

A Different Kind Of Drug War

by Michael H. Davis

Against the Odds: The Story of AIDS Drug Development, Politics, and Profits

by Peter S. Arno and Karyn L. Feiden
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The acquired immunodeficiency syndrome (AIDS) epidemic represents the first time that an incurably fatal disease has affected a large number of otherwise healthy, educated, and young people in an age of consumer activism and government deregulation. The convergence of those factors has led to fundamental problems of national health policy. *Against the Odds* focuses specifically on AIDS, but more broadly, it is really about how poorly dogmatic ideology mixes with law and medicine.

Against the Odds has three main theses: (1) the federal government, especially the Food and Drug Administration (FDA), has been unresponsive to people with AIDS; (2) the pharmaceutical industry has acted irresponsibly throughout the AIDS crisis and has seemed at times to be out of control; and (3) the scientific establishment has engaged in research and testing protocols with insufficient regard for people with AIDS. Authors Peter Arno and Karyn Feiden contend that while "indifferent leadership, cumbersome bureaucracy and corporate greed" share responsibility for these deficient policies, lack of national leadership was key: "For the first four years of the epidemic, Ronald Reagan refused to utter the word AIDS."

However, the authors applaud the government's attempts to impose restrictions upon companies that benefit from public research, especially on the amount they can charge for drugs developed with government

funds. They support the FDA's expanding its focus from simply protecting society from dangerous drugs to monitoring drugs' effectiveness and assuring their delivery. They also praise the scientific community's attempts to minimize the need for placebo studies by using parallel-track protocols, to make some drugs available before testing has been completed, and to include AIDS patients and activists on various boards.

Federal Response

AIDS drug testing led to disputes over the relative merits of government-directed and investigator-initiated research. Arno and Feiden disapprove of "the bureaucrats'" decision in favor of the latter, which was, effectively, a deregulatory and decentralizing decision. It is remarkable, however, that a medical establishment so committed to double-blind placebo testing could fail to see the ethical problems of the National Institutes of Health (NIH)—namely, the "close, lucrative, and often undisclosed ties many of its investigators had to pharmaceutical firms." It is naïve to believe, as the authors seem to, that a centrally directed program of national research would have been less subject to conflicts of interest than were individual researchers. The authors also criticize the Bush administration's decision to deploy research based on future industrial benefit.¹ This raises the question of whether the decision was merely another part of so-called deregulation or simply an opportunity to subsidize private industry through public funds. Both instances show that deregulation may really have nothing to do with whether government intervenes but rather with whether the private sector profits.

Giving patients greater autonomy (for instance, by allowing preapproval access to drugs and personal-importation exemptions for unproven drugs) and allowing pharmaceutical manufacturers to charge whatever price the market will bear share the same result: freedom from government intervention. But is granting patient autonomy really

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deregulation? And is patient autonomy the same thing as industrial corporate autonomy? I think not. Furthermore, the book makes clear that where deregulation was not profitable, the Bush administration was not embarrassed to engage in its opposite.

The authors' observation that the Orphan Drug Act of 1983 was "enacted in the hands-off industry climate that has prevailed during the Reagan and Bush eras" is deliciously ironic. The Orphan Drug Act is an obvious government intervention in the free market. It provides a monopoly to drug manufacturers even though they have invented nothing that might be patentable and frequently manufacture drugs that have been in the public domain for decades. The act—which provides a monopoly for illnesses that affect fewer than 200,000 patients—is a bald admission that the free market does not work. As such, it is much less a "hands-off" measure than a simple government handout.

Indeed, Arno and Feiden write that the Orphan Drug Act became necessary because "drug companies had little reason to become involved in research because competitors were able to sell identical products without restriction." A straightforward economic reading of that observation (Arno is a medical economist) leads to the conclusion that the free market failed for health care and that the Orphan Drug Act was necessary to make the market work, however lamely.

Industry Response

When AIDS activists succeeded in importing pentamidine under the FDA's controversial 1988 personal-use policy, the response of Lyphomed (the U.S. manufacturer) was, according to the authors, that patients had a personal stake in encouraging drug companies to invest. In other words, it was shortsighted for people with AIDS to deprive Lyphomed of its profits by seeking pentamidine from manufacturers overseas; only if assured full profits could U.S. manufacturers continue to make progress. In a pure free-enterprise economy, that would undoubtedly be true. But in our mixed econ-

omy, with such a huge public investment in health care, it is at least doubtful.

Arno and Feiden also reveal how zidovudine (AZT), developed from start to finish by National Cancer Institute (NCI) director Samuel Broder and his hand-picked team, was hijacked by Burroughs Wellcome. The authors disclose that "American taxpayers footed the bill . . . at least five times over" in developing AZT and that finally Burroughs Wellcome adroitly acquired unparalleled tax advantages and orphan drug protection, to "write off as much as 70 percent of its clinical trial costs."

