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AIDS Activists, FDA Regulation, and the Amendment of America's Drug Constitution

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AIDS ACTIVISTS, FDA REGULATION, AND THE AMENDMENT OF AMERICA'S DRUG CONSTITUTION

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This Article explores how AIDS activists, desperate for access to potentially life-saving pharmaceuticals, permanently transformed America's "drug constitution." Their advocacy altered the FDA's interpretation and application of the federal Food, Drug, and Cosmetic Act (FDCA) so as to expedite the availability of new, unproven drugs for critical illnesses, thus enhancing individual patients' autonomy to make therapeutic choices without government interference.

The FDCA is more than simple set of instructions to a federal agency—it is a source of vitally important and deeply entrenched institutional and normative frameworks. Like major civil rights, antitrust, and environmental statutes, the FDCA should be viewed as a quasi-constitutional "superstatute." Therefore, the AIDS activists' FDA reform campaign of the late 1980s and early 1990s should be understood as a "constitutional" movement, even though it rarely invoked the United States Constitution and pursued its goals entirely outside of court. As a result of the AIDS movement's efforts, federal drug regulation today reflects not only the FDCA's original foundational principle of protecting consumers from hazardous protects, but also the (often contrary) fundamental goal of promoting the expeditious release of potentially effective treatments for severe illnesses. The AIDS activists' successful advocacy regarding drug access permanently shifted decision-making power previously exercised by the FDA to individual patients and their physicians.

In addition to linking the AIDS movement to other major civil rights campaigns focused on the implementation of statutes, this Article details a particularly remarkable advocacy effort that has gone mostly overlooked in the legal literature. The Article examines how a movement composed largely of members of a scorned and marginalized population—HIV-positive gay men—significantly altered a crucial body of law administered by one of the country's most powerful agencies. As the Article describes, the AIDS movement achieved this success in a seemingly incongruous alliance with conservative libertarians. Rather than simply telling a triumphal story, however, this Article explores how the AIDS movement was ultimately torn apart by deep schisms that prevented it from ever coalescing around a fully coherent medical libertarian philosophy. The most profound of these divisions, rooted in the very nature of controlled clinical research, concerned the moral acceptability of limiting terminally ill people's freedom to try experimental drugs so as to ensure the production of reliable data regarding the treatments' effectiveness. Ambivalence about the proper resolution of this quandary—among activists and society as a whole—has inhibited a radical dissolution of the FDA's gatekeeping power. Nevertheless, as this Article concludes, federal regulation of medical products is now very different than it would have been without the AIDS activists' determined efforts.

INTRODUCTION

The Parklawn Building, a massive, bland edifice erected in the late 1960s, looms over a neighborhood of nondescript office buildings and auto repair shops in Rockville, Maryland, about four miles outside the Washington, D.C. Beltway. Until recently, the building contained the headquarters of the U.S. Food and Drug Administration (FDA), as well as other Department of Health and Human Services (HHS) offices. It is an unlikely setting for a mass protest. For a thousand boisterous AIDS activists who stormed it on October 12, 1988, however, the Parklawn Building was the Bastille. And as this Article will explain, their demonstration sparked a profound transformation in the government's approach to regulating treatments for serious illnesses.

The "Seize Control of FDA" protesters—many of them bused in by the recently formed AIDS Coalition to Unleash Power (ACT UP)—demanded that the agency speed the availability of drugs for Acquired Immune Deficiency Syndrome. Since it had emerged in the United States in 1981, AIDS had spread with particular virulence among gay and bisexual men.[1]

[1] CDC FACT SHEET: ESTIMATES OF HIV INFECTIONS IN THE UNITED STATES, 2 (2008), http://www.cdc.gov/nchhstp/newsroom/docs/fact-sheet-on-hiv-estimates.pdf.

They dominated the crowd surrounding the Parklawn Building, although many women joined the protest, too. For an entire workday, the demonstrators loudly condemned the federal government's inaction in the face of AIDS. They denounced the apathy of President Ronald Reagan and Vice-President George H. W. Bush (the 1988 Republican nominee). Their primary target, however, was the FDA itself.

In truth, the FDA had not been completely inert in response to the horrific rise of the epidemic. In 1986, the agency had made azidothymidine (AZT)—an investigational antiretroviral drug that targeted the human immunodeficiency virus (HIV)—available to patients outside of formal clinical trials on a "compassionate use" basis. The following year, it had approved AZT's New Drug Application (NDA) with extraordinary speed. In addition, the FDA had issued a "treatment IND" rule in 1987, formalizing its longstanding ad hoc practice of allowing therapeutic use of investigational new drugs in desperate situations.[2]

AIDS activists were nonetheless enraged in the fall of 1988. AZT remained the only FDA-approved therapy for HIV/AIDS. At best, this drug delayed the disease's inevitably fatal outcome, and many people with AIDS (PWAs) could not tolerate its severe side effects. In October 1987, an FDA advisory committee had recommended against the approval of ganciclovir, a promising drug for a blindness-inducing eye infection common among PWAs. Meanwhile, the treatment IND process was not significantly increasing access to AIDS drugs still under investigation. At the time of the Parklawn protest, the FDA had made only one AIDS-related experimental therapy available pursuant to the new procedure—trimetrexate, a medicine for an often fatal form of pneumonia acquired by many PWAs.[3]

American scientists were studying scores of other compounds, and many in the HIV-positive population were eager to try each one as soon as it showed the slightest evidence of efficacy, rather than wait the seven to ten years the FDA ordinarily took to approve a drug.[4] Accompanied by whistles and noisemakers, the crowd around the Parklawn Building chanted its

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[2] *See infra* p. [ ].

[3] In July 1988, FDA had approved one out of four treatment IND requests for AIDS-related drugs and four out of eight for other drugs. Philip M. Boffey, *New Initiative to Speed AIDS Drugs is Assailed*, N.Y. TIMES, July 5, 1988, at C1.

[4] The details of the demonstration related below are drawn from various sources, including video footage of the event collated by SuchIsLife Videos, https://www.youtube.com/watch?v=s70aCOflRgY; the documentary *How to Survive a Plague*; interviews in the AUOHP, http://www.actuporalhistory.org/interviews/; Paul Duggan, *1,000 Swarm FDA's Rockville Office to Demand Approval of AIDS Drugs*, WASHINGTON POST, October 12, 1988, at 1; *176 Arrested at FDA AIDS Drug Protest, Many Employees Don't Go to Work*, HEALTH DAILY, October 12, 1988, at 2–4; *FDA Resumes Business After AIDS Demonstration*, HEALTH DAILY, October 17, 1988, at 7.

demands for pharmaceutical access. "AZT is not enough, give us all the other stuff!" "Release the drugs now!" Most provocatively, the demonstrators, referring to the FDA Commissioner, yelled "Frank Young, you can't hide, we charge you with genocide!" Their placards and banners were no gentler. "AIDS Doesn't Discriminate—Our Government Does." "Federal Death Administration." Many signs displayed a pink triangle, evoking the patch sewn onto the uniforms of gay inmates in Nazi concentration camps.

The action's theatrical elements captured the attention of cameramen from the television networks and major newspapers. Protestors lay down on the street holding cardboard tombstones bearing epitaphs such as "RIP, Killed by FDA" and "I Died for the Sins of FDA." Others paraded around in "blood"-stained white doctors' coats. ACT UP's Peter Staley, a J. P. Morgan bond trader turned full-time activist, hoisted himself onto the portico over the building's main entrance, wearing a bandana that made him look, in the eyes of a fellow protestor, like the Karate Kid.[5] Once there, he attached a giant "Silence=Death" sign on the façade and set off smoke bombs, to the cheers of the throng.

The event was peaceful overall. A glass door and a couple of windows were shattered. Six activists snuck inside the building and briefly occupied some non-FDA offices. One protester was arrested after knocking a police officer off his motorcycle. Other demonstrators, some in T-shirts declaring "Gay and Positive," occupied the driveway in front of the building and refused to move. Eventually, police—some wearing latex gloves—escorted or dragged 175 handcuffed activists to buses, which carted them off to be booked for loitering. Despite the gravity of the cause, the event was characterized by inspired camp and an almost festive camaraderie. As the buses rolled away to transport the arrestees to the police station, the passengers crooned the theme song from television's *Carol Burnett Show*: "I'm so glad we had this time together."[6] One activist recalled, "It was really fun. I mean, it was really fun."[7]

The day of the protest was not a productive one inside the Parklawn Building. Many employees stayed home or failed to breach the blockade. Those who managed to reach their desks spent hours peering through windows at the commotion outside.

When the workforce arrived en masse the next morning, things seemed back to normal. But in fact, the FDA never really resumed business as usual

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[5] Michael Nesline interview, Mar. 24, 2003, at 43 (interview # 014 of the ACT UP Oral History Project (hereinafter AUOHP), available at http://www.actuporalhistory.org/).

[6] Jay Blotcher interview, Apr. 24, 2004, at 54 (interview # 054 of the ACT UP Oral History Project).

[7] Nesline interview, *supra* note [ ], at 43.

after ACT UP seized the agency in October 1988. This Article will examine how the AIDS social movement spurred changes in the agency's implementation of the Food, Drug, and Cosmetic Act (FDCA) and, eventually, in the language of the statute itself. The resulting reforms have made access to potentially life-saving drugs a fundamental goal of the Act, alongside the protection of consumers from unsafe and ineffective products.[8]

In describing and analyzing the AIDS activists' impact on FDA drug regulation, this Article draws on a number prominent contemporary developments in legal scholarship. One scholarly trend, articulated most prominently by William N. Eskridge and John Ferejohn, focuses on how this country's foundational legal principles are contained not only in the United States Constitution, but also in quasi-constitutional "superstatutes" and their implementation by administrative agencies.[9] The FDCA, enacted in 1938 as the successor to the Pure Food and Drugs Act of 1906, is one such statute.[10] Congress passed the FDCA largely in response to a crisis precipitated by insufficient government protection of drug consumers—namely, the death of more than a hundred people who consumed a medicine called Elixir Sulfanilamide.[11] The statute was premised on the principle that the national government should shield consumers from unsafe and (in the case of medical products) ineffective goods, including food, drugs, cosmetics, and medical devices.[12] Later amendments, in 1962 and 1976, strengthened the statute by requiring the FDA to block new drugs and some medical devices from entering the market until the agency was satisfied that their benefits outweighed their risks.[13] Despite occasional protests, the

[8] 21 U.S.C. §§ 301-399f.

[9] William N. Jr Eskridge & John Ferejohn, *Super-Statutes*, 50 DUKE LAW J. 1215 (2001); WILLIAM N. ESKRIDGE & JOHN A. FEREJOHN, A REPUBLIC OF STATUTES: THE NEW AMERICAN CONSTITUTION (2010); Cf. BRUCE ACKERMAN, WE THE PEOPLE, VOLUME 3: THE CIVIL RIGHTS REVOLUTION 9 (2014) (emphasizing the constitutional character of the seminal civil rights statutes of the 1960s).

[10] Eskridge and Ferejohn identify both the Pure Food and Drugs Act and the FDCA as "super-statutes." Eskridge and Ferejohn, *supra* note 9 at 1226, 1257–58.

[11] PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD AND DRUG LAW: CASES AND MATERIALS 11 (4th ed. 2014).

[12] In 2009, tobacco products were added to this list. 2009 Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776-1858 (2009), codified primarily at 21 U.S.C. §§ 387-387t.

[13] Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780-96 (1962); Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539-83 (1976). In addition, the Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (1958), and the Color Additive Amendment of 1960, Pub. L. No. 86-618, 74 Stat. 397 (1960), established FDA premarket approval regimes requiring manufacturers to demonstrate safety (but not effectiveness) prior to sale.

American public has broadly endorsed FDA's role as the gatekeeper for medical products.[14]

The quasi-constitutional nature of the FDCA is reflected not only in the important, deeply-entrenched government structures and functions it has created, but also in its corresponding effect of restricting American consumers' choices within some of the most essential product categories in the human economy. As a formal matter, the Act curbs the conduct of manufacturers and distributors, not their customers. Nevertheless, when the FDA prevents the sale of a product altogether, the Agency also indirectly limits the rights of consumers who want that product. Americans usually quietly accept this constraint on their freedom of choice because they value the FDA's role in safeguarding their health. On occasion, however—and with increasingly frequency since the 1970s—citizens have resisted FDA restrictions on the sale of certain drugs as unwarranted infringements on their autonomy. As we will see, these protests have been especially fervent with respect to potentially life-saving medications, as patients have condemned government curbs on the distribution of such products as violations of the most fundamental right of all—the right to attempt to preserve one's own life.

The AIDS activists' struggle to loosen the FDA's gatekeeping role with respect to drugs can thus be viewed as a form of constitutional struggle, even though they rarely invoked the language of the U.S. Constitution itself. By forcing a change in the FDA's regulatory practices, the campaign effectively amended the country's "drug constitution"—a term I use in this Article to refer to the human drug provisions of the FDCA and the agency's interpretation and application of them. Before the AIDS movement took to the streets, the FDA viewed the sole core purpose of the FDCA as guarding the public health by protecting consumers from hazardous and ineffective products. By the time AIDS activism waned in the early 1990s, the Act—as interpreted and applied by the agency—also embodied the (sometimes contrary) fundamental purpose of promoting the expeditious release of potentially effective treatments, both to advance public health and to enhance consumer choice. Before the turn of the century, Congress would embody this transformation in the language of the FDCA itself.[15]

This Article is also a contribution to the growing body of scholarship, dubbed "demosprudence" by Lani Guinier and Gerald Torres, that focuses on the "dynamic equilibrium of power between law and social

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[14] See generally DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA (1st ed. 2010).

[15] *See infra* [ ].

movements."[16] Work in this vein considers how citizen mobilizations create the conditions for durable legal change, including by opening space for marginalized minorities to participate in policy formation.[17] This approach is becoming an important component of constitutional law scholarship in particular. While some of this work focuses on the influence social movements have on the judicial interpretation and application of the U.S. Constitution itself (what Eskridge and Ferejohn call "large 'C' Constitutionalism"),[18] an important more recent strain emphasizes their impact on the language and post-enactment implementation of quasi-constitutional superstatutes ("small 'c' constitutionalism"). This Article is a contribution to this latter body of work, which examines how constitutional values are forged by interactions between social movements and nonjudicial government officials, such as agency administrators and legislators.

The story of the AIDS activists' struggle to reform FDA drug regulation thus demonstrates how extralegal popular mobilization can play an important constitutive function in the administrative law sphere. This Article is not the first work of legal scholarship to emphasize the importance of interactions between social movements and administrative agencies in shaping the nation's core values.[19] Such studies are a small but growing component of the growing body of work about "administrative

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[16] Lani Guinier & Gerald Torres, *Changing the Wind: Notes Toward a Demosprudence of Law and Social Movements*, 123 YALE LAW J. 2740–2804, 2749 (2014); For other examples of the growing literature on the interaction between social movements and law, see Steven A. Boutcher, *Mobilizing in the Shadow of the Law: Lesbian and Gay Rights in the Aftermath of Bowers v. Hardwick*, 31 RES. SOC. MOV. CONFL. CHANGE 175–205 (2010); Tomiko Brown-Nagin, *Elites, Social Movements, and the Law: The Case of Affirmative Action*, 105 COLUMBIA LAW REV. 1436 (2005); Susan D. Carle, *Social Movement History of Title VII Disparate Impact Analysis, A*, 63 FLA. LAW REV. 251 (2011); Michael C. Dorf, *Identity Politics and the Second Amendment*, 73 FORDHAM LAW REV. 549 (2004); William N. Jr Eskridge, *Channeling: Identity-Based Social Movements and Public Law*, 150 UNIV. PA. LAW REV. 419 (2001); Michael McCann, *Law and Social Movements, in* THE BLACKWELL COMPANION TO LAW AND SOCIETY 506–522 (Austin Sarat ed., 2004); Edward L. Rubin, *Passing through the Door: Social Movement Literature and Legal Scholarship*, 150 UNIV. PA. LAW REV. 1 (2001); Reva B. Siegel, *Constitutional Culture, Social Movement Conflict and Constitutional Change: The Case of the de facto ERA - 2005-06 Brennan Center Symposium Lecture*, 94 CALIF. LAW REV. 1323 (2006).

[17] Guinier and Torres, *supra* note 16 at 2749–56.

[18] ESKRIDGE AND FEREJOHN, *supra* note 9 at 3; For an example of this type of scholarship, see Jack M. Balkin & Reva B. Siegel, *Principles, Practices, and Social Movements*, 154 UNIV. PA. LAW REV. 950 (2005).

[19] See, e.g. Eskridge, *supra* note 16; ESKRIDGE AND FEREJOHN, *supra* note 9; Gillian E. Metzger, *Administrative Constitutionalism*, 91 TEX. LAW REV. 1897–1936 (2013); Vicki Schultz, *Taking Sex Discrimination Seriously*, 91 DENVER UNIV. LAW REV. 995–1119 (2015).

constitutionalism."[20] Nevertheless, legal academics have produced few detailed analyses, from the ground-up, of the tactics particular social movements have used to shape particular agencies' policies.[21] This Article adds to the literature by providing such an examination. The AIDS movement's FDA campaign offers a particularly interesting example of a social movement's administrative reform effort, for the notice-and-comment rulemaking procedure established by the Administrative Procedure Act of 1946 (APA) was far less crucial to it than other, non-APA techniques, such as street protests, media appearances, private meetings with agency officials, and testimony at public hearings.

This Article also offers insight into the distinct dynamic of social movement campaigns focusing on scientific agencies that deal with highly technical issues. In contrast to agencies like the Equal Opportunity Employment Commission (recently examined from a social movement perspective by Vicki Schultz), the FDA bases its decisions largely on hard scientific data. Although some legal scholars have discussed social movements' efforts to reform the practices of scientific agencies, particularly in the environmental area,[22] close studies of the particular challenges confronting such efforts appear primarily in the social science literature.[23] As I explore below, the scientific nature of the FDA's mission shaped the AIDS movement's activism, requiring the development of a cadre of technically sophisticated "treatment activists" who forged productive working relationships with government officials and scientists. This development in turn produced irresolvable tensions within the movement itself, and a bitter split ultimately occurred between these "insider" treatment activists and their less scientifically literate, more radical "outsider" counterparts.

Finally, this Article highlights two distinctive aspects of patient activism concerning the regulation of medical products. One distinguishing feature is the especially fraught *intra-movement* divisions rooted in the very

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[20] See generally Metzger, *supra* note 19.

[21] See, e.g., Ruth Landridge, *When Do Challengers Succeed--Nongovernmental Actors, Administrative Agencies, and Legal Change: Shifting Rules for Oregon's Private Forests*, 36 LAW SOC. INQ. 662 (2011); Schultz, *supra* note 19.

[22] See, e.g., Cary Coglianese, *Social Movements, Law, and Society: The Institutionalization of the Environmental Movement*, 150 UNIV. PA. LAW REV. 118 (2001); Landridge, *supra* note 21.

[23] See, e.g., STEVEN EPSTEIN, IMPURE SCIENCE: AIDS, ACTIVISM, AND THE POLITICS OF KNOWLEDGE (1996); Steven Epstein, *The Construction of Lay Expertise: AIDS Activism and the Forging of Credibility in the Reform of Clinical Trials*, 20 SCI. TECHNOL. HUM. VALUES 408–437 (1995); David J. Hess, *Medical Modernisation, Scientific Research Fields and the Epistemic Politics of Health Social Movements*, 26 SOCIOL. HEALTH ILLN. 695–709 (2004).

nature of medical research.[24] Modern clinical science depends primarily on the double-blind controlled investigation—a methodology that treats ill people as randomly-assigned subjects of study rather than as autonomous patients. As we will see, AIDS activists were passionately divided on the morality of restricting patient choice in the interest of obtaining scientific evidence of efficacy.

This Article also explores an *inter-movement* phenomenon characteristic of medical product activism. The ideological dynamics of body politics can forge remarkable left-right coalitions. In the case of AIDS drugs, left-leaning champions of gay and women's liberation who supported government intervention in many arenas joined forces with right-leaning libertarians who promoted sweeping deregulation. As we will see, this alliance of convenience presented the AIDS movement with challenges as well as opportunities.

This Article will proceed as follows. Section I introduces the special problems AIDS activists confronted as the first major movement for freedom of therapeutic choice focused not on alternative cures but on orthodox medicine. Section II lays out the legal framework for drug regulation established by the FDCA. It also describes the FDA's general approach to implementing this statute prior to the AIDS crisis. Section III describes how even before the rise of the AIDS movement, conservative libertarians fought, with limited success, to make unapproved drugs more available to PWAs and others with deadly diseases.

Section IV discusses the emergence of FDA-focused activism among PWAs and their allies, culminating in the Parklawn protest. Section V explores a variety of tactical and ideological questions faced by the AIDS movement following the FDA demonstration. Section VI considers the movement's initial regulatory victory, the publication of "Subpart E" procedures expediting the development of drugs for serious illnesses, and Section VII describes its greatest triumph, the creation of a "parallel track" allowing PWAs to take unapproved drugs for treatment purposes while clinical trials were still ongoing. Section VIII describes the schism that subsequently developed, dividing scientifically literate "treatment activists" from the broader movement. Section IX analyzes the vicious conflict that occurred between these factions over FDA's proposed "Accelerated Approval" procedure, which lowered the evidentiary requirements for initial marketing of some AIDS drugs. Finally, this Article's Conclusion considers the legacy of the AIDS movement's FDA campaign: the amendment of America's "drug constitution" in a way that still shapes medical product regulation today.

[24] Schultz emphasizes the importance of studying intra-movement divisions. Schultz, *supra* note 21.

I. A MOVEMENT FOR FREEDOM OF CHOICE WITHIN ORTHODOX MEDICINE

AIDS activism was not the first social movement to target the FDA; as I have examined in other work, movements fighting for access to dietary supplements and Laetrile (an alternative cancer treatment derived from apricot pits) had done so in the 1970s.[25] Nonetheless, something different was going on when ACT UP took up its struggle. Unlike their forerunners, the leading AIDS activists did not reject the scientific premises of modern drug development. To the contrary, they focused their demands on cutting-edge pharmaceutical treatments produced by the government-industrial-academic biomedical complex. AIDS activism was the first mass movement for freedom of therapeutic choice *within* orthodox scientific medicine.

The AIDS movement thus invited a fundamental tension into its ideology—a tension that, more than anything else, distinguished it from prior campaigns for freedom of therapeutic choice. As I have described elsewhere, American opponents of government restrictions on *alternative* therapies have long stressed the value of unfettered experimentation by practitioners and patients. They have considered free inquiry to be essential to both effective individual treatment and to the advancement of medical knowledge.[26]

By contrast, in the worldview of modern scientific medicine, a treatment's efficacy is determined not by decentralized trial-and-error experimentation, but by meticulously designed, FDA-regulated, controlled clinical studies. Indeed, those who embrace the modern clinical research model believe that the unrestricted use of experimental drugs actually undermines the quest for scientific truth by diverting patients away from such controlled studies. The AIDS activists thus pinned their medical hopes on a system in which the advancement of knowledge requires not *free* inquiry, but rather highly *regulated* inquiry. As we will see, this tension between access and knowledge bedeviled the AIDS movement's campaign to reform FDA drug regulation and, ultimately, prevented it from ever coalescing around a unified, comprehensive medical libertarian ideology.

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[25] Lewis A. Grossman, *FDA and the Rise of the Empowered Consumer*, 66 ADMIN. L. REV. 627–677, 646–51, 666–68 (2014); Lewis A. Grossman, *FDA and the Rise of the Empowered Patient*, *in* FDA IN THE 21ST CENTURY (Holly Fernandez Lynch & I. Glenn Cohen eds., 2015).

[26] Lewis A. Grossman, *The Origins of American Health Libertarianism*, 13 YALE J. HEALTH POLICY LAW ETHICS 76–134, 118–20 (2013); Lewis A. Grossman, *Orthodoxy and "The Other Man's Doxy": Medical Licensing and Medical Freedom in the Gilded Age*, *in* YOU CAN CHOOSE YOUR MEDICINE: FREEDOM OF THERAPEUTIC CHOICE IN AMERICAN HISTORY AND LAW (forthcoming).

The fact that AIDS activism was a movement for freedom of therapeutic choice *within* orthodox medicine also impelled the AIDS community to embrace different tactics. Protesters against government curbs on alternative medicine have generally approached their tasks as outsiders. They have stood apart from, and resisted the authority of, establishment institutions and orthodox systems of knowledge. AIDS activists sometimes adopted an "outsider" approach, particularly when they engaged in disruptive direct actions, not only at the FDA, but also, for example, at the National Institutes of Health (NIH), St. Patrick's Cathedral, the New York Stock Exchange, the American Medical Association headquarters, and North Carolina Senator Jesse Helms's house (which they sheathed in a giant condom). Such demonstrations called attention to PWAs' plight, challenged the homophobic values of the dominant culture, and satisfied the expressive and identity-building needs of the AIDS community itself.

But leading AIDS activists recognized that street protests alone could not achieve their more instrumental goal of reforming the FDA's approach to drug regulation. That mission, they concluded, required members of their movement to enter the halls of power and, using the technical language of modern scientific medicine, interact directly with the government, the pharmaceutical industry, and the clinical research community. Consequently, an organized group of "treatment activists" emerged within ACT UP to lead the FDA reform effort. This determined coterie of eloquent laymen mastered the science of AIDS and the complexities of pharmaceutical research. Due to their emergence, the AIDS movement did not, like most social movements focused on science or medicine, simply attack the trustworthiness of "experts" or embrace an anti-scientific epistemology. Instead, as contemporaneously described by sociologist Steven Epstein:

> These activists wrangle with scientists on issues of truth and method. They seek not only to reform science by exerting pressure from the outside but also to perform science by locating themselves on the inside.… Most fundamentally, they claim to speak credibly as experts in their own right—as people who know about things scientific and who can partake of this special and powerful discourse of truth.[27]

In both formal proceedings and informal meetings, this cluster of autodidacts engaged in highly technical discussions with the FDA and other stakeholders about how best to tackle the AIDS crisis. This "inside" complement to outside action was perhaps the defining characteristic of AIDS activism and subsequent movements for freedom within orthodox

[27] EPSTEIN, *supra* note 23 at 13.

medicine.[28] As we will see, however, it also represented a widening schism that ultimately tore the AIDS movement apart.

II. LEGAL FRAMEWORK OF FDA DRUG REGULATION

Although the FDA arguably lacked sensitivity, creativity, and a sufficient sense of urgency in its early response to AIDS, nobody could charge it with violating the law by severely restricting access to drugs not yet definitively shown to be safe and effective. To the contrary, the agency was following the provisions of the Federal Food, Drug, and Cosmetic Act (FDCA to the letter. Unfortunately for PWAs clamoring for an opportunity to try new medications, that statute's primary goal was to keep unsafe and ineffective drugs off the market.

In 1938, Congress passed the FDCA largely in response to a catastrophe in more than 100 Americans, many of them children, died as a result of taking "Elixir Sulfanilamide," an early antibiotic. Before this time, the FDA lacked any power to review the safety of drugs prior to sale. The FDCA created the modern system under which submission of a New Drug Application (NDA) to the agency must precede the introduction of a new drug onto the market. Notably, however, the 1938 version of the statute required NDAs to contain evidence of safety, but not of effectiveness. Furthermore, the 1938 FDCA created a premarket notification process rather than a true premarket approval process; an NDA would automatically "become effective" after 60 days unless the FDA intervened and affirmatively disapproved it.

The groundbreaking 1962 Drug Amendments were a reaction to another public health disaster. This time, the source of the problem was thalidomide, a popular sedative used in many nations around the world. Soon after pregnant women began to take thalidomide as a treatment for morning sickness, it became apparent that the drug caused severe birth defects—most distinctively malformed and stunted limbs. Thanks to the resoluteness of a now-legendary FDA medical officer named Frances Kelsey, the agency never allowed thalidomide's American NDA to become effective. Congress recognized how narrowly the United States had averted tragedy, however, and it promptly amended the FDCA to strengthen the regulation of new drugs—in ways that went far beyond correcting any deficiencies revealed by the thalidomide crisis.[29]

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[28] Epstein, *supra* note 23.

[29] Accounts of the thalidomide crisis and Kelsey's role in it appear in *id.* at 228–97 and MORTON MINTZ, BY PRESCRIPTION ONLY: A REPORT ON THE ROLES OF THE UNITED STATES FOOD AND DRUG ADMINISTRATION, THE AMERICAN MEDICAL ASSOCIATION, PHARMACEUTICAL MANUFACTURERS, AND OTHERS IN CONNECTION WITH THE IRRATIONAL

The main features of the regulatory framework established by the 1962 Drug Amendments remain intact today. The Amendments introduced the requirement that investigators notify the FDA prior to commencing any study of an unapproved drug in human beings. Moreover, Congress authorized the agency to disallow or halt any investigation that did not satisfy requirements set forth in FDA regulations, including human subject protections.[30] The FDA issued these "Investigational New Drug" (IND) regulations in 1963.[31] One section of this rule established the enduring three-phase structure for human drug experiments familiar to researchers today.[32] Phase 1 studies are performed in a small number of (usually healthy) volunteers and are designed primarily to assess the drug's safety at increasing doses. Phase 2 studies are conducted in a larger but limited number of subjects suffering from the target disease and are performed with the goal of assessing the treatment's effectiveness as well as safety. Phase 3 studies are large trials intended to gather all the information the FDA needs to perform an overall risk-benefit assessment of the drug and to review the proposed physician labeling.[33]

The 1962 Amendments also made important changes to the FDA drug approval process. They converted the NDA procedure into a true premarket approval scheme, under which a manufacturer cannot legally market a new drug until the FDA has positively approved it.[34] More importantly, the 1962 Amendments revised the Act to require the agency to reject an NDA, not only if the applicant fails to demonstrate that the drug is safe, but also if "there is a lack of substantial evidence that the drug will have the effect it purports … to have … in the proposed labeling."[35]

Although the 1962 Amendments listed proof of safety and proof of effectiveness as separate requirements, the FDA immediately recognized the inextricable relationship between them and embraced a drug approval calculus that weighs benefit against risk.[36] This interpretation of the statute

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AND MASSIVE USE OF PRESCRIPTION DRUGS THAT MAY BE WORTHLESS, INJURIOUS, OR EVEN LETHAL 248–64 (1967).

[30] FDCA § 505(i).

[31] 28 Fed. Reg. 179 (Jan. 8, 1963). These regulations, as amended, are now at 21 C.F.R. Part 312.

[32] 28 Fed. Reg. at 180.

[33] 21 C.F.R. § 312.21.

[34] FDCA § 505(a).

[35] FDCA § 505(d). FDA reviewers had in fact been taking efficacy considerations into account when considering NDAs since the late 1940s. CARPENTER, *supra* note 14 at 118–227.

[36] Testimony of FDA Commissioner George Larrick, "Drug Safety," Hearings before a Subcommittee of the House Committee on Government Operations, 88th Cong., 2nd Sess 150, 153-54 (1964).

was sensible and probably inevitable. Many useful pharmaceutical products (including most AIDS and cancer drugs) pose significant risks. If FDA considered the safety of such products in isolation from their benefits, it would reject many indispensable treatments. But this risk-benefit approach also exposed the FDA to a new type of challenge to its NDA decisions—attacks on the agency's policy judgments rather than (or in addition to) its scientific findings. After all, a decision by the FDA to reject an effective drug because of excessive risks is not merely a scientific conclusion. Rather, it is a determination that the particular product's risks so clearly outweigh its benefits that the government should deny patients and their physicians the opportunity to perform their own risk-benefit assessment and make their own treatment decision. The AIDS activists were among the first to attack FDA rulings on this basis.

Another critical feature of the 1962 Amendments was their definition of "substantial evidence" of effectiveness: "evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved."[37] Congress left the precise meaning of this phrase to FDA regulation. As the AIDS activists would later realize, the agency's interpretations and applications of this statutory standard were also policy judgments subject to challenge, particularly in the context of an inevitably fatal disease whose victims might not demand the same level of certainty as people suffering from less serious ailments.

The FDA has always interpreted the plural form of the word *investigations* in the definition of "substantial evidence" to signify that a drug sponsor must ordinarily present at least two adequate and well-controlled studies demonstrating efficacy.[38] In practice, the agency almost always demands that these two studies be phase 3 trials. In construing the term *adequate and well controlled investigations* in its regulations implementing the 1962 Amendments, the agency embraced the methodology broadly adopted by the field of clinical pharmacology during the 1950s: the randomized, double-blind, controlled study.[39] The FDA's 1970 rule on "adequate and well-controlled studies"—as elaborated by subsequent agency practices and guidance documents—established this type

[37] FDCA 505(d).

[38] FDA, PROVIDING CLINICAL EVIDENCE OF EFFECTIVENESS OF HUMAN DRUGS AND BIOLOGICAL PRODUCTS 3 (1998). In 1997, Congress amendment the FDCA to provide that FDA could deem "data from one adequate and well-controlled clinical investigation and confirmatory evidence … sufficient to constitute substantial evidence." FDCA 505(d).

[39] CARPENTER, *supra* note 14 at 136, 159 n. 62. Agency reviewers were embracing this standard even before 1962. *Id.* at 175–82.

of trial as the "gold standard" for demonstrating drug efficacy.[40] The rule declared: "Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered [in assessing efficacy]."[41]

Consequently, for the past half century, almost all "pivotal" trials conducted to demonstrate drug efficacy in support of an NDA have shared certain characteristics. They are "controlled"—that is, they compare, according to predefined diagnostic criteria, a group of people taking the experimental drug to one or more distinct "control" groups. Ideally, the control group takes a placebo, although other types of controls sometimes suffice, including the "active treatment" controls used when "administration of a placebo would be contrary to the interest of the patient."[42] To minimize bias, the subjects are assigned to the experimental arm or the control arm of the study on a random basis ("randomization"), and both investigators and subjects are ignorant with respect to which arm of the study each subject is in ("double-blinding"). To ensure scientific integrity, drug investigations are conducted according to detailed, pre-established protocols, and only people who satisfy strict eligibility criteria are permitted to participate.

Because of the rigorous, multistep drug development and approval process that Congress and the FDA imposed on manufacturers starting in 1962, many drugs took significantly longer to reach the market in the United States than in other advanced nations.[43] During the quarter of a century following 1962, both the time that industry spent researching new drugs and the time FDA spent reviewing NDAs ballooned.[44] The average total interval that elapsed between the commencement of clinical research and final FDA approval grew from a little over four years in 1963 to more than ten years by 1990.[45] While scholars and policymakers debated the significance and causes of this "drug lag," PWAs feared that without a change in approach, the AIDS treatments they needed would not reach the market until years after they had perished.

AIDS patients derived some solace from the FDA's March 1987 approval of AZT. The approval was based on the results of one successful phase 2 study, a placebo-controlled trial that the agency terminated early because of its strikingly positive data. Only 22 months passed between the

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[40] 35 Fed. Reg. 7250 (May 8, 1970). The current version of this rule is at 21 C.F.R. § 314.126.

[41] 21 C.F.R. § 314.126(e).

[42] 35 Fed. Reg. at 7251 (codified at 21 C.F.R. § 130.12(a)(5)(ii)(a)(4)).

[43] CARPENTER, *supra* note 14 at 374–80.

[44] HUTT, MERRILL, AND GROSSMAN, *supra* note 11 at 744–51.

[45] Joseph A. DiMasi, *New Drug Development in the United States 1963 to 1999*, 69 CLIN. PHARMACOL. THER. 286–296, 291.

start of clinical trials and approval of the NDA—a process so fast that one agency official likened AZT to a "greased pig."[46] But AZT was not a cure. Moreover, it was intolerably toxic for many people at the prescribed dose. PWAs desperately sought access to additional drugs, and they did not want to wait for FDA approval.

When the AIDS crisis arose, neither the FDCA nor FDA regulations explicitly allowed any use of unapproved drugs for the *treatment* of patients, as opposed to their administration for research purposes.[47] Nonetheless, the agency had for decades sometimes permitted seriously ill patients with no satisfactory alternatives to obtain experimental drugs for treatment. It had done so on a largely ad hoc basis, under various rubrics, including "single patient exceptions" and "compassionate use INDs." Moreover, since 1976, the National Cancer Institute, with FDA acquiescence, had furnished the most promising cancer therapies it was investigating ("Group C" drugs) to physicians prior to approval for treatment use. The FDA had also overseen some quite large "open label IND" programs, in which doctors administered unapproved medications, primarily cardiovascular drugs, to ill patients and collected safety data.[48]

Even before the emergence of AIDS, the FDA thus had significant flexibility within the terms of the FDCA to expedite the availability of unapproved drugs. Indeed, the Act as a whole was written in broad terms that left much to agency discretion. In 1972, FDA Chief Counsel Peter Barton Hutt famously declared: "the Act must be regarded as a constitution. It establishes a set of fundamental principles … without attempting to specify every detail of regulation."[49]

But Hutt himself, at the time, defined that mission as one of *protecting* consumers from adulterated and misbranded products, not of promoting the availability of potentially useful ones.[50] Hutt was hardly alone in viewing this type of consumer protection as the FDA's main "constitutional" function. Around the same time, Milton Katz, after remarking on other agencies' missions to "promote" the development and application of technology, observed that the "mission of the [FDA] is not promotional, but

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[46] AIDS DRUG DEVELOPMENT AND RELATED ISSUES, 103 (testimony of Harry Meyer, Director, Center for Drugs and Biologics) (1986); On the AZT approval process, see CARPENTER, *supra* note 14 at 433–438.

[47] Then, as now, FDA interpreted the FDCA to permit doctors to prescribe already-approved drugs for unapproved *uses*.

[48] HUTT, MERRILL, AND GROSSMAN, *supra* note 11 at 768–70. For a list of major treatment protocols approved through March 1987, see FDA PROPOSALS TO EASE RESTRICTIONS ON THE USE AND SALE OF EXPERIMENTAL DRUGS, 104 (1987).

[49] Peter Barton Hutt, *Philosophy of Regulation Under the Federal Food, Drug and Cosmetic Act*, 28 FOOD DRUG COSMET. LAW J. 177–188, 178–79 (1973).

[50] *Id.* at 178.

protective."[51] In the words of the scholar and former FDA Chief Counsel Richard Merrill, the FDA long believed that its job was "to prevent harm to consumers rather than facilitate the introduction of useful new medical products."[52] Consequently, preapproval access to drugs and rapid drug approvals were relatively rare phenomena.

A prominent judicial struggle over the meaning of the country's "drug constitution" took place in the 1970s. Terminally ill cancer patients filed a suit challenging the FDA's prohibition on the sale of Laetrile. They argued that the FDCA's statutory objective of protecting patients from "unsafe" and "ineffective" drugs simply had no relevance for terminally ill people and that the court should therefore infer an exception for them. The U.S. Court of Appeals for the Tenth Circuit agreed with the plaintiffs, asking, "[W]hat can … 'safe' and 'effective' mean as to such persons who are so fatally stricken with a disease for which there is no known cure?"[53] But in its 1979 decision in *Rutherford v. United States*, the United States Supreme Court reversed this decision, concluding, "[W]e have no license to depart from the plain language of the Act, for Congress could reasonably have intended to shield terminal patients from ineffectual or unsafe drugs."[54]

In light of the *Rutherford* decision, those seeking to force a change in the FDA's approach in the face of AIDS realized that they would have to pursue their goals outside of court. Conservative libertarians were the first to try.

III. THE REAGAN ADMINISTRATION AND THE TREATMENT IND

Ronald Reagan rolled into the presidency on a wave of anti-government fervor. The day after taking office, he announced the establishment of a Presidential Task Force for Regulatory Relief chaired by Vice-President (later President) George H. W. Bush. This body was charged with eliminating and reforming inefficient and burdensome federal regulations. The next month, Reagan issued his famous Executive Order 12291, which required agencies to perform a cost-benefit analysis on all

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[51] Milton Katz, *The Function of Tort Liability in Technology Assessment*, 38 UNIV. CINCINNATI LAW REV. 587–662, 597 (1969).

[52] Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. LAW REV. 1753–1866, 1843 (1996).

[53] *Rutherford v. United States*, 582 F.2d 1234, 1237 (10th Cir. 1978).

[54] *United States v. Rutherford*, 442 U.S. 544, 555 (1979). The plaintiffs also claimed that the FDA's ban on Laetrile violated their privacy rights under the Due Process Clause of the Fifth Amendment of the United States Constitution. They initially prevailed on this ground in the district court, 438 F. Supp. 1287 (W.D. Okla 1977), but the court of appeals rejected this constitutional holding on remand from the U.S. Supreme Court. 616 F.2d 455, 457 (10th Cir. 1980).

"major rules" and transmit these analyses for review to the Office of Management and Budget (OMB).[55] The essential philosophy behind 12291 was that "Regulatory Action should not be undertaken unless the potential benefits to society for the regulation outweigh the potential costs to society."[56]

The Reagan Administration viewed the FDA as a prime target for its deregulatory efforts. Bush's Task Force identified the drug approval process as one of 20 government regulatory programs in greatest need of reform.[57] Although the administration's primary goal with respect to the FDA was shrinking the "drug lag," it also resolved to formalize the system by which severely ill patients could gain access to unapproved therapies. In June 1983, as part of a proposed broad reform of the IND requirements, the agency announced its intention to codify the agency's various pre-approval access practices under the name "Treatment IND."[58] The FDA explained that it was acting "in accordance with Executive Order 12291 [and] the mandate of the President's Task Force on Regulatory Relief."[59]

This initial proposal was rather restrained. It limited treatment INDs to situations involving patients with serious diseases and no alternative therapies. It authorized the FDA to deny a request for a treatment IND whenever there was "not sufficient evidence of the drug's safety and effectiveness to justify its intended treatment use." Moreover, the proposal provided that investigational drugs would ordinarily become available for treatment use only after the end of phase 2 studies.[60] Finally, the FDA proposed that companies be permitted to charge for (rather than donate) the drugs released pursuant to a treatment IND only with the express written approval of the agency, based upon a showing that such sale was "required." This restriction was a major disincentive to participation by industry.[61]

The treatment IND proposal was not a response to the AIDS crisis. At the time of its issuance in 1983, the disease had only recently emerged as a matter of public concern outside the gay community. Over the next few years, however, the treatment IND became closely linked to AIDS in particular. As the disease spread virulently, PWAs learned to their distress

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[55] E.O. 12291 (Feb. 17, 1981), at 46 Fed. Reg. 13193.

[56] E.O. 12291, Sec. 2(b).

[57] 47 Fed. Reg. 46622, 46622 (Oct. 19, 1982).

[58] 48 Fed. Reg. 26,720, 26,742 (June 9, 1983). "Treatment protocol" was the term attached to requests initiated by drug companies rather than physicians, but "treatment IND" became the generic term for all such requests.

[59] 48 Fed. Reg. at 27,720.

[60] 48 Fed. Reg. at 26,721, 26,742;

[61] 48 Fed. Reg. at 26,737.

that they could rarely obtain experimental therapies through the FDA's existing compassionate use programs. Between 1983 and 1987, the agency permitted the compassionate use of only two unapproved AIDS-related drugs.[62] AIDS advocates thus began urging the administration to finalize the treatment IND rulemaking.

PWAs were not the only ones exasperated by the FDA's caution with respect to investigational treatments. Some of the loudest voices in favor of lowering the regulatory barriers were from the conservative side of the spectrum. Ronald Reagan himself was famously apathetic about AIDS—he publicly mentioned it only once before 1987.[63] Nonetheless, the treatment IND program promised to benefit victims of all life-threatening illnesses, not just AIDS. Moreover, it fit the conservative movement's broader deregulatory mission.

Some libertarians implored the FDA to help PWAs in particular. In a January 1987 *New York Times* op-ed column drawn from a Cato Institute report, Dale Gieringer declared: "Reform is needed to allow [AIDS] patients freedom of access to experimental drugs…. A country that honors free choice in religion, speech, and politics should also honor free choice in medicine."[64] The next month, the *Washington Post*'s conservative columnist Charles Krauthammer called for the immediate approval of AZT. "Now that we have strong evidence that AZT works for some with AIDS, you cannot ethically deny it to any AIDS sufferer who would risk taking it." Acknowledging that "turning AZT loose on the market" would make clinical research "very difficult," Krauthammer nonetheless concluded that "surely the claims of scientific knowledge have their limits."[65]

The FDA was not ignoring the treatment IND proposal during this period, but rather clashing with more committed deregulators at OMB.[66] In

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[62] In 1984, FDA cleared the treatment use of ganciclovir, the previously-mentioned treatment for a blindness-inducing retinal infection common among PWAs. This action suggested that the agency was prepared to open the gate wide for AIDS victims, for it allowed the compassionate use of ganciclovir based solely on laboratory evidence, before the manufacturer had even commenced human trials. William C. Buhles, *Compassionate Use: A Story of Ethics and Science in the Development of a New Drug*, 54 PERSPECT. BIOL. MED. 304–315 (2011). PWAs had to wait more than two years for the next compassionate use program, however, and this one—for AZT—was restricted to a particular subset of AIDS sufferers and commenced just a few months before the drug's ultimate approval. Caroline Rand Herron & Katherine Roberts, *A Ray of Hope for AIDS Patients*, N.Y. TIMES, September 21, 1986; CARPENTER, *supra* note 14 at 436–37.

[63] [cite]

[64] Dale Gieringer, *Twice Wrong on AIDS*, N.Y. TIMES, January 12, 1987, at A21.

[65] Charles Krauthammer, *Saying No to AIDS Patients: Which Ones Get AZT?*, WASHINGTON POST, February 27, 1987, at A27.

[66] This history is laid out, with supporting documentation, in FDA PROPOSALS, *supra* note 48 at 94–105 (testimony of Frank E. Young).

July 1985, FDA Commissioner Frank Young decided to issue a final version of the IND amendments with the treatment IND provisions unchanged from the 1983 proposal. Seven months later, however, OMB—reviewing the rule under Executive Order 12291—demanded various revisions to the treatment IND section. These changes included, among others, the elimination of the requirement that those seeking treatment INDs show "sufficient evidence" of safety and effectiveness and the deletion of the language restricting the sale of products distributed pursuant to a treatment IND. Months of discussions ensued in which HHS and FDA officials attempted, largely unsuccessfully, to obtain OMB's permission to re-insert safeguards and limitations into the rule.[67]

In March 1987, the FDA published a reproposal of the treatment IND rule.[68] Compared with the 1983 proposal, the reproposal promised to dramatically increase the availability of investigational drugs. First, it *required* the agency to grant treatment INDs if the listed criteria were satisfied. Second, it shifted the evidentiary burden onto the FDA, requiring the agency to approve a treatment IND request unless "the drug clearly does not provide a therapeutic benefit" or would expose patients "to an unreasonable and significant additional risk of illness or injury."[69] Third, whereas the original proposed rule had provided that experimental drugs could ordinarily become available for treatment use only after the end of phase 2 studies, the reproposal explicitly authorized the FDA to permit such use earlier in the investigational process "in the case of an immediately life-threatening disease, or in other appropriate circumstances."[70]

Finally, the 1987 reproposal recognized that unless manufacturers could charge for unapproved drugs under the rule, "[t]here might be no incentive for a sponsor to supply investigational drugs for treatment use, thus denying the drug to patients who . . . choose to avail themselves of this treatment."[71] The reproposal thus allowed drug sponsors to charge for

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[67] The only notable concessions they appear to have won were, first, to apply the lower evidentiary burden only to drugs for "immediately life-threatening diseases" and, second, to publish the treatment IND provisions as a reproposal, rather than as a final rule along with the rest of the IND regulations.

[68] 52 Fed. Reg. 8,850, 8,855-57 (Mar. 19, 1987).

[69] 52 Fed. Reg. at 8,856. The preamble explained that for immediately life-threatening diseases, "Requiring a degree of proof only slightly less than is necessary for general market distribution would unnecessarily restrict a drug that could provide real benefits in the particular case under treatment." *Id.* 8851.

[70] 48 Fed. Reg. at 26,742; 52 Fed. Reg. at 8,856. Because one condition for granting a treatment IND was that the drug be "under investigation in a controlled clinical trial under an IND," the proposal seemed to contemplate that a treatment IND drug must at least have entered phase 2 studies. *Id.*

[71] 52 Fed. Reg. at 8,854.

treatment IND drugs after merely notifying the FDA, although it forbade them to commercially promote or market such products and allowed the agency to prohibit prices that were "manifestly unfair."[72]

The reproposal triggered a ferocious negative reaction. A diverse assortment of forces lined up to oppose what they perceived to be an excessive diminishment of FDA's gatekeeping role.

There were Democratic congressmen who advocated a traditional, precautionary approach to consumer protection, such as Representative Ted Weiss of New York and Senator Edward Kennedy of Massachusetts. Weiss, who chaired a hearing on the treatment IND reproposal in April 1987, opened the proceedings by warning: "The proliferation, in uncontrolled settings, of inadequately evaluated, potentially dangerous experimental drugs is a prescription for the premature deaths and needless suffering of large numbers of people."[73] Weiss further contended that OMB, "under the guise of assisting people with AIDS … is, in fact, attempting to dismantle the whole regulatory process."[74]

There was the biomedical research establishment, which worried primarily about the impact the proposal would have on clinical research.[75] Dr. Charles Moertel of the Mayo Clinic, for example, asserted at Weiss's hearing: "I am confident that this reproposed rule would seriously impair our ability to conduct the adequate and well controlled studies necessary to confirm the true safety and effectiveness of new drugs…. [T]here would be absolutely no motivation for a patient to enter a randomized study."[76] Dr. Maureen Myers, the Chief of the AIDS Treatment Branch at the National Institute for Allergy and Infectious Diseases, similarly rued the impact the reproposal would have on NIH's ability to conduct studies of AIDS drugs. She concluded, "As an example of deregulation, I feel this is a disastrous choice."[77]

There was the FDA bureaucracy itself, which embraced the same scientific worldview as the researchers and, moreover, took pride in its own consumer protection function. An FDA official informed Weiss's staff that he did not know of a single person within the agency's drug center who supported the treatment IND reproposal.[78] Previous FDA leaders expressed skepticism as well. Richard Cooper, testifying at Weiss's hearing on behalf

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[72] 52 Fed. Reg. at 8,856.

[73] FDA PROPOSALS, *supra* note 48 at 2; Senator Kennedy submitted to the record a letter condemning the proposal. *Id.* at 155–56.

[74] FDA PROPOSALS, *supra* note 48 at 127.

[75] Weiss and Kennedy also voiced this concern.

[76] FDA PROPOSALS, *supra* note 48 at 38 (testimony of Charles G. Moertel).

[77] *Id.* at 32.

[78] *Id.* at 100.

of a bipartisan group of five former FDA commissioners and four former chief counsels, urged that the reproposal be revised to require that there be "some scientific evidence on the basis of which an expert could rationally conclude that the drug may be effective in the intended population." The rule as written, Cooper cautioned, "could provide an unintended opportunity for the marketing of governmentally legitimized quack drugs …."[79]

There were the influential consumer protection organizations, who were uniformly opposed to the reproposal.[80] Sidney Wolfe, the head of the Health Research Group within Ralph Nader's Public Citizen, opined that PWAs and their advocates were making a grave error by pushing for earlier release of drugs. "I see this really as against the interests of a large proportion of AIDS patients. We have drug safety and efficacy laws so that we can tell the difference between something better than what may be around and something that may be worse."[81]

Finally, there was the pharmaceutical industry. Despite many liberals' suspicions that the treatment IND reproposal was part of a corporate plot, the industry was not enthusiastic about it.[82] Although drug companies unambiguously favored a faster and less burdensome drug *approval* process, they were ambivalent at best about a rule that would facilitate *pre-approval* release. The distribution of unapproved drugs for treatment use presented product supply challenges and posed tort liability risk. Although the reproposal allowed manufacturers to charge, it prohibited the commercial promotion of unapproved drugs and subjected their prices to FDA review. Finally, pre-approval distribution of drugs might disrupt the clinical investigations the manufacturers had to complete to obtain FDA approval. The Pharmaceutical Manufacturer's Association (PMA), the trade association for large drug companies, did not take a public position on the reproposal, but it may have worked behind the scenes to weaken it.[83] The *Wall Street Journal* editorial page, which championed the reproposal, angrily charged the PMA with obstructing it.[84]

The combined forces arrayed against radical deregulation succeeding in overcoming OMB. The final rule, issued in May 1987, pulled back

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[79] *Id.* at 5. (testimony of Richard M. Cooper).

[80] JONATHAN KWITNY, ACCEPTABLE RISKS 148–49 (1992).

[81] Gina Kolata, *Odd Alliance Would Speed New Drugs*, N.Y. TIMES, November 26, 1988, at 9.

[82] Frank Young had a meeting about the reproposal with the Pharmaceutical Manufacturer's Association (PMA), the trade association for large drug companies. FDA PROPOSALS, *supra* note 48 at 70.

[83] FDA Commissioner Frank Young later told Martin Delaney, a leading AIDS activist, that PMA "would not live with" the reproposal. KWITNY, *supra* note 80 at 192.

[84] *Drug-Lag Defenders* (editorial), WALL STREET JOURNAL, May 15, 1987.

significantly from the reproposal.[85] Now, the regulation authorized FDA to deny a treatment IND for a drug for an immediately life-threatening disease "if the available scientific evidence, taken as a whole, fails to provide a reasonable basis for concluding that the drug may be effective for its intended use."[86] Because the regulation did not define "reasonable basis," this provision gave the FDA great latitude to block a treatment IND for any drug that had not completed phase 2 trials. Moreover, the final rule capped the amount companies could charge for treatment IND drugs at the price "necessary to recover costs of manufacture, research, development, and handling" of the product.[87]

IV. AIDS ACTIVISTS JOIN THE FRAY

While this battle over the treatment IND rule raged within the government, gay rights and AIDS organizations mostly sat on the sidelines. The gay community remained surprisingly uninvolved in FDA drug policy during the first five years of the epidemic. It focused more on other problems, such as widespread virulent homophobia and the potential imposition of coercive disease control measures.

As AIDS spread in the early 1980s, powerful religious conservatives voiced venomous attitudes about gay people and PWAs. Senator Jesse Helms, for example, declared: "Americans who don't want to risk being killed by AIDS have a clear choice and a safe bet available: Reject sodomy and practice morality."[88] Influential televangelist Jerry Falwell, co-founder of the Moral Majority, commented: "If we choose to violate God's law, we bring that retribution upon ourselves."[89] Such statements echoed the anti-gay views of a depressingly broad swath of the population. In a national poll conducted in July 1986—two weeks after the United States Supreme Court upheld the constitutionality of state prohibitions on homosexual sex

[85] 52 Fed. Reg. 19,466 (May 22, 1987).

[86] *Id*. at 19,476, codified at 21 C.F.R. § 312.34(b)(3). The rule also allowed FDA to deny a treatment IND if the evidence as a whole failed to provide a reasonable basis for concluding that the drug "[w]ould not expose the patients ….. to an unreasonable and significant additional risk of illness or injury." *Id.*

[87] 52 Fed. Reg. at 19,476, codifed at 21 C.F.R. § 312.7(d)(2), (3).

[88] Senator Helms and the Guilty Victims (editorial), N.Y. TIMES, June 17, 1987, at A30; Morris S. Thompson, *Bennett Urges Steps on AIDS in Jails*, WASHINGTON POST, June 15, 1987, at A14; Jesse Helms, *Only Morality Will Effectively Prevent AIDS from Spreading (Letter to the Editor)*, N.Y. TIMES, November 23, 1987, at A22.

[89] Joseph Berger, *AIDS Patients Pose Difficult New Test for Clerics*, N.Y. TIMES, January 10, 1986, at A14.

in *Bowers v. Hardwick*[90]—57 percent of respondents opined that "gay or lesbian relations between consenting adults … should not be legal."[91]

Public opinions about homosexuality at this time were shaped not only by traditional morals, but also by panic about AIDS. Although the disease was still confined largely to gay men and intravenous drug users,[92] Americans feared that it would evolve into a pandemic transmitted through heterosexual sex or even nonsexual exposure. The July 1985 cover of *Life* warned: "Now No One is Safe from AIDS."[93] Like the Jews accused of causing the Black Death by poisoning wells, gay men were almost inevitable scapegoats for this emerging modern plague.[94] They increasingly found themselves fired from their jobs, evicted from their apartments, physically assaulted, and socially shunned.[95]

The nation debated various coercive measures to quell the epidemic. Many politicians (including Vice President Bush) advocated mandatory AIDS testing in certain situations.[96] In the *New York Times*, conservative commentator William F. Buckley appeared to recommend universal AIDS testing and the compulsory tattooing of those found to be HIV-positive.[97] Various government officials publicly entertained the idea of an AIDS quarantine.[98] In the *Washington Post*, a physician who supported quarantine rejected the very notion that AIDS victims had "rights." He concluded, "[T]he threat of AIDS demands from us all a discrimination based on our instinct for survival against a peril that, if not somehow controlled, can destroy this society."[99]

Accordingly, until the late 1980s, AIDS advocates had a primarily defensive agenda, namely, warding off measures such as mandatory testing and internment. Activist Gregg Bordowitz remembers: "Our first charge was to awaken the community to the possibilities of some very serious

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[90] 478 U.S. 186 (1986).

[91] http://www.gallup.com/poll/1651/gay-lesbian-rights.aspx

[92] CDC FACT SHEET, *supra* note 1 at 2.

[93] *Life*, July 1985, Cover.

[94] Jews in the Middle Ages were accused of causing the Black Death by poisoning wells, PHILIP ZIEGLER, THE BLACK DEATH 100–102 (Reprint edition ed. 2009).

[95] Fran Smith, *Anxiety Over AIDS Prompts Attacks Against Gays*, PHILADELPHIA INQUIRER, January 27, 1985, at C3.

[96] Philip M. Boffey, *Bush Favors Requiring AIDS Tests for Marriage License Application*, N.Y. TIMES, April 9, 1987, at B8.

[97] Buckley, William F. Jr., *Identify All the Carriers (Op-Ed)*, N.Y. TIMES, March 18, 1986, at A27.

[98] Michael Hirsley, *Talk of AIDS Quarantine Spreads Like a Disease*, CHICAGO TRIBUNE, November 12, 1985, at 1; Thompson, *supra* note 88.

[99] Richard Restak, *Worry About Survival of Society First; Then AIDS Victims' Rights*, WASHINGTON POST, September 8, 1985, at C01.

repressive actions against us, and to defend ourselves."[100] FDA reform was simply not their first priority.

The FDA demonstration in October 1988 thus represented an important pivot point for the AIDS movement. As Bordowitz explains:

> What [the] FDA [action] did was shift the group away from a defensive posture to an offensive posture … and enabled us to come up with a vision for the way that healthcare should be done in this country, the way that drugs should be researched, and sold, and made available. Most importantly [sic] … was the idea that people with AIDS should be at the center of the public discussion on AIDS.[101]

What explains the timing of this reorientation? Overwhelming frustration with the government's inadequate response to AIDS certainly had something to do with it. But there was also an important attitudinal shift within the gay community itself. American homophobia was no longer simply an obstacle for ACT UP; it was becoming a source of cohesion and strength. The activists' struggle with the FDA was bolstered by an intensifying sense of gay pride and a fierce commitment to fighting societal hostility and apathy. The Parklawn Building protest was not only an effort to mobilize the government against a horrific disease; it was also a forum for the declaration of gay rights and for the assertion of gay identity.[102]

An additional prerequisite for the FDA demonstration was the emergence of a new attitude among activists regarding the proper role of government in the crisis. Before 1988, representatives of the major gay rights and AIDS groups tended to cling to their pro-regulation progressive roots and defend the FDA's authority. For example, Jeff Levi, the Executive Director of the National Gay and Lesbian Task Force, opposed the 1987 treatment IND reproposal discussed above, even though it would have made experimental drugs more readily available to PWAs. He sneered: "This is a scheme by the drug companies to get rid of government regulation…. This is Ronald Reagan trying to deregulate the pharmaceutical industry."[103] But around that time, a new type of AIDS advocate was emerging. These activists rejected the notion that as "liberals" they should always favor more regulation. Their foremost goal of "getting drugs into bodies" trumped all other concerns.

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[100] Gregg Bordowitz interview, Dec. 17, 2002, at 31 (interview # 004 of AUOHP).

[101] *Id.* at 31-32.

[102] See Deborah Gould, *Rock the Boat, Don't Rock the Boat, Baby: Ambivalence and the Emergence of Militant AIDS Activism*, *in* PASSIONATE POLITICS: EMOTIONS AND SOCIAL MOVEMENTS 135–57 (Jeff Goodwin, James M. Jasper, & Francesca Polletta eds., 2001); DEBORAH B. GOULD, MOVING POLITICS: EMOTION AND ACT UP'S FIGHT AGAINST AIDS (2009).

[103] KWITNY, *supra* note 80 at 148.

One such figure was San Francisco-based Martin Delaney, the founder of Project Inform. Delaney, gay but HIV-negative, had been a Roman Catholic seminarian, elementary school teacher, and management consultant before becoming a full-time AIDS treatment activist in the early 1980s.[104] In April 1987, he told the 10,000 subscribers to his newsletter, *PI Perspective*, that the treatment IND reproposal, though a useful step, did not go far enough.[105] After the more restrictive final rule came out in October, Delaney met with the prominent Washington, D.C. lawyer C. Boyden Gray, counsel to Vice-President Bush and to the Presidential Task Force on Regulatory Relief.[106] Gray, one of the brains behind the Reagan Administration's deregulatory efforts, told Delaney that the Treatment IND rule was "our pride and joy." Delaney responded that the final version of the regulation was a "sham" and "a lemon."[107] Gray promised to study the matter further, and the two men established a working relationship that continued into Bush's own presidency.

For several years, Delaney had been helping to forge an alternative method for PWAs to obtain unapproved medications—importation from foreign countries. Although the importation of unapproved drugs is illegal under the FDCA, the FDA had long exercised enforcement discretion and permitted individuals to transport "personal use" amounts of such products into the country in their luggage or by mail.[108] After the start of the AIDS epidemic, PWAs and their supporters began importing ever-increasing volumes of unapproved drugs from other countries, particularly Mexico. Many of these imported batches—too large to conform to any common-sense understanding of "personal use"—were, with Project Inform's advice and coordination, distributed by underground networks and sold in "buyers' clubs" and "guerilla clinics."[109] FDA acquiesced to most of these operations without explanation.

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[104] Elaine Woo, *Martin Delaney, 1945-2009 (Obituary)*, LOS ANGELES TIMES, January 27, 2009, at B5.

[105] KWITNY, *supra* note 80 at 149.

[106] The Task Force was officially disbanded in August 1983 and reconstituted in December 1986. On Gray, see Kenneth B. Noble, *Fulfilling a Promise on Deregulation*, N.Y. TIMES, August 29, 1983, at A16.

[107] KWITNY, *supra* note 80 at 187.

[108] PETER BARTON HUTT, RICHARD A. MERRILL & LEWIS A. GROSSMAN, FOOD AND DRUG LAW: CASES AND MATERIALS 664–665 (3rd ed. 2007). In 1977, FDA Regulatory Procedures Manual was amended to explicitly allow importation of personal use quantities of unapproved drugs by individuals in their baggage or by mail. *Id.*

[109] See, e.g., Marilyn Chase, *For Some AIDS Patients, Bootleg Drugs Are One Way to Preserve Some Hope*, WALL STREET JOURNAL, October 5, 1987; For descriptions of smuggling operations, see KWITNY, *supra* note 80.

Then, in early 1988, the U.S. Customs Service began seizing packages of an unapproved AIDS drug called dextran sulfate mailed from Japan.[110] Delaney personally lobbied FDA officials to issue a written document that would clarify the personal importation policy.[111] On July 23, 1988, in a widely-publicized speech at a gay and lesbian health conference in Boston, Frank Young announced the release of a new "Pilot Guidance for Release of Mail Importations."[112] An unnamed federal official speculated to *Science* magazine that the commissioner had gone "temporarily insane."[113] In truth, the guidance was merely an affirmation of existing FDA policy.[114] But Young's action had symbolic import and, as a practical matter, prevented further seizure of dextran sulfate shipments.

Meanwhile, activists on the East Coast also began to demand that the FDA expedite access to AIDS drugs. One of the first was Marty Robinson, who in 1986 helped form a group of aggressive AIDS protesters in New York called the Lavender Hill Mob.[115] At Weiss's congressional hearing, Robinson, representing this group, testified that even the OMB-shaped reproposal of the treatment IND was too restrictive. He dismissed it as "tokenism and public relations, nothing more" and demanded "greater availability of drugs undergoing Phase II testing."[116]

Larry Kramer, a confrontational and abrasive New York author and playwright, soon moved to the forefront of the East Coast cohort of AIDS activists challenging the FDA. Kramer co-founded the Gay Men's Health Crisis in 1982. He left the organization the following year, after the other directors—tired of his shouting, wary of his militancy, affronted by his condemnation of reckless sexual conduct—forced him off the board.[117] On

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[110] KWITNY, *supra* note 80 at 195–97.

[111] *Id.* at 203–207.

[112] Philip M. Boffey, *F.D.A. Will Allow AIDS Patients to Import Unapproved Medicines*, N.Y. TIMES, July 24, 1988.; FDA Office of Regional Operations, Pilot Guidance for Release of Mail Importations (1988).

[113] William Booth, *An Underground Drug for AIDS*, 241 SCIENCE 1279, 1279 (1988).

[114] In accordance with the agency's longstanding approach, the policy was limited to personal use quantities not intended for commercial distribution. Indeed, the guidance added a new condition by requiring that the patient provide a written affirmation that the product was for his own use. HUTT, MERRILL, AND GROSSMAN, *supra* note 109. Two days after its initial story, the N.Y. Times itself acknowledged the limited significance of the Guidance. Philip M. Boffey, *Importing AIDS Drugs: Analysis of F.D.A. Policy*, N.Y. TIMES, July 26, 1988, at C1. An FDA "Talk Paper" explaining the the new guidelines presented them as an affirmation of existing policy. FDA Talk Paper, Policy on Importing Unapproved AIDS Drugs for Personal Use, (1988).

[115] On Robinson, see http://www.actupny.org/documents/earlytactics.html

[116] FDA PROPOSALS, *supra* note 48 at 132.

[117] RANDY SHILTS, AND THE BAND PLAYED ON: POLITICS, PEOPLE, AND THE AIDS EPIDEMIC 135, 166–67, 209–10, 275, 309–11 (2000).

March 10, 1987, Kramer—not yet aware that he was HIV-positive—delivered a speech at the Lesbian and Gay Community Services Center in Greenwich Village calling for the creation of a new AIDS organization committed to direct action.[118] Two days later, Kramer and other activists (including Robinson) gathered at the Center and founded the group that would soon be named the Aids Coalition to Unleash Power—ACT UP.[119] The organization's initial demands included, among others, the appointment of an FDA "undercommissioner" from within the AIDS community, the "*immediate* testing and expeditious release of experimental drugs," the elimination of placebo trials, and the removal of FDA's authority over trials of AIDS drugs.[120]

On March 23, Kramer wrote a scathing opinion essay in the *New York Times* titled "The F.D.A.'s Callous Response to AIDS."[121] The FDA had approved the NDA for AZT three days earlier, but Kramer scornfully dismissed this action as a "sop to the gay community." He furiously attacked the agency's reluctance to allow pre-approval access to other medications. "Doctors everywhere are waiting to put into immediate use a battery of drugs that have passed Phase One safety trials," he insisted. "AIDS sufferers, who have nothing to lose, are more than willing to be guinea pigs…. [W]e cannot understand for the life of us, or for what life in us many of us still cling to hungrily, why the F.D.A. withholds [these drugs] especially when the victims are so eager to be part of the experimental process."[122]

The next day, ACT UP conducted its first public demonstration—a march on Wall Street in which protesters demanded the immediate release of seven specific drugs and burned FDA Commissioner Young in effigy.[123] A year and a half later, ACT UP demonstrators descended on the Parklawn Building.

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[118] Larry Kramer interview, Nov. 15, 2003 at 7-8 (interview # 035 of AUOHP).

[119] On the first meetings, see Nesline interview, *supra* note [ ], at 8-9; Maxine Wolfe interview, Feb. 19, 2004, at 40-42 (interview # 043 of AUOHP); Ron Goldberg interview, Oct. 25, 2003, at 59-60 (interview # 032 of AUOHP).

[120] *Id.*

[121] Larry Kramer, *The F.D.A.'s Callous Response to AIDS*, N.Y. TIMES, March 23, 1987, at A19.

[122] *Id.*

[123] LINDA HIRSHMAN, VICTORY: THE TRIUMPHANT GAY REVOLUTION 197 (Reprint ed. 2013).

V. TACTICAL AND IDEOLOGICAL CHALLENGES

A. Getting Inside the Agency

The FDA was a tricky target for this burgeoning social movement. Even in an age of diminishing trust in government, the agency retained the broad approval of the American population.[124] The public, and FDA employees themselves, saw the agency's primary role as protecting people from dangerous and ineffective products. Moreover, the FDA's decisions were not always transparent to ordinary Americans; they occurred behind a veil of scientific complexity, technical expertise, and administrative bureaucracy. Finally, some of the country's widespread homophobia inevitably bled into the agency itself. In an article that appeared soon after the Parklawn action, an unnamed top FDA official corroborated the protesters' claims that the agency was lagging on AIDS drugs because the majority of PWAs were homosexuals. He himself observed: "Most of [the demonstrators] were of the gay bent and thus they have to face the consequences of their lifestyle."[125]

What tactics were available for AIDS activists to influence the procedures and decisions of a federal administrative agency like the FDA? The Administrative Procedure Act (APA) grants citizens a right to submit comments on rules proposed by agencies.[126] Nevertheless, despite court decisions requiring the preambles accompanying final rules to address the points raised by comments,[127] agencies maintain extremely broad discretion to reject commenters' objections and suggestions. The APA also compels agencies to provide interested persons the right to petition for new rules,[128] but agencies have no obligation whatsoever to grant such petitions. In any event, many of the critical determinations the FDA makes with respect to drugs—including its decisions on INDs and NDAs—are not "rules" subject to the APA's public participation provisions.

The AIDS activists thus decided that their campaign for bodily freedom must commence with their mass bodily presence at the FDA itself. When they concocted the idea of a protest at FDA headquarters, ACT UP's David Barr and Mickey Wheatley explained:

> "… we have this idea for a strategy that would be very different than things that have been tried before in activism.… [M]any groups have gone to Washington and protested in front of the White House. Many groups have protested in front of Congress. For our movement, we need to go to the Food

[124] CARPENTER, *supra* note 14 (get pincites).
[125] FDA Resumes Business After AIDS Demonstration, *supra* note 4.
[126] 5 U.S.C. § 553(c).
[127] See, e.g., *U.S. v. Nova Scotia Food Products Corp.*, 568 F.2d 240 (2d Cir. 1977).
[128] 5 U.S.C. § 553(e).

> and Drug Administration…. This is an institution that is very specific to the issues that we're facing." [129]

Importantly, the Parklawn action's organizers always viewed the event as merely a first step. Their ultimate objective was to be invited *inside* the building, to participate in the meetings where FDA employees forged drug policy with scientists and industry representatives. "The idea was to cut through the bureaucratic red tape of the Food and Drug Administration," Bordowitz recalls. "But more than that, that people with AIDS should be involved in every level of decision-making concerning research for a treatment and a cure for our disease."[130] It is telling that ACT UP titled the action "Seize Control of FDA" rather than, for example, "Burn Down FDA." Unlike the dietary supplement and Laetrile protesters of the 1970s, most AIDS activists thought the FDA had an important role to play. Rather than seeking to eliminate FDA regulation of AIDS drugs, they strove to participate in the agency's processes and thus reform its scientific and regulatory vision.[131]

The outside component of ACT UP's outside-inside strategy was nonetheless vital to the movement's success. The mass actions at the FDA and (in 1990) at NIH helped not only to thrust the treatment activists inside the halls of government, but also to ensure that the federal bureaucracy and the public at large would perceive the development and release of AIDS drugs as a momentous matter of social justice. To this day, members of the "insider" treatment group credit their achievements to both aspects of the outside-inside approach.[132] As we will see, however, once ACT UP's treatment specialists gained access to the government policymakers, a growing divide developed between them and the broader AIDS activist community. Their views diverged regarding not only tactics, but also the movement's fundamental principles and goals.

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[129] Gregg Bordowitz interview, *supra* note [ ], at 23 (paraphrasing Barr and Wheatley). The notion of conducting a demonstration at the FDA building was not in fact as unprecedented as these men believed. In 1975, the Women's National Health Network conducted a much smaller demonstration there—a "memorial service" to protest the agency's labeling policies for hormone-containing drugs. SANDRA MORGEN, INTO OUR OWN HANDS: THE WOMEN'S HEALTH MOVEMENT IN THE UNITED STATES, 1969-1990 29 (1st ed. 2002). Nevertheless, David Barr continues to believe "there had never been a demonstration at the Food and Drug Administration before, ever." David Barr interview, May 15, 2007, at 36 (interview # 073 of AUOHP).

[130] Bordowitz interview, *supra* note [ ], at 23 (paraphrasing Barr and Wheatley).

[131] Sidney Tarrow examines the "outsiders inside" phenomenon in social movements extensively in STRANGERS AT THE GATES: MOVEMENTS AND STATES IN CONTENTIOUS POLITICS (2012).

[132] Mark Harrington interview, Mar. 8, 2003, at 45 (interview # 012 of AUOHP); David Kirschenbaum interview, Oct. 19, 2003, at 45 (interview # 031 of AUOHP).

B. "With Friends Like These …"

As the AIDS movement forged ahead with its FDA reform agenda following the Parklawn protest, it confronted a major conundrum: how to manage its alliance with conservative deregulators.

When sociologists began to study AIDS activism, the prevailing theory of social movements was the "political process" theory, which viewed political opportunities as a precondition to the formation of such movements.[133] As enumerated by Sidney Tarrow, such opportunities included access to power, the availability of influential allies, and divisions within the ruling elites.[134] Deborah Gould, a leading scholar of AIDS activism, concluded that ACT UP did not conform to the political opportunity model because it "arose as a national movement in 1987, amidst the growing conservatism of the Reagan/Bush years. Lesbians, gay men, and AIDS advocates lacked meaningful access to power and influential allies, and benefitted from no significant splits in the ruling alignment or cleavages among elites."[135] Gould thus sought out other explanations for ACT UP's rise and settled on the role of shifting emotions in the gay and lesbian communities.[136]

Though Gould's focus on emotion is an invaluable addition to the literature, she overstates the AIDS movement's lack of political opportunity in the late 1980s, particularly with respect to FDA reform. First of all, it is important to observe that by this time, a solid majority of Americans shared ACT UP's position with respect to drug regulation. The country's views had shifted dramatically in a strikingly brief period. In 1979, when a national poll asked respondents whether they agreed that a drug for a serious health problem "should not be made available until it is known to be completely safe and effective," 60 percent agreed strongly and 14 percent agreed mildly.[137] By contrast, in 1989, no less than 79 percent of respondents told a pollster that the government should allow people with

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[133] SIDNEY TARROW, POWER IN MOVEMENT: SOCIAL MOVEMENTS, COLLECTIVE ACTION AND POLITICS (1994); CHARLES TILLY, FROM MOBILIZATION TO REVOLUTION (1978); DOUG MCADAM, POLITICAL PROCESS AND THE DEVELOPMENT OF BLACK INSURGENCY, 1930-1970, 2ND EDITION [PAPERBACK] [1999] 2ND ED. DOUG MCADAM (2nd edition ed. 1999).

[134] TARROW, *supra* note 133 at 18.

[135] Gould, *supra* note 102 at 136; *see also* GOULD, *supra* note 102 at 10–14. Steven M. Engel, by contrast, believes that political opportunity structure provides a useful framework for analyzing the AIDS movement. STEPHEN M. ENGEL, THE UNFINISHED REVOLUTION: SOCIAL MOVEMENT THEORY AND THE GAY AND LESBIAN MOVEMENT 14, 47–53, 100 (2001).

[136] See generally GOULD, *supra* note 102.

[137] Survey by Pfizer Pharmaceuticals, January 25-February 11, 1979 (available on "iPoll" on Roper Center website, http://www.ropercenter.uconn.edu/ipoll-database/).

AIDS to be treated with drugs that had not been fully tested and approved.[138] Moreover, despite Gould's assertion, there *was* a significant split in the ruling elite regarding drug regulation, as illustrated by the battle between OMB and other stakeholders over the Treatment IND rule.

Finally, notwithstanding Gould's statement, the AIDS activists had significant allies on the conservative side of the political spectrum, among libertarians and radical deregulators. Just hours after the 1988 Parklawn demonstration, ACT UP's Peter Staley (the aforementioned "Karate Kid") appeared on the CNN political debate show *Crossfire*. Patrick Buchanan, the interlocutor "on the right," told him: "Mr. Staley, this is going to astonish you, but I agree with you a hundred percent. I think if someone's got AIDS and someone wants to take a drug, it's their life and if it gives him hope he oughta be able to take it."[139] Although Staley may have been startled to hear this statement of support from the often intolerant Buchanan in particular, he doubtless was already aware that some conservatives supported facilitating access to AIDS drugs. After all, a recent *New York Times* article on critics of the final Treatment IND rule had included an excerpt from a report by the Heritage Foundation, a conservative think tank, alongside a quotation from Martin Delaney.[140]

Following the "Seize the FDA" action, leading AIDS advocates suggested publicly that they welcomed this alliance. Delaney observed, "AIDS activists are aligning themselves with deregulators. The liberals who want to be our friends are obstacles to F.D.A. deregulation."[141] Larry Kramer acknowledged that conservative Republicans were "strange bedfellows" for his largely gay, overwhelmingly left-leaning movement, but he concluded, "[W]hat liberal support is there?"[142]

It was not the first time in American history that an unlikely coalition was forged in the cause of medical liberty.[143] This particular alliance was striking, however, because of the extremely narrow range of issues on

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[138] Poll by Associated Press/Media General, May5 – May 13, 1989 (available on Roper iPoll). In 1988, 68 percent of respondents to a different poll said they favored the early access provided by the recently published Treatment IND rule. Survey by American Medical Association, February 1 – February 15, 1988 (available on Roper iPoll).

[139] Crossfire [date], excerpted in *How to Survive a Plague* and also available at https://www.youtube.com/watch?v=ZUCUAEZsBuU

[140] Boffey, *supra* note 1; CARPENTER, *supra* note 13 at 445 ("AIDS activists were aware that their demands ... dovetailed with a long-running conservative poltical agenda for pharmaceutical deregulation....").

[141] Kolata, *supra* note 81.

[142] *Id.*

[143] Consider, for example, the alliance between progressives and Spencerian conservatives in opposition to medical licensing in the Gilded Age. Grossman, *supra* note 26.

which the two sides agreed. The worldviews of ACT UP and the Reagan/Bush conservatives were breathtakingly different outside narrow questions of FDA drug policy. Despite its demands that the FDA loosen up its drug regulations, ACT UP generally favored activist government. Indeed, the organization was simultaneously conducting a campaign for national healthcare. By contrast, Reagan famously intoned in his first inaugural address that "government is not the solution to our problem; government is the problem,"[144] and his administration was guided by this principle in all areas besides national security.

Indeed, apart from FDA's role, AIDS activists and Republican libertarians even diverged on how best to address the AIDS crisis. The former contended that the search for a cure demanded the unstinting financial support and extensive involvement of the federal government. Kramer, for instance, urged the establishment of a federal "Manhattan Project" for AIDS.[145] Throughout the Reagan presidency, however, government funding for AIDS research, though steadily climbing, fell far short of what AIDS activists (and scientists) believed was needed.[146] The spending increases that did occur reflected the demands of Congressional Democrats, not the Reagan Administration; in his 1986 budget, the president actually proposed *cutting* the appropriation for AIDS research by 22 percent.[147]

The two groups also differed in their ultimate ambitions regarding FDA drug regulation generally. The true motives of at least some libertarians on the right were revealed when the *Wall Street Journal*'s editors invoked the AIDS crisis in calling for repeal of the FDCA's requirement that manufacturers demonstrate efficacy prior to approval.[148] The Heritage Foundation, meanwhile, proposed that the FDA be stripped of its gatekeeping power over drugs altogether and that the agency's role be

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[144] Ronald Reagan: Inaugural Address, http://www.presidency.ucsb.edu/ws/?pid=43130 (last visited Nov 11, 2015).

[145] Larry Kramer, *A "Manhattan Project" for AIDS*, N.Y. TIMES, July 16, 1990, at A15.

[146] Erik Eckholm, *AIDS: Scientists Voice Concern Over Research*, N.Y. TIMES, November 4, 1986; See generally AIDS Funding for Federal Government Programs: FY1981-FY2006 - RL3073103232005.pdf, , http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL3073103232005.pdf (last visited Jul 20, 2015).

[147] Bernard Weinraub, *Reagan Orders AIDS Report, Giving High Priority to Work for Cure*, N.Y. TIMES, February 6, 1986, at B7; Eckholm, *supra* note 146; See generally AIDS Funding for Federal Government Programs: FY1981-FY2006 - RL3073103232005.pdf, *supra* note 146.

[148] An AIDS Crisis Proposal (editorial), WALL STREET JOURNAL, June 15, 1988, at 1; AIDS and 1962 (editorial), WALL STREET JOURNAL, July 14, 1988, at 26.

reduced to ensuring accurate labeling.[149] By contrast, the *ACT UP FDA Action Handbook*, distributed to participants in the Parklawn demonstration, warned: "AIDS advocates must be careful to keep their agenda, supporting earlier access to promising life-saving drugs …., from becoming confused with the Bush deregulation/Wall St. Journal/Heritage Foundation agenda of sweeping drug industry deregulation. It would be a disaster for all American consumers, including people with HIV infection, if the Kefauver [1962] Amendments were repealed and drug companies were no longer required to prove safety [sic] and efficacy for most drugs."[150]

When George H. W. Bush took the reins of power in January 1989, he inherited the Reagan administration's deregulatory philosophy and mechanisms. The beginning of Bush's presidency coincided with the initial meetings of an organization called the "National Committee to Review Current Procedures for Approval of New Drugs for Cancer and AIDS." Then-Vice President Bush had established this body in 1988, when he was serving as the head of Reagan's Task Force on Regulatory Relief.[151] The committee, chaired by Louis Lasagna of Tufts University, was tasked with exploring ways to "improve access … to promising new treatments, and facilitate the transfer of new therapies to medical practice."[152] At one of the committee's first sessions, Lasagna made his own ideological predilections clear.

> There is a tendency for the public to favor a more libertarian point of view today. They're saying, "I don't want Big Daddy to make judgments for me." … Personally, I don't want patients with remedial cancer that could be successfully treated by other means to go to Laetrile. But if the cancer is nonresponsive, if they are terminal, I would rather have the patient go to their physician and get Laetrile, if that's what they want, than run off to Mexico.[153]

The AIDS activists needed to decide how closely to work with such conservative deregulators. Delaney seemed less reluctant than most, but other treatment activists also overcame their aversion to sitting in the same room as Republicans. Nevertheless, AIDS movement leaders recognized that this was, at best, an alliance of convenience and that they would have to manage the relationship carefully.

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[149] Kolata, *supra* note 81.

[150] ACT UP/New York FDA Action Handbook 9-12-88, , http://www.actupny.org/documents/FDAhandbook1.html (last visited Jul 20, 2015).

[151] Warren Leary, *Panel Seeks to Streamline F.D.A. for Cancer and AIDS Drugs*, N.Y. TIMES, January 5, 1989, at B12.

[152] FINAL REPORT OF THE NATIONAL COMMITTEE TO REVIEW CURRENT PROCEDURES FOR APPROVAL OF NEW DRUGS FOR CANCER AND AIDS, viii (1990).

[153] Quoted in Laurie Garrett, *Discovery: The Battle over FDA Drug Policy*, NEWSDAY, February 14, 1989, at 1.

C. Articulating an Ideology of Liberty

A related challenge confronted by the AIDS movement was articulating the nature and extent of the freedom they demanded. Few members of the AIDS community embraced a thoroughgoing libertarianism like that of some deregulators on the right. So what type of liberty were they advocating for?

Elsewhere, I have elucidated four "strands" of liberty that together supported the notion of freedom of therapeutic choice in the nineteenth century: bodily freedom, economic freedom, freedom of religion/conscience, and freedom of inquiry.[154] These strands combined into a robust, multidimensional vision of a right to medical choice—a right that was clearly "constitutional," even though nineteenth-century Americans vindicated it almost entirely outside of court. By contrast, the AIDS activists of the late twentieth century wholeheartedly embraced only the first of these strands. The second and third were not core elements of their worldview. Even more problematically, unregulated inquiry, once promoted as an engine of medical progress, had become, in the context of modern medicine, a threat to the development of an AIDS cure.

Bodily freedom was always a central feature of the AIDS movement's liberty rhetoric. As early as 1983, the quasi-constitutional "Denver Principles," drawn up at the first national gathering of AIDS activists, listed as one of the "Rights of People with AIDS" a right "[t]o full explanations of all medical procedures and risks, to choose or refuse their treatment modalities, to refuse to participate in research without [sic] jeopardizing their treatment and to make informed decisions about their lives."[155] When ACT UP formed four years later, the organization's "first principle," activist Jim Eigo remembered, was "the whole idea that people with AIDS, or people with HIV, had a right to make decisions about their lives, their treatment, how they were treated at every stage of their disease …."[156]

Such statements illustrate the AIDS movement's indebtedness to the patients' rights movement of the early 1970s and its emphasis on informed consent.[157] The AIDS activists sought a level of bodily autonomy that transcended these earlier calls for patients' rights, however. First, their ideology of bodily freedom extended beyond health issues to sexual

[154] Grossman, *supra* note 26 at 112–123; Grossman, *supra* note 26.

[155] Denver Principles, , http://www.actupny.org/documents/Denver.html (last visited Aug 5, 2015).

[156] Jim Eigo interview, Mar. 5, 2004, at 16-17 (interview # 047 of AUOHP).

[157] See, e.g., American Hospital Association's 1973 Patients' Bill of Rights, reprinted in RUTH R. FADEN JOHNS HOPKINS UNIVERSITY SCHOOL OF PUBLIC HEALTH & TOM L. BEAUCHAMP GEORGETOWN UNIVERSITY, A HISTORY AND THEORY OF INFORMED CONSENT 93 (1986).

conduct and expression.[158] Furthermore, in addition to demanding informed consent with regard to already-available drugs, they also pressed for access to treatments that the government was denying them. In both of these respects, the true progenitor of ACT UP's bodily freedom philosophy was the women's health movement of the 1970s.

From the time of its inception, ACT UP included a large cohort of women, many with experience in feminist, women's health, and reproductive rights advocacy.[159] These women—many of them lesbians—shared their ideology and tactical experience with their gay male counterparts.[160] ACT UP member Robert Vazquez-Pacheco opined: "ACT UP, historically, directly came from … the women's health movement."[161] Fellow activist Heidi Dorow observed that "a lot of … issues were overlapping" in the reproductive rights and AIDS advocacy movements. "Whether it's—access to reproductive health services; safer sex information; control of your body …. They have common cause."[162]

The abortion rights aspect of the women's health movement was a particularly potent model for ACT UP members. Brian Zabcik "always saw a very strong relationship" between abortion rights and AIDS advocacy. He explained, "In both instances, we were trying to work for a solution that would help people avoid being punished for their sexual mistakes."[163] ACT UP members participated enthusiastically in pro-choice mobilization events because, in one member's words: "They're the same issue. It's about control over our bodies."[164] Not coincidentally, "choice" became the most important word in ACT UP's verbal arsenal. Jim Serafini of ACT UP San

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[158] Kevin Michael DeLuca, *Unruly Arguments: The Body Rhetoric of Earth First!, ACT UP, and Queer Nation*, 36 ARGUM. ADVOCACY 9–21.

[159] See, for example, Jean Carlomusto interview, Dec. 19, 2002, at 12 (interview # 005 of AUOHP); Marion Banzhaf interview, Apr. 18, 2007, at 15-21 (interview # 070); Denenberg interview, *supra* note [ ], at 9-19 (interview # 093); Maxine Wolfe interview, *supra* note [ ], at 21-22, 28-32.

[160] For instance, ACT UP's Women's Caucus in New York City compiled an enormous handbook on the women's health movement and presented it in a "teach-in" to hundreds of men. Barbara Seaman, HEALTH ACTIVISM, AMERICAN FEMINIST | JEWISH WOMEN'S ARCHIVE, http://jwa.org/encyclopedia/article/health-activism-american-feminist (last visited Jul 23, 2015).

[161] Robert Vazquez-Pacheco interview, Dec. 14, 2002, at 63 (interview # 002 of AUOHP). Risa Denenberg, a leader of the ACT UP Women's Caucus, explained that feminism contributed directly to the PWA empowerment ideology, in particular the "empowerment that takes place … when concepts change about things that are as basic as who has control over your body. So if it came up to something like drugs into bodies, it was just nice to kind of have that perspective." Denenberg interview, *supra* note [ ], at 33.

[162] Heidi Dorow interview, Apr. 17, 2007, at 31 (interview # 069 of AUOHP).

[163] Brian Zabcik interview, Sept. 8, 2008, at 40 (interview # 102 of AUOHP).

[164] Steve Quester interview, Jan. 17, 2004, at 16 (interview # 040 of AUOHP).

Francisco declared: "Real choice in treatment, parity with established medical authority and freedom to learn and risk intelligently, sums up what ACT UP demands. Sounds all-American, doesn't it? It is because it is about freedom and choice."[165]

In the nineteenth century, the bodily freedom strand of the right to medical choice was bolstered by a strong commitment to economic freedom. During the AIDS crisis, some conservative deregulators took a similar position, contending that FDA drug regulation improperly violated contractual liberty. For example, Sam Kazman of the Competitive Enterprise Institute opined:

> Restoring the right of contract might do more for [PWAs] than any other change in the world of law…. [I]n cases of untreatable diseases … unapproved drugs would no longer be categorically barred. Instead, they could now be available by prescription, with a clear warning of their unapproved status…. Those who wished to rely on FDA's judgment could continue to do so. The rest of us could knowingly, and contractually, assume the risks of unconventional therapies…. Such an exercise of the right of contract is nothing more than what the Framers intended 200 years ago ….[166]

Although Mark Milano of ACT UP similarly suggested that the FDA require drug manufacturers to "put the data on the label" and let the "marketplace" decide, such arguments were relatively rare among AIDS activists.[167] The AIDS community as a whole did not want to abolish the FDA's gatekeeping role. Moreover, AIDS groups did not hesitate to urge government intervention into the free market when, for example, protesting high drug prices.[168]

Meanwhile, the traditional freedom of religion/conscience strand of medical liberty—so essential when the therapies being defended were Christian Science and Mind Cure—were largely absent from the AIDS activists' campaign for FDA reform. Faith and belief were not core elements of their modern scientific approach to finding a cure. The closest the AIDS activists came to acknowledging a nonmaterialist element of medicine were their occasional paeans to the value of "hope."

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[165] Jim Serafini, *ACT UP's Challenge to the Establishment*, SAN FRANCISCO CHRONICLE, June 20, 1990, at A19.

[166] Sam Kazman, *The FDA's Misbegotten AIDS Rules are Killing with Kindness*, WASHINGTON POST, July 16, 1989, at B5.

[167] EARLY AVAILABILITY OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES, 1–178 (Milano) (1994).

[168] To the extent that AIDS activists embraced a vision of economic freedom, it was expressed in their occasional objections to a purportedly corrupt alliance between FDA and large pharmaceutical companies to block new drugs from the market. Martin Delaney voiced such suspicions. KWITNY, *supra* note 80 at 180, 193.

Finally, in stark contrast to their nineteenth-century forebears, the leading AIDS treatment activists emphatically *rejected* the value of the fourth strand—"freedom of inquiry"—in the sense of unrestricted experimentation by individual patients and doctors. Advocates for therapeutic choice had once celebrated the decentralized, unfettered gathering of information as the most effective method for advancing society's therapeutic knowledge. But since the middle of the twentieth century, modern scientific medicine—the system in which AIDS activists placed their hopes—has deemed such individualized experimentation to be irrelevant to the determination of a treatment's efficacy. The FDA-regulated controlled clinical trial has become the "gold standard" for establishing efficacy. Because such trials are randomized and controlled (ideally, placebo-controlled), this model of investigation is, at root, premised on *denying* participants a free choice of therapy. Indeed, because such studies are double-blinded, patients and physicians are not even aware of what therapy (if any) the patients are taking.

Furthermore, in the eyes of the FDA, medical researchers, and even some AIDS activists, the widespread trial-and-error use of experimental AIDS drugs outside of clinical studies was not merely irrelevant to medical progress, but actually threatened to undermine it. Why, they asked, would a PWA enroll in a controlled clinical study of a promising new medicine, and risk receiving the control, when he could obtain the experimental drug for certain elsewhere? If too many patients were diverted away from clinical trials, and these trials were thus not completed, nobody would ever know for sure whether new AIDS treatments provided any clinical benefit.

In the face of this tension, AIDS activists were left with only two options. Some flatly insisted that PWAs' personal right to choose was more important than the advancement of medical knowledge. Others, by contrast, prioritized the acquisition of scientific understanding but tried to reconceptualize medical research so that the use of experimental drugs outside of controlled studies would not interfere with the research, and perhaps even contribute to it. Eventually, as we will see, these different approaches proved to be irreconcilable, and bitter conflict divided the movement. But first came some collective triumphs.

VI. EARLY VICTORY: SUBPART E

The Parklawn action quickly bore fruit. On October 19, 1988, barely more than a week after the demonstration, the FDA issued a rule that, at least on its face, promised speedier approval of AIDS drugs.

A chief demand of the AIDS activists was that the FDA should, when considering the NDA for a drug for an incurable fatal disease, require less

conclusive proof of efficacy than usual and instead err on the side of approving the product and allowing patients to make their own risk-benefit assessments. The FDA had seemed to embrace this approach in 1987 with its extraordinarily rapid approval of AZT based on a single phase 2 study. The activists had hoped that the agency would regulate other AIDS drugs similarly, but at the time of "Seize the FDA," AZT remained the only approved treatment for the disease.

Two months before the Parklawn protest, Vice President Bush, acting as chairman of the Task Force on Regulatory Relief, had charged the FDA with developing procedures for the expedited approval of therapies for AIDS and other life-threatening diseases.[169] The day after the demonstration, the *Wall Street Journal* reported that the administration's plan to "telescope the three phases of new-drug testing into two" was "on the verge of collapsing" because of the resistance of "[c]areer bureaucrats inside FDA."[170] Then, six days later, the FDA suddenly announced a new, immediately effective rule establishing procedures designed to speed the approval of drugs for "life-threatening and severely debilitating illnesses."[171] Although the rule was not limited to AIDS drugs, the *Washington Post* reported that the FDA issued it "primarily to assuage AIDS activists."[172]

These "Subpart E" expedited development procedures (still in effect today and partially codified in the FDCA under the rubric "Fast Track"[173]) invite drug sponsors to request early meetings with the FDA regarding the design of animal and human studies. The most important such consultation is an "end-of-phase 1 meeting" intended to discuss how the sponsor might design data-rich phase 2 trials that will obviate the need to proceed to phase 3 before approval.[174] The Subpart E regulations also bind the FDA, when considering NDAs for drugs for life-threatening and severely debilitating illnesses, to perform a risk-benefit analysis that "tak[es] into consideration the severity of the disease and the absence of satisfactory alternative therapy."[175] The preamble to the 1988 rule declared: "The agency recognizes that safety and effectiveness are not absolute (i.e., not all drugs are free of risk or have unequivocal benefits), but must be assessed in light

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[169] 53 Fed. Reg. 41516, 41516 (Oct. 21, 1988).

[170] The FDA for Itself (Editorial), WALL STREET JOURNAL, October 13, 1988, at A22.

[171] 53 Fed. Reg. 41,516; Michael Specter, *FDA Amends Rules to Speed AIDS Drugs*, WASHINGTON POST, October 20, 1988, at A1.

[172] *Id.* In the rule's preamble, FDA stressed that it had "met informally with representatives of AIDS interest groups." 53 Fed. Reg. at 41,516.

[173] FDCA § 506(b), (d).

[174] 21 C.F.R. § 312.82.

[175] 21 C.F.R. § 312.84(a).

of what condition the drug treats."[176] The FDA thus embraced the AIDS activists' essential argument regarding drug approval—namely, that victims of grave illnesses are willing to accept greater uncertainty and risk than are people suffering from less serious ailments.[177]

Although major newspapers gave the FDA's announcement of the Subpart E regulations front-page coverage, the AIDS community was unenthusiastic. Martin Delaney acknowledged that the rule represented "a touch of common sense" but added, "We got a nickel when we needed a dollar."[178] Other AIDS activists dismissed the FDA's action as a cynical campaign ploy by Bush, then in the final weeks of his ultimately successful presidential race.[179] The rule's detractors asserted that it was merely a statement of flexibility and powers that the FDA already possessed—as demonstrated by the AZT approval the previous year. Activists also bemoaned the complete voluntariness of the Subpart E procedures and the agency's lack of sufficient resources to implement them.[180]

In short, though the publication of Subpart E may have been a welcome signal that the government now considered the AIDS movement a force to be reckoned with, activists recognized that different tactics would be required to realize truly meaningful change in FDA drug regulation.

VII. THE ACTIVISTS TRIUMPH: PARALLEL TRACK

A. Genesis of an Idea

Despite their dissatisfaction with the Subpart E regulations, the activists quickly turned their attention to other matters. Because no anti-HIV drugs were nearing FDA approval in autumn 1988—even under the most expedited procedures—the activists focused instead on gaining access to *unapproved* drugs earlier in their development, before they had even entered phase 2 trials.[181]

As discussed above, the final version of the 1987 Treatment IND rule essentially required that there be a "reasonable basis" for concluding that the unapproved drug was effective. The FDA was thus unlikely ever to grant a treatment IND before positive results emerged from at least one

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[176] 53 Fed. Reg. at 41,520.

[177] 53 Fed. Reg. at 41,518.

[178] Specter, *supra* note 171.

[179] Warren Leary, *F.D.A. Announces Changes to Speed Testing of Drugs*, N.Y. TIMES, October 20, 1988, at A1.

[180] Specter, *supra* note 171; Leary, *supra* note 179.

[181] In June 1989, FDA approved two drugs intended to treat *secondary* infections suffered by PWAs: aerosol pentamidine, for a severe type of pneumonia, and ganciclovir, for cytomegalovirus retinitis.

phase 2 trial. In practice the agency tended to permit treatment use only after the completion of phase 3.[182] This regime frustrated PWAs, who were desperate to try potential therapies as soon as possible. AIDS groups thus began demanding access to experimental drugs based solely on the results of phase 1 trials, even though these uncontrolled studies are designed primarily to assess safety, and they provide, at most, preliminary indications of effectiveness.

The FDA sometimes allowed individuals to obtain drugs prior to the commencement of phase 2 studies pursuant to compassionate use INDs or "single patient exceptions," but it was extremely reluctant to authorize broader treatment access at this stage. Such a step would represent a dramatic diminishment of the agency's traditional consumer protection role. Moreover, in the opinion of most regulators and researchers, widespread release of a drug this early in the clinical research process would jeopardize the enrollment and completion of controlled studies.

In an October 1988 speech before the Infectious Diseases Society of America, Martin Delaney presented one of the first detailed arguments in favor of nonetheless allowing PWAs to try drugs for which there was only minimal evidence of effectiveness. He started by declaring his vision of the nation's fundamental values: "If public and individual good are not clearly harmed, then the government should not stand in the way. That is the American way."[183] Therefore, he contended, "the burden of proof should not be on those seeking access to experimental therapy but upon those who seek to deny such access."[184] Delaney rejected the argument, frequently advanced by regulators, that PWAs must be protected from their own desperation. This view, he opined, "smack[ed] of 'big brother.'" He also dismissed the common assertion that PWAs should be denied experimental drugs because they "may do more harm than good." He declared:

> Although risks may exist, it is often equally possible that the treatment may do more good than harm….
> …. The question should be, "who gets to decide what risks are acceptable: the bureaucracy in Washington or the patient whose life is on the line?" … [W]e

[182] The new Subpart E regulations stated that FDA could invite sponsors to seek treatment INDs—but only if "the preliminary analysis of phase 2 test results appears promising." 21 C.F.R. 312.83. In the views of patient advocates, the treatment IND was used primarily "as a bridge between Phase III and the NDA while FDA reviewed the data." Jeffrey Levi, *Unproven AIDS Therapies: The Food and Drug Administration and ddI*, *in* BIOMEDICAL POLITICS 9–37, 14 (Kathi E. Hanna ed., 1991).

[183] Martin Delaney, *The Case for Patient Access to Experimental Therapy (reprint of address presented at the 26th annual meeting of the Infectious Diseases Society of America in October 1988)*, 159 J. INFECT. DIS. 416–419, 416 (1989).

[184] *Id.* at 416.

> feel that patients should be given some say in the final choice, acting along with his or her [sic] physician ….[185]

Finally, in a groundbreaking portion of his speech, Delaney addressed the concern that wide access to experimental drugs would make clinical research difficult or impossible to conduct. He observed that regardless of any impact on research, "[m]any patients and their advocates find it morally repugnant to deny potentially life-saving treatment to the masses to force the few into clinical studies."[186] Fortunately, Delaney continued, a choice between individual liberties and the advancement of science in the public interest was not necessary, because—contrary to widely held assumptions—early treatment use of unapproved drugs served both.

Delaney urged his listeners to consider how clinical research actually proceeds "in the laboratory of the real world."[187] He explained that because people join clinical trials for a variety of reasons (including "simple and admirable altruism"[188]), researchers would find sufficient numbers of subjects for their controlled studies even if the experimental drugs were also available through other avenues. Delaney then presented a daring and counterintuitive argument. He contended that providing wide access to unapproved drugs for treatment would actually *enhance* the clinical research enterprise. He explained

> the real-world AIDS experience … shows us that the policy of restriction is itself destroying our ability to conduct clinical research. AIDS study centers throughout the nation tell of widescale [sic] concurrent use of other treatments; frequent cheating, even bribing, to gain entry to studies; mixing of drugs by patients to share and dilute the risk of being on placebo; and rapid dropping out of patients who learn that they are on placebo….
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> … If patients had other means of obtaining treatment, force-fitting them into clinical studies would be unnecessary. Volunteers that remained would be more likely to act as pure research subjects, entering studies not solely out of a desperate effort to save their lives.[189]

Delaney further argued that the simultaneous provision of experimental therapies for treatment use outside clinical studies "in a structured and monitored fashion" would itself provide "useful evidence of long-term benefits and drawbacks."[190]

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[185] *Id.* at 417.
[186] *Id.* at 417.
[187] *Id.* at 417.
[188] *Id.* at 418.
[189] *Id.* at 418.
[190] *Id.* at 418.

Delaney emphasized that the fight against AIDS, "the medical equivalent of war," demanded a new approach.[191] "Inflexibly applied to the AIDS epidemic, regulatory practices contribute to the failure of science, demean the public good, and tread heavily on our civil liberties." He concluded: "[S]cience and patient alike would be better served by a system that permits life-threatened patients some form of access to the most promising experimental therapies, peacefully coexisting alongside a program of unencumbered clinical research."[192] Although he did not use the precise words, Delaney had eloquently advocated the creation of what would soon come to be known as the "parallel track."

The term "parallel track" apparently entered public discourse in June 1989 at the International Conference on AIDS in Montreal. At this meeting, members of ACT UP's Treatment and Data (T&D) Committee presented a document titled "A National AIDS Treatment Research Agenda."[193] Among many other items, this agenda proposed a "parallel track" procedure permitting the treatment use of experimental drugs while controlled efficacy trials were ongoing.

A revised version of the agenda published three months later elaborated: "Parallel Track should encompass post-Phase I open-label treatment protocols for people unable to participate in controlled clinical trials for AIDS and HIV-related treatments."[194] According to the document, various categories of HIV-infected patients should be deemed "unable to participate" in clinical trials and thus eligible for parallel track. They included, among others, people who could not tolerate the standard treatment being used as the active control, people for whom that standard treatment had already failed, and people who were too sick to enroll in a clinical trial or too distant from a study site.[195] The agenda emphasized that safety and (if possible) efficacy data should be collected on parallel track subjects, thus providing important early information on "real world" usage of the experimental drug.[196] Finally, the document proposed that the parallel track program be implemented by a newly created Parallel Track Advisory Committee composed of government and industry representatives, AIDS

[191] *Id.* at 417.

[192] *Id.* at 419.

[193] ACT UP/New York, A NATIONAL AIDS TREATMENT RESEARCH AGENDA, V INTERNATIONAL CONFERENCE ON AIDS, MONTREAL (1989). Excerpts of the Montreal press conference introducing the Agenda appear at 35', 35" of the documentary *How to Survive a Plague*. The agenda was presented by Peter Staley, Mark Harrington, Jim Eigo, and Iris Long.

[194] *Id.* at 6.

[195] *Id.* at 7.

[196] *Id.* at 6–7.

primary care physicians, representatives of community-based research groups, and—critically—"people with AIDS, HIV, and their advocates."[197]

During the months following the Montreal conference, ACT UP began to participate in policy discussions inside the federal bureaucracy itself. Simultaneously, and perhaps inevitably, T&D activists who had achieved some mastery of the complex subjects of drug development and FDA regulation began to dominate the organization's pharmaceutical-related efforts. With the exception of Iris Long, a straight female chemist, ACT UP's T&D Committee was composed of self-taught gay men. Jim Eigo, for example, was an HIV-negative avant-garde writer in his 30s with a graduate degree in theater but no post-secondary science education. Despite extensive experience in antiwar and human rights activism, Eigo had no connection to the gay rights movement before joining ACT UP. Another prominent ACT UP treatment specialist was Mark Harrington, an HIV-positive aspiring screenwriter in his 20s. Harrington, who had majored in visual and environmental studies at Harvard, had no background in medicine other than menial temporary jobs in a hospital. He had been entirely apolitical before becoming involved in AIDS activism. The tactics and attitudes of this brilliant cluster of autodidacts increasingly differentiated them from the broad mass of ACT UP members.

The person most responsible for ushering the treatment activists into the decision-making processes of the federal government was Dr. Anthony Fauci, the Director of the National Institute of Allergy and Infectious Diseases (NIAID) within NIH. An articulate AIDS expert with a Brooklyn accent, Fauci had no direct authority over FDA policies. Nonetheless, NIAID's function as the chief overseer and funder of AIDS drug investigations around the country made him an extremely influential figure on the issue of access to unapproved therapies.

Fauci initially opposed extensive pre-approval use of AIDS drugs for treatment, fearing it would deter participation in clinical trials. He changed his mind, however, both because of his growing distress over the plight of dying PWAs and because AIDS activists persuaded him that clinical research would survive, and perhaps even improve, if accompanied by treatment access.[198] After meeting Martin Delaney in spring 1989, Fauci instructed an assistant to begin sketching out an early access program with the Californian.[199] Following the Montreal conference, Fauci invited some ACT UP T&D Committee members to NIH to discuss their plan.[200] Days

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[197] *Id.* at 7.

[198] Gina Kolata, *AIDS Researcher Seeks Wide Access to Drugs in Tests*, N.Y. TIMES, June 26, 1989, at A1; Levi, *supra* note 182 at 15–16.

[199] KWITNY, *supra* note 80 at 218, 224, 235–36.

[200] ACT UP Chronology

later, on June 23, 1989, Fauci delivered a speech in San Francisco outlining a new program, titled Parallel Track, that would make unapproved AIDS drugs available for treatment use as soon as they were proved safe, even as clinical trials were ongoing.[201] Although he presented this proposal as his own initiative, the NIAID chief acknowledged that it resulted from "constructive pressure" from AIDS advocacy groups.[202] In fact, the AIDS activist community deserves most of the credit for the idea.[203]

Fauci did not confer with the FDA or HHS before delivering this speech—a striking lapse, in view of the fact that the FDA, not NIAID, would be responsible for designing and implementing any parallel track mechanism. FDA Commissioner Young quickly insisted, "I've been pushing [parallel track] as much as Tony has"—and then commenced the difficult work of putting flesh on Fauci's skeletal proposal.[204] As one scholar remarked: "Overnight, Fauci became the hero of the activist community and … made the [FDA] regulators into the stumbling block to reform."[205]

B. Congressional Hearing

Less than a month later, Young and James Mason, the HHS Assistant Secretary in charge of the National AIDS Program, were sitting beside Fauci on Capitol Hill, defending his parallel track proposal before a House subcommittee.[206] The Subcommittee on Health and the Environment was chaired by Congressman Henry Waxman, a traditional consumer protection advocate who had opened the proceedings by emphasizing the FDCA's critical role of "protect[ing] consumers from dangerous products and from snake oil remedies" and by defending the morality of imposing "a policy of limited distribution today, so that we will have adequate information for tomorrow."[207]

The panel of government witnesses explained that the proposed parallel track program (which was limited to AIDS and HIV drugs) would provide access to experimental medications much earlier than the Treatment IND—"at the earliest possible stage" of their clinical development, namely, after

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[201] Kolata, *supra* note 198; Victor F. Zonana & Marlene Cimons, *Ease AIDS Drug Rules, Health Chief Urges*, LOS ANGELES TIMES, June 24, 1989, at 23; Levi, *supra* note 182 at 16.

[202] Zonana and Cimons, *supra* note 201.

[203] Levi, *supra* note 182 at 14.

[204] Kolata, *supra* note 198.

[205] Levi, *supra* note 182 at 16.

[206] AIDS ISSUES: PARALLEL TRACK PROPOSAL FOR CLINICAL DRUG DEVELOPMENT, 5–26 (1989). Samuel Broder, the Director of the National Cancer Institute, was also on the panel.

[207] *Id.* at 1.

the completion of phase 1 trials.[208] In response to Waxman's suggestion that the proposal was "an opening for laetrile," Mason assured the congressman that the program would be limited to drugs that showed "some promise" of efficacy—either in animal experimentation or in phase I.[209] The panel expressed confidence that the existence of a parallel track would not undermine clinical trials by discouraging participation in them. Mason pointed out that because AIDS trials now used AZT rather than a placebo as a control, potential clinical trial subjects did not have to fear that they would go entirely untreated in a controlled study.[210] Fauci emphasized that because only PWAs unable to participate in a clinical trial were eligible for the parallel track, nobody could choose the parallel track *instead* of a controlled study, in any event.[211]

In his testimony, Martin Delaney took issue with Fauci's proposal to make the parallel track off-limits to anyone eligible and able to participate in a clinical trial. He opined that policymakers were still too concerned with preserving the integrity of the clinical trial process and too little concerned with protecting PWAs' medical autonomy. "Research outcomes are not the only objective of what we're trying to accomplish here, and there's a broad enough pool of patients here that we can give a degree of choice to those who are at the most near-term risk of losing their own lives. We think choice has to be given to those people."[212] Interestingly, Jim Eigo of ACT UP did not similarly emphasize choice when he testified. He instead agreed with Fauci that the parallel track should be open only to those who could not participate in a clinical trial.

Delaney and Eigo fully agreed on one critical point, however—that PWAs should play a central role in the implementation of any parallel track program. Delaney was skeptical that FDA staffers, focused on the ultimate approval of drugs, would adequately consider PWAs' desire for therapies prior to approval. He thus insisted that the parallel track program be administered by an independent standing committee that included patients and their advocates.[213] Eigo similarly urged that community representatives be involved, noting: "The AIDS establishment can learn from those who have been dealing with this disease daily for nearly a decade now."[214]

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[208] *Id.* at 6–7 (Mason), 9 (Young).
[209] *Id.* at 11 (Mason).
[210] *Id.* at 10 (Mason).
[211] *Id.* at 10 (Fauci).
[212] *Id.* at 30.
[213] *Id.* at 28–29 (Delaney).
[214] *Id.* at 41.

C. Advisory Committee Meeting

Following the congressional hearing, Young convened an FDA advisory committee (a body of outside experts) to help resolve the complex issues surrounding parallel track.[215] The resulting August 17, 1989 meeting of FDA's Anti-Infective Drugs Advisory Committee in Bethesda, Maryland was an extraordinary event.[216] Traditionally, advisory committee meetings had been the exclusive domain of government bureaucrats, scientists, industry representatives, and, sometimes, members of established consumer protection groups. In this meeting, AIDS activists played a prominent—even dominant—role. The FDA, sensing the shifting political dynamics, invited Delaney, Eigo, and several other AIDS activists to testify. About ten additional activists and patients took the microphone during the open public hearing. ACT UP bused in members to fill the spectators' seats. The result was a departure from the normally staid atmosphere of such events; the highly engaged audience punctuated the proceedings with applause and laughter dozens of times. The activists thus established an important precedent for extensive patient involvement in advisory committee meetings.

The start of the meeting resembled the Congressional hearing of the previous month, with Mason, Young, and Fauci speaking favorably but guardedly about the creation of a parallel track program. Next, Delaney and Eigo emphasized the burning need for such a program and urged that community members be afforded a central role in its design and implementation.[217] Delaney and Eigo both contended that PWAs with no treatment alternatives had a "right" to take an informed risk on an experimental drug, and they both explicitly rejected the notion that currently infected individuals should make a "sacrifice" for the future greater good.[218] Indeed, Eigo moved closer to Delaney's position on absolute choice by arguing that the "AZT recalcitrant"—that is, people with a "personal animosity" toward that drug—should be considered "unable" to participate in clinical trials with an AZT control and thus entitled to opt for the parallel track.[219] Still, a subtle difference remained between the two men's views, representing a growing East Coast/West Coast divide among AIDS treatment activists. Eigo stressed the importance of obtaining "real world" safety and efficacy information from the parallel track. Delaney, by contrast, favored limiting mandatory data collection in the parallel track to

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[215] *Id.* at 19.
[216] TRANSCRIPT OF PROCEEDINGS, (1989).
[217] *Id.* at 83–85 (Eigo), 86, 90–91 (Delaney).
[218] *Id.* at 80, 84 (Eigo); 88, 99 (Delaney).
[219] *Id.* at 77 (Eigo).

information required to safeguard patients. He worried that significant paperwork requirements would "choke the system" and discourage participation by community doctors. Delaney insisted that "the objective of parallel track is not to conduct research. It is to provide treatment."[220]

The eloquent and passionate testimony of community representatives that followed heightened the feeling of urgency and highlighted the national scope of the movement. The right to choose was a recurring refrain. For example, Michelle Roland of ACT UP San Francisco endorsed Fauci's parallel track proposal only ambivalently because it did not address the "bottom line issue of patient choice." She warned that her organization would continue to agitate until *all* AIDS patients had "the right to choose to use an experimental therapy once it has been shown to be reasonably safe and there is some indication of efficacy."[221] Various speakers reiterated Delaney's assertion that data collection requirements should not be allowed to interfere with the parallel track's treatment goals.[222] Jeff Levi of the Gay Men's Health Crisis reaffirmed the critical importance of ongoing PWA involvement in the administration of the program.[223] Larry Kramer, predictably, provided a fiery coda:

> If we do not get these drugs you will see an uprising, the likes of which you have never seen before since the Vietnam War in this country. We will sabotage all of your Phase II studies. We will continue to get our drugs on the underground. Our chemists will duplicate your formulas….[224]

Meanwhile, the testimony of two traditional consumer advocates highlighted how far many of the AIDS activists had diverged from the consumer protection movement of the 1960s and 1970s. Sidney Wolfe remarked: "With the shift of power from industry, from researchers, from FDA to include in a much more important way patients comes responsibility as well." He then scolded Eigo and Delaney for taking a position that "would undermine … controlled trials."[225] William Schultz of the Public Citizen Litigation Group similarly emphasized the tension between early access and the quest for scientific truth:

> … It seems to me that … we are striving … to make possibly effective drugs available to the widest number of people as early as possible.

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[220] *Id.* at 93.

[221] *Id.* at 171 (Roland). Derrick Hodel of the PWA Health Group similarly opined: "Our position has always been that given low toxicity, people have the right to acquire drugs that they feel might be efficacious. *Id.* at 162.

[222] TRANSCRIPT OF PROCEEDINGS, *supra* note 216 at 172 (Roland), 193 (Kramer).

[223] *Id.* at 131–32 (Levi).

[224] *Id.* at 194 (Kramer).

[225] *Id.* at 156–57 (Wolfe).

> If in doing that, it turns out that we are slowing down clinical trials and impeding them, to me, the advantage of actually having some treatment—it may make doctors feel good; it may make patients feel good, but if it is not doing any good, if it is not curing anybody and if it is slowing down clinical trials, I am against it.[226]

The advisory committee meeting ended with one looming quandary unsolved: the parallel track program would not help a single PWA if pharmaceutical manufacturers declined to participate in it. Drug companies had various reasons to shun parallel track, including fear of product liability lawsuits, interference with the controlled trials that would form the basis for ultimate approval, and the prohibition against charging an amount higher than needed for cost recovery. HHS Assistant Secretary Mason nonetheless expressed blithe assurance that manufacturers would participate enthusiastically because of the good will and publicity they would get from doing so.[227] Eigo, too, suggested that companies would eagerly take part in parallel track—without charging patients—once they realized that "the short-term economic loss of paying for [the] drug will be outweighed by the long-term gain of short trials, clean data, … good community relations and some free publicity."[228]

Some were less confident, however. ACT UP's Mark Harrington—always intensely skeptical about the industry's motives—doubted that the AIDS community could count on its voluntary participation and advocated government coercion.

> I question a parallel track program that would rely exclusively on the voluntary involvement of pharmaceutical companies. Are we not in a war? If we were fighting a foreign enemy, the government would be issuing massive contracts and compelling large manufacturers to provide war materiel. In the war on AIDS new treatments are war materiel.[229]

A few speakers more modestly suggested conditioning NIH funding or ultimate FDA approval on an agreement by the manufacturer to create and fund a parallel track.[230]

By the end of this August 1989 advisory committee meeting, the parallel track idea had unstoppable momentum. Indeed, the agency was already on the verge of allowing treatment access following Phase I trials to dideoxyinosine (ddI), an antiretroviral product without AZT's severe

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[226] *Id.* at 218–19 (Schulz).; *Id.* at 147.

[227] AIDS ISSUES: PARALLEL TRACK PROPOSAL FOR CLINICAL DRUG DEVELOPMENT, *supra* note 206 at 21–22 (Mason).

[228] TRANSCRIPT OF PROCEEDINGS, *supra* note 216 at 74 (Eigo); AIDS ISSUES: PARALLEL TRACK PROPOSAL FOR CLINICAL DRUG DEVELOPMENT, *supra* note 206 at 40.

[229] TRANSCRIPT OF PROCEEDINGS, *supra* note 216 at 179–80 (Harrington).

[230] *Id.* at 133–34 (Levi), 158 (Wolfe).

toxicity.[231] In September—after negotiations between the FDA, NIH, Bristol-Meyers (ddI's manufacturer), and AIDS activists—the secretary of HHS announced a treatment IND for ddI with a protocol that bore all the marks of a parallel track program.[232]

D. The Policy

In May 1990, the FDA published a proposed policy statement setting forth the parallel track mechanism.[233] The policy applied only to individuals with AIDS or HIV-related diseases, although the agency expressed a willingness to consider expanding the program to other life-threatening diseases later.[234] The proposal limited patient choice and prioritized the pursuit of data more than Delaney, and perhaps Eigo, would have preferred. The parallel track was open only to patients who could not tolerate AZT or for whom AZT was contraindicated or demonstrably did not work.[235] Moreover, the FDA emphasized the importance of including "sufficient safeguards and oversight to ensure that [the parallel track] neither delays nor compromises the controlled clinical trials."[236] Accordingly, the proposed policy did not allow patients to join the parallel track if they were eligible for a controlled study in which they could realistically participate.[237] Finally, the proposal emphatically required physicians participating in the parallel track procedure to collect and report safety data, and sometimes efficacy data.[238]

Despite these conditions, the creation of parallel track was an indisputable triumph for the AIDS activists. It allowed PWAs who satisfied the eligibility requirements to try an unapproved drug at a very early point in its development, when evidence of efficacy was little more than suggestive. The activists also prevailed in their demand that the AIDS community play a role in administering parallel track; under the policy, the

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[231] At the advisory committee meeting, FDA Commissioner Young announced the submission of the ddI treatment IND application and promised to respond to it within 30 days. *Id.* at 16 (Young).

[232] Levi, *supra* note 182 at 26–28.

[233] 55 Fed. Reg. 20,856 (May 21, 1990). Interestingly, parallel track was never published in the form of a proposed or final rule.

[234] *Id.*

[235] *Id.* 20,858. The proposed policy actually referred to "standard therapy," rather than AZT in particular, but at the time AZT was the only one.

[236] *Id.* 20,857.

[237] Eligibility for parallel track was thus limited to patients that failed to meet the controlled trials' entry criteria, were too ill to participate, or could not participate without undue hardship (for example, because of geographic distance), or to situations in which the controlled studies were already fully enrolled.

[238] *Id.* 20,859.

FDA would presumptively refer all parallel track proposals to the AIDS Research Advisory Committee (ARAC), a committee chartered by NIAID that included PWAs as well as scientists and physicians.[239] Although the 1990 document was only a *proposed* policy statement, the fact that the FDA had already authorized the release of ddI under a parallel-track-like protocol suggested that the agency was committed to the concept.

If there was any doubt that the FDA would ultimately finalize the policy, it disappeared a few months later, when the Lasagna Committee endorsed a parallel track for AIDS and cancer drugs in its final report.[240] Although the report stated that parallel track protocols should be permitted only when "there is assurance that adequate clinical trials are in progress and will not be compromised," it then declared that "the committee supports the rights of patients to obtain investigational drugs under these circumstances. Faced with the consequences of a lack of therapy for AIDS and cancer, an expanded mechanism for early access to investigational drugs is morally, ethically, and scientifically justified."[241] The committee remarked: "[A]lthough [earlier access] will clearly present greater risks to patients, because some of the drugs may eventually be found either to be ineffective or to present an unacceptable benefit/risk ratio, patients with life-threatening diseases who have no alternative therapy are entitled to make this choice."[242] Not coincidently, the report also praised the FDA's recent responsiveness to patient advocacy groups.[243]

In April 1992, the FDA published its final parallel track policy statement, which remained essentially unchanged from the proposal.[244] Once again, the interests of AIDS activists and Republican deregulators had aligned.

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[239] *Id.* 20,858.

[240] FINAL REPORT OF THE NATIONAL COMMITTEE TO REVIEW CURRENT PROCEDURES FOR APPROVAL OF NEW DRUGS FOR CANCER AND AIDS, *supra* note 152 at 11–12. The report also supported the use of treatment INDs earlier in the drug development process, a recommendation essentially identical to parallel track. *Id.* at 10-11.

[241] *Id.* at 11.

[242] *Id.* at 11.

[243] *Id.* at 7.

[244] 57 Fed. Reg. 13,250 (April 15, 1992). To ensure the continuation of controlled research, some commenters urged the FDA to prohibit the commencement of any parallel track program prior to the full enrollment of phase 2 trials. The agency declined to take this step, pointing out that patients were ineligible for parallel track protocols unless they could not participate in the controlled trials, in any event. *Id.* at 13,251-52.

VIII. SCHISM: THE TREATMENT ACTIVISTS BREAK AWAY

Despite its success with parallel track, the AIDS activist community was coming apart at the seams. Around 1990, it started dividing into two indistinct and overlapping but nonetheless identifiable camps. On one side were the "treatment activists," primarily middle-class, white, HIV-positive gay males who prioritized, above all, the goal of getting "drugs into bodies." They increasingly clashed with the "social activists," a group composed largely of women (especially lesbian, HIV-negative women) and people of color (many of them gay and HIV-positive). The social activists embraced a mission much broader than the development and approval of AIDS drugs. They advocated social services for PWAs and equal access to health care, and they demanded that the government pay special attention to the particular challenges confronted by HIV-infected women, African-Americans, and Latinos.[245]

The conflict was particularly bitter within ACT UP/NY, where members of the Treatment and Data Committee feuded with the Women's Caucus. The Caucus mobilized ACT UP to challenge a Centers for Disease Control and Prevention (CDC) definition of AIDS that excluded many infected women; T&D viewed such efforts as diversions from ACT UP's primary objective of promoting the development and release of pharmaceuticals. The Caucus also protested an NIH placebo-controlled trial designed to determine whether AZT could reduce the transmission of HIV from mothers to infants during pregnancy, contending that the study privileged fetuses' health over women's. T&D members generally supported this (ultimately successful) study and were enraged by the Caucus's disruption of a Newark community meeting led by the principal investigator.[246]

The most contentious issue of all was an early 1991 proposal by Tracy Morgan, a Women's Caucus leader, that ACT UP conduct a six-month moratorium on meetings with government officials.[247] Moratorium proponents believed that T&D members were being corrupted by their increasingly cooperative relationships with the federal AIDS bureaucracy. T&D activists, pleased by their hard-won access to government decision-makers, responded to the proposal with horror. David Barr, an HIV-positive treatment activist, scolded Morgan: "You know, what you're saying would

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[245] GOULD, *supra* note 102 at 328–394.

[246] AIDS Oral History Project (add pincites). This PI was an African-American woman, and the controversy thus illustrated the complexity of ACT UP racial politics.

[247] GOULD, *supra* note 114 at 366; AIDS Oral History Project (add pincites). The range of federal officials and discussions that would have been subject to this moratorium is unclear.

kill me."[248] The ACT UP membership voted down the moratorium, but the controversy added to T&D's sense of exasperation and alienation. In January 1992, the T&D leadership split off from ACT UP and formed the Treatment Action Group (TAG), an independent nonprofit organization with invitation-only membership devoted exclusively to speeding the development and availability of AIDS therapies.

The TAG secession is the episode that ACT UP veterans are usually referring to today when they mention the "schism." But within a couple of years, an equally significant breach opened up within the treatment community itself. The fault line was the inherent tension, discussed above, between freedom of choice and the pursuit of medical truth. The issue that triggered the rupture was a new mechanism called accelerated approval.

IX. THE INTERNECINE BATTLE OVER ACCELERATED APPROVAL

A. Birth of the Procedure

Whereas the parallel track program made drugs available *prior* to FDA approval, accelerated approval—promulgated by the agency as a final rule in 1992—hastened the actual approval of drugs for life-threatening diseases. It authorized approval of an NDA before the acquisition of any concrete evidence that the drug actually lengthened survival. Instead, accelerated approval was based on studies (frequently phase 2 studies) demonstrating the product's effect on an unvalidated "surrogate endpoint"—a laboratory measurement reasonably likely, but not certain, to correlate with clinical benefit.[249]

Accelerated approval was another product of the unusual alliance between AIDS activists and Republican deregulators. In 1990, to the frustration of many, AZT, a nucleoside analog, remained the only FDA-approved drug intended to suppress the HIV virus itself. The August 1990 final report of the Lasagna Committee urged the agency to "exercise its statutory and administrative flexibility to approve AIDS and cancer drugs for marketing at the earliest possible point in their development" and, in particular, to make progress "in approving drugs on the basis of surrogate endpoints."[250] Several months later, a coalition of San Francisco-based AIDS activists petitioned the FDA to quickly review NDAs for two newer

[248] Tracy Morgan interview, Oct. 12, 2012, at 52 (interview # 129 of AUOHP).

[249] 57 Fed. Reg. 58, 942, 58,958 (Dec. 11, 1992) (codified at 21 C.F.R. § 314.510).

[250] FINAL REPORT OF THE NATIONAL COMMITTEE TO REVIEW CURRENT PROCEDURES FOR APPROVAL OF NEW DRUGS FOR CANCER AND AIDS, *supra* note 152 at iii–iv.

nucleoside analogs, ddI and ddC, and consider approving them based on surrogate endpoints rather than improved survival.[251]

On October 9, 1991, before the completion of phase 2 clinical trials, the FDA approved ddI for patients not helped by AZT. The parallel-track-like program implemented by Bristol-Meyers in 1989, discussed above,[252] had made ddI available to about 23,000 patients and generated important safety data. No evidence yet existed, however, that ddI actually extended the lives of PWAs. Nonetheless, the FDA approved it "conditionally" based on preliminary results showing an increase in patients' T-4 cells (signaling a strengthening of the immune system). The agency said it would revisit the approval when the clinical trial was finished.[253] Thus was born the procedure that would soon be called "accelerated approval."

The accelerated approval of ddI changed the rules of the drug's distribution in critical ways, compared to parallel track. For example, it would now be available to all PWAs, not just those who satisfied the parallel track's protocol. Moreover, Bristol-Meyers would now be permitted to sell the drug at a profit. Under parallel track, the company had been providing ddI to patients free, foregoing the cost-recovery price the FDA might have allowed it to charge. Now, the retail price of the product would be about $2,000 per year. Accelerated approval thus gave the company a financial incentive to maximize the drug's distribution. But who would pay for the medication? Insurance drug plans rarely covered experimental treatments outside the cancer area, but they virtually always covered FDA-approved products. The day of ddI's approval, David Kessler, the FDA Commissioner, clarified that accelerated approval was no different from traditional drug approval in this respect. He "expected government and private insurers to pay for ddI like any other F.D.A.-approved drug."[254] Despite ddI's high price, it would thus be available to potentially hundreds of thousands of individuals under Medicaid and some private insurance plans. Bristol-Meyers pledged to provide ddI free to low-income PWAs who did not qualify for Medicaid. The drug's accelerated approval was thus news that both industry and patient advocates could cheer.

The deregulators within the Bush administration were pleased as well. When Bush took office, the task of overseeing systemic deregulation passed

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[251] Gina Kolata, *Petition Seeks to Speed Approval of AIDS Drugs*, N.Y. TIMES, December 21, 1990, at A31.

[252] *Supra* p. [ ].

[253] Malcolm Gladwell, *Second AIDS Drug Given Conditional Approval; FDA Allows Sale on Basis of Incomplete Tests*, WASHINGTON POST, October 10, 1991, at A4; Milt Freudenheim, *F.D.A. Approves a Second Drug, Still Being Tested, to Treat AIDS*, N.Y. TIMES, October 10, 1991, at B2.

[254] Freudenheim, *supra* note 252.

to a new body called the Council on Competitiveness, chaired by Vice President Dan Quayle.[255] By explicitly inviting lobbyists for regulated industries to suggest rules that should be amended or repealed, Quayle left little doubt that the Council was motivated by a desire to help business, not by an abstract devotion to limited government.[256] In November 1990, Quayle established, under the aegis of the Council, a Working Group on the Drug Approval Process and charged it with reviewing the Lasagna Report.[257] A year later, one month following ddI's approval, the Council endorsed the approval of drugs prior to phase 3 testing based on surrogate evidence of effectiveness, accompanied by sponsor commitments to conduct post-marketing studies.[258]

As noted previously, pharmaceutical companies were ambivalent at best about parallel track, largely because of the program's limitations on charging. By contrast, they were undoubtedly thrilled at the prospect of selling drugs for a profit earlier than usual (and with less evidence of clinical efficacy) pursuant to accelerated approval. The industry did not initially take the lead role in promoting accelerated approval, however, perhaps because it calculated that the procedure would be far less controversial if championed by those who demanded it solely for public health and humanitarian reasons.

On April 15, 1992 (the same day it issued its final parallel track policy statement), the FDA published a proposed rule establishing accelerated approval for drugs intended to treat serious or life-threatening illnesses.[259] The rule stated: "FDA may grant marketing approval for a new drug product on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely … to predict clinical benefit…. Such approval will be subject to the requirement that the applicant study the drug further … to

[255] Statement of the White House Secretary (June 15, 1990), in COUNCIL ON COMPETITIVENESS AND FDA PLANS TO ALTER THE DRUG APPROVAL PROCESS AT FDA, 176 (1992).

[256] Robert Pear, *The Federal Budget: The Overview; Mood of Compromise Prevails on Election-Year Budget*, N.Y. TIMES, January 31, 1992, at A14.

[257] Letter from Allan B. Hubbard, Executive Director, Council on Competitiveness, to David Kessler, FDA Commissioner (Nov. 19, 1990), in COUNCIL ON COMPETITIVENESS AND FDA PLANS TO ALTER THE DRUG APPROVAL PROCESS AT FDA, *supra* note 254 at 194.

[258] Council on Competitiveness Fact Sheet: Improving the Nation's Drug Approval Process (1991), http://quod.lib.umich.edu/c/cohenaids/5571095.0474.099 (last visited Nov 24, 2015).

[259] 57 Fed. Reg. 13,234 (April 15, 1992).

verify and describe its clinical benefit."[260] The proposal created expedited withdrawal procedures for drugs approved under the rule if the follow-up studies were not performed or failed to verify clinical benefit.[261]

In June 1992, even though the rule was not yet finalized, the FDA used the procedure to approve ddC, a third nucleoside analog. The agency approved the drug for combination use with AZT based on two small studies showing an increase in the number of CD4 T cells in the immune system. This time, the FDA did not even have safety data from a parallel use program—Hoffmann-La Roche, ddC's manufacturer, had refused to establish one. The company immediately announced that ddC's annual wholesale price would be $1,826.[262]

In December 1992, the FDA issued the final accelerated approval rule without significant revisions.[263]

B. TAG's Misgivings

Despite widespread satisfaction in the AIDS movement, some treatment-focused activists were uneasy about accelerated approval. As a member of the advisory committee considering ddC in 1992, Mark Harrington doubted that it had any clinical benefit. He voted in favor of accelerated approval of the drug anyway, because he felt bound to follow the majority sentiment of his community.[264] Later, as Hoffmann-La Roche failed to complete the confirmatory studies it had promised, Harrington and some of his TAG colleagues increasingly regretted his "yes" vote. These East Coast activists began to feel that "the AIDS community, in its understandable desperation, was being manipulated by industry to demand the expeditious approval of inadequately tested drugs."[265] TAG was becoming exasperated by "the access-obsession of other community activists, who no longer seemed to think drugs were worth studying once they were on the market, and yet who clamored endlessly for access to drugs in the early stages of testing."[266]

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[260] *Id.* 13240. The proposed rule also permitted accelerated approval in situations in which the agency concluded that the drug could be safely used only if subject to restrictions on its distribution or use. *Id.*

[261] *Id.* (21 C.F.R. § 314.530).

[262] Marlene Cimons, *FDA Approves AIDS Drug for Use with AZT*, LOS ANGELES TIMES, June 23, 1992, at A1; AP, *3d AIDS Drug Wins Conditional Approval*, N.Y. TIMES, June 23, 1992, at C11.

[263] 57 Fed. Reg. 58,942 (Dec. 11, 1992).

[264] Mark Harrington, *Introduction*, *in* TEN TEXTS ON SAQUINAVIR: ITS RAPID RISE AND FALL 1–5, 3 (Mark Harrington ed., 2001), http://www.treatmentactiongroup.org/publications/2001/ten-texts-saquinavir.

[265] *Id.* at 3.

[266] *Id.* at 7.

Two years later, when the advisory committee considered accelerated approval of d4T, another nucleoside analogue, Harrington's seat had been inherited by his TAG colleague Gregg Gonsalves, a thirty-year-old, HIV-positive Tufts dropout. Gonsalves voted "no" on D4T, although the committee as a whole recommended approval and the FDA followed the majority's advice.[267] Enraged by Gonsalves' vote, other AIDS activists launched vicious attacks at him and TAG. A pamphlet circulated at an ACT UP/NY meeting sarcastically urged: "JOIN TAG TODAY. Speak as a 'community representative' while destroying everything AIDS activists have fought and died for! Be a conservative nihilist and … be … self-hating and GENOCIDAL."[268]

The rancor would soon intensify. In 1994, PWAs were vesting great hope in a new class of antiviral drugs called protease inhibitors. In May, Hoffmann-La Roche announced the results of a small, short-term phase 2 trial of one of these drugs, saquinavir. The study showed that a triple combination of AZT, ddC, and saquinavir had a modestly positive effect on CD4 cell counts.[269] On June 16, four TAG members (including Harrington and Gonsalves), along with representatives of three other AIDS organizations, sent FDA Commissioner Kessler a letter pleading that the FDA *not* grant accelerated approval to saquinavir. The letter's authors explained: "[W]e believe that people with AIDS are entitled to information about new therapies that is sufficient to make necessary risk/benefit analyses regarding their treatment." Accelerated approval of saquinavir, they argued,

> would penalize people with AIDS/HIV by setting an inappropriately low standard of evidential requirements that would govern the regulation of this entire class of therapies…. Saquinavir … is not yet an appropriate candidate for an accelerated NDA because it has not been studied for safety in a broad enough patient population for a long enough time … and because the use of surrogate markers to evaluate potential efficacy … is completely untested in this class of therapies.[270]

The TAG letter further contended that accelerated approval of saquinavir would ensure that nobody would ever perform the studies

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[267] Laurie Garrett, *Battle on AIDS Drugs*, NEWSDAY, September 6, 1994, at 4; Mark Harrington, TEN TEXTS ON SAQUINAVIR 8 (2001), http://www.treatmentactiongroup.org/publications/2001/ten-texts-saquinavir.

[268] Quoted in Garrett, *supra* note 266.

[269] TAG, *ACTG 229: AZT/ddC/Saquinavir vs. AZT/Saquinavir v. AZT/ddC (May 1994)*, *in* TEN TEXTS ON SAQUINAVIR: ITS RAPID RISE AND FALL 12–13 (2001).

[270] Letter from David Barr et al. to David Kessler, FDA Commissioner (June 16, 1994), *in* TEN TEXTS ON SAQUINAVIR: ITS RAPID RISE AND FALL , 14 (Mark Harrington ed., 14-15), http://www.treatmentactiongroup.org/publications/2001/ten-texts-saquinavir.

necessary to determine whether the drug had any clinical benefit. "We have learned through difficult experience that [after approval] we cannot depend on the goodwill of pharmaceutical industry sponsors to produce the information that is necessary to make life or death treatment decisions." As an alternative to accelerated approval, the authors urged the commencement of a pre-approval 3-arm "large simple trial" (LST) comparing two doses of saquinavir to placebo in a total of 18,000 patients.[271] (An LST is a study with an unusually large sample size, broad eligibility criteria, multiple sites, and a simplified method of data collection.) This approach, they argued, would provide information on actual clinical outcomes.

The TAG representatives who signed this letter did not consult with their former comrades in ACT UP beforehand. When ACT UP's membership learned about the letter, it responded with fury. In a tempestuous weekly meeting, one member observed that accelerated approval "is something we've been fighting hard and long for. We've been *arrested* to get accelerated approval through." A female activist roared: "I am not interested in mud-wrestling with the boys. I am absolutely enraged that there are people who have appointed themselves elitist representatives and represent themselves as the single voice of this epidemic… I'm going to fight them…. You goddamn well better fight them!"[272]

C. Advisory Committee Meeting

In September 1994, the FDA Antiviral Drugs Advisory Committee tackled the question of accelerated approval. The list of witnesses at the meeting included not only FDA officials and AIDS advocates, but also two representatives of pharmaceutical companies, who, unsurprisingly, offered positive reviews of the utilization of the accelerated approval procedure on their products.[273]

As Mark Harrington recalled, the meeting was a "circus."[274] Scores of activists hooted, hollered, applauded, and harangued the participants. Strikingly, they directed their vitriol not at government bureaucrats or pharmaceutical industry officials, but at other AIDS activists—TAG members. The first day of the meeting ended with Gonsalves charging

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[271] Letter from David Barr et al. to David Kessler (June 16, 1994), in *id.* at 14–15.

[272] *How to Survive a Plague* at 1 hr., 32-34 min. A group of TAG representatives, including Harrington and Gonsalves, attended the subsequent ACT UP meeting and tried to defend their actions. *Id*.

[273] EARLY AVAILABILITY OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES, *supra* note 167 at I-145-51, 193-96 (testimony of Waijen Soo, Hoffman-LaRoche, & Andre Pernet, Abbott Laboratories),.

[274] Mark Harrington, *Access versus Answers (1996 Version)*, *in* TEN TEXTS ON SAQUINAVIR: ITS RAPID RISE AND FALL 6–11, 10 (Mark Harrington ed., 2001), http://www.treatmentactiongroup.org/publications/2001/ten-texts-saquinavir.

Martin Delaney with not "telling the truth to people with HIV" and with launching "cheap personal crap" at him and his allies."[275]

The TAG witnesses tried, with little success, to assuage their opponents' anger. They insisted that they supported the accelerated approval procedure in principle, even though they opposed its use for saquinavir. They also corrected the widespread misconception that under TAG's proposal, saquinavir would be available *only* through the controlled large simple trial, emphasizing that they supported the simultaneous establishment of a parallel track for treatment. The anti-TAG camp responded that this parallel track (which the TAG letter to Kessler unfortunately termed a "salvage protocol") would be open only to patients who met specified criteria, such as a drop of CD4 cells to grave levels. PWAs who did not meet these criteria would be forced into the LST, with a one-in-three chance of receiving a sugar pill instead of saquinavir.

The proposed use of a placebo arm in the LST was particularly infuriating to many of TAG's foes. The community had long passionately resisted the use of placebos in clinical trials for AIDS drugs.[276] Indeed, Harrington himself had once described the use of placebo controls as "a shameful legacy … of excluding people from access to experimental treatments … [which] stretches [back to] the Tuskegee syphilis experiment of the 1930s."[277] Now, TAG representatives assured their opponents that none of the participants in their proposed saquinavir LST would—like the African-American subjects in the notorious Tuskegee trial—go *untreated*. Instead, all participants would be permitted concomitantly to take any other medications they wanted (besides protease inhibitors).[278] This did not mollify the anti-TAG forces, however. Martin Delaney explained: "We just don't believe you can put people on a placebo ethically in this disease at this point, even if it's a placebo of the new agent while continuing old mono therapy arms or standard regimens."[279] Mark King, of the Atlanta mayor's Task Force on AIDS bluntly declared: "Any trial featuring a placebo is an inhumane way to treat someone counting on a potentially lifesaving drug."[280]

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[275] EARLY AVAILABILITY OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES, *supra* note 168 at 1-388–89.

[276] [Martin Delaney], *Placebos: Time to Say No*, PI PERSPECTIVE, 1988, at 1–4.

[277] TRANSCRIPT OF PROCEEDINGS, *supra* note 216 at 178 (Harrington testimony).

[278] Indeed, since the approval of AZT, FDA had prohibited placebo-only arms in AIDS trials. 53 Fed. Reg. at 41,519.

[279] EARLY AVAILABILITY OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES, *supra* note 167 at I-385 (Delaney testimony).

[280] *Id.* at I-129 (King).

In sum, TAG's foes demanded that PWAs have absolute autonomy to choose their desired treatments. They invoked the ideal of "personal choice" repeatedly, often elevating it into a quasi-constitutional principle. Brenda Freiburg, the president of a Los Angeles group called Research Access, asserted: "I firmly believe that individuals have a basic inalienable right to choose their own treatments."[281] Greg Haas of the Committee of Ten Thousand insisted that people with life-threatening illnesses have a "fundamental right" to choose their therapies, and Michael Onstott of ACT UP/San Francisco termed it an "absolute right."[282] Fred Schaich, representing various Florida AIDS groups, declared: "Our country is based on freedoms. Every PWA should be permitted the freedom to enter a clinic, request a list of AIDS treatment options to combat the HIV virus and make an individual choice."[283]

TAG and its supporters minimized the value of therapeutic choice in the absence of scientific evidence of efficacy.[284] TAG member Spencer Cox testified: "With no reliable information about treatment effects, one sometimes has to make a treatment guess. But this is not an act of reason. This is an act of desperation."[285] TAG demanded only a "right to make *rational* treatment decisions."[286] Its opponents, by contrast, insisted that desperately ill patients had a right to make therapeutic guesses. ACT UP's

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[281] EARLY AVAILABILITY OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES, *supra* note 168 at I-78.

[282] *Id.* at II-70 (Haas); *Id.* at II-109-110 (Onstott). Onstott decried the "assumption that most people with AIDS and other life-threatening illnesses are too naive, ignorant and/or desperate to make rational and informed treatment choices" as "an insidious and paternalistic assumption that many bureaucrats, physicians, politicians and even a few AIDS activists share." *Id.* 110.

[283] EARLY AVAILABILITY OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES, *supra* note 167 at II-104 (Schaich).

[284] It was unclear how much evidence of effectiveness TAG