts that currently arise when a company is deciding the price at which to market a new drug. Yet, subsequent pricing decisions must also be made to account for things like inflation, changes in industry cost structures, and shifting competitive structures within the industry or within a particular product-market segment. Just as the public has a stake in the initial pricing decision, so it has a stake in subsequent pricing decisions that occur over the life of the patent. A system of negotiated drug pricing must provide a mechanism for alterations in pricing as well as initial market-entry pricing decisions.

What factors should be considered in developing a system for pricing changes? Most importantly, it is necessary to keep in mind the essence of negotiated drug pricing: it is a method for allocating decision-making authority to the true stakeholder-owners of patented products. The essential requirements for a price-changing model are: (1) maintenance of a policy-making voice that is representative of the stakeholder base; and, (2) avoidance of unnecessary and harmful decision-making delay.

These two considerations are fundamentally at odds whenever decisions are made. Adding a layer of decision makers with a perspective that is potentially different from that of the incumbent decision makers will tend to add new insights capable of improving the quality of decision. However, this new layer of decision makers will create a cost in terms of expediency because difficulty in achieving consensus is magnified by the number of voters.[202] Of course, the delay at this stage is probably less potentially harmful than delays that may occur during market entry. When price change decisions are made, the product is already on the market and the critical goal of quickly introducing the product is not the concern. Still, undue delay in making necessary pricing alterations can be harmful to both public and private interests and, therefore, must be avoided.[203]

202. *See supra* note 199 and accompanying text.

203. Although this Article leaves the complete explication and development of the specific nego-

IV. CONCLUSION

Regulatory initiatives regarding pricing of drugs for the treatment of AIDS must carefully account for the ethics and economics of sound public policy. This Article has attempted to present a balanced explication of the most crucial considerations affecting the interests of patients, the public at large, and private industry. My recommendation in favor of negotiated drug pricing has been built on several observations.

First, all interests are best served by a public policy that maintains incentives of the patent system which truly serve to expedite applied research regarding causes and treatments of AIDS. Second, regulation mandating private pricing concessions, or public subsidization of private treatment, cannot legitimately be predicated upon rights culled carelessly from the air, without due consideration of the legitimacy of the duties which will inevitably be called upon in support of the proposed rights. Third, notwithstanding such rigorous scrutiny, the public has a right to insist on some return on its investment in both public and private forms of research that redound to the benefit of private industry in the development of patented products. This right is not preserved under the patent system, which ascribes solely to the patent holder all proprietary rights and interests in the patented product or process. Fourth, while the public voice may insist on its return in forms other than price concessions, both moral and pragmatic justifications exist for requesting price concessions during negotiations. These justifications are both charitable, as embodied in compassion, and self-interested, as incorporated into the social contract. Last, regulation providing for acknowledgement of the public stake in the quasi-public good of AIDS treatments must address product-to-market issues. Policy makers must be particularly sensitive to the need to expedite distribution of essential products by reducing bureaucratic impediments to product dispersion.

This Article has proposed negotiated drug pricing as a mechanism for recognizing and protecting both the public and private interests in new

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tiated drug pricing model for later analysis, two possibilities for pricing alteration policies should be considered. First, pricing changes can be linked to stipulated strategic variables, such as the consumer price index, spot-market prices for key inputs, and other fluctuating standards. Second, public hearings could be implemented, extending the negotiation process from initial price determinations to include subsequent changes as well. This process would probably resemble rate-making hearings for public utilities. The former alternative seems preferable from at least one standpoint—it is less bureaucratic, and thereby avoids the pitfall of creating a policy that is inexpedient and unwieldy.

products derived from research and development activity as currently funded out of both sectors. The purpose of this Article is limited—it has sought to provide the theoretical, principled justification for such a system, given both the realities of economic incentive systems and the nature of the rights and duties attached to all parties concerned.

Because the Article's approach is conceptual, it has placed little emphasis on the many questions that will inevitably be associated with implementation. It has suggested that additional layers of public decision makers, particularly those whose interests may be in conflict with private corporate concerns, can be potentially harmful in effect. While the quality of pricing decisions should improve, reflecting both greater breadth of informational input and more representative assertion of interests truly at stake, the amount of time taken to arrive at pricing decisions is likely to expand, given an expected diminution of consensus. Delays may also occur because of bureaucratization of decision making which impedes the socially desirable end of rapid distribution of essential pharmaceutical products.

These problems are merely suggestive of many potential difficulties that are likely to be associated with the implementation of a negotiated pricing system. While the scope of this Article has emphasized the theoretical over the practical, the next important step is the detailed explication of a practicable negotiation framework. As this Article's goal was limited to providing economic and ethical justification for negotiated pricing, future research questions addressing logistical concerns remain to be examined.