The authors note that virtually all of the AZT research was performed by government scientists and that in the end, Burroughs Wellcome "did not even corroborate NCI's findings [that AZT was effective] because it had neither the facilities nor the courage to work with live AIDS virus." The authors characterize Broder as "driven by compassion, foresight and ambition" but add that he "privately admitted they [at NCI] were somewhat naïve." According to the book, Burroughs Wellcome refused to cooperate with government investigators and others to reveal its revenues and expenses for AZT. "In the Bush administration," the authors state, "[t]here was neither the leadership nor the political will to rein in a corporate violator of the public trust." This account makes clear that a fundamental problem in health law is how to manage the private part of an effectively public enterprise.

The ultimate marketing of ddl (dideoxyinosine), so far the only rival of AZT, further demonstrates the failure of the free market. The government was careful to patent the drug to avoid the AZT fiasco, but its decision to license ddl to Bristol-Myers is more problematic. Since the main economic function of a patent is to recoup research and development investment, and since the government obviously had no intention of recapturing these costs through its license to Bristol-Myers, why then license the drug to only one company? Why not simply dedicate the drug to the public (as the authors indicate Jonas Salk did with the polio vaccine)? If no company needs to recoup the investment, there should be plenty of profits

to go around. I conclude that either the drug companies are unwilling to risk competition, or the free market in pharmaceuticals is so distorted that no profit can be made from marketing a drug—even one that cost the manufacturer nothing to develop—without monopoly pricing. Perhaps pharmaceutical companies are too accustomed to monopoly prices, or perhaps health-related products are ill suited to a free-enterprise system. The authors do not say.

The system collapsed at the other end as well. Insurance companies were unwilling to pay for unapproved uses of therapeutic drugs, and insured persons were frequently unwilling to signal their infection by making claims in the first place. The story of AIDS seems to imply that health care is too important to be left to the health care industry.

AIDS Community's Response

In the chapter "Grassroots Trials Come of Age," Arno and Feiden note that the "clinical trials engineered in the gay communities . . . ushered in a radical change." The communities mostly rejected placebo trials, which the authors view as "mainstream ideas," a "time-honored value," and a "traditional pillar" of scientific research. In place of placebo-controlled trials, the communities favored different-dose trials, which some mainstream researchers praised as the best way to get information on "patient tolerance and efficacy in the real world." The authors welcome the addition of community-based trials, but they tend to skirt the fact that in many ways different-dose testing repeats the dilemmas of placebo testing.

No matter how mainstream, both protocols inevitably grind against the rock of cold reality. Recent literature confirms that the randomized clinical trial—including placebos where necessary—is still the only way an AIDS cure will be found.² And AIDS Controlled Trial Group (ACTG) Protocols 016 and 019 (which demonstrated the efficacy of AZT and which the authors describe as landmark) were placebo-controlled studies. Like most compassionate people, Arno and Feiden find it difficult to reconcile the need

for different-dose or even placebo studies with the understandable desire to guarantee patients with fatal illnesses immediate access to the best and most hopeful treatments.

Concluding Comments

Against the Odds is an invaluable resource. There is no comparable record of what has occurred. The failure to discover a cure for AIDS or better treatments for opportunistic diseases is not by itself an indictment of any particular scheme of scientific research. The way in which Burroughs Wellcome misappropriated AZT, the prices it charged, and the manner in which it obstructed research was indeed scandalous and even may have slowed overall progress toward finding a cure or treatment. But it is doubtful whether national leadership is the panacea the authors think it is. Furthermore, the authors' implicit suggestion that we need an AIDS "czar" raises troubling parallels with how we have managed drug addiction thus far. Indeed, the problem may not be the absence of a czar but rather a failure to understand the problem itself.

The AIDS crisis has raised basic questions about whether society can reform national health policy so long as it is based upon a dogmatic ideological commitment to a fictional free market. *Against the Odds* demands reflection because the authors leave ultimate solutions to the reader, to the American public, and to the future.

NOTES

1. "U.S. Will Tighten Health-Lab Goals," *The New York Times*, 24 August 1992, A1. ("The plan has alarmed many scientists, who say . . . Washington is trying to set a national industrial policy. . . . But in an interview, Dr. Bernadine P. Healy, director of the National Institutes of Health . . . said, 'I don't understand why industrial policy is such a bad word'."); "Budgetary Roller Coaster Hurts U.S. Science: An Unhealthy Mix," *The New York Times*, 24 September 1992, A28; and H.E. Varmus and M.W. Kirschner, "Don't Undermine Basic Research," *The New York Times*, 29 September 1992, A23.
2. C. Levine, N.N. Dubler, and R.J. Levine, "Building a New Consensus: Ethical Principles and Policies for Clinical Research on HIV/AIDS," *IRB* (January–April 1991): 1–24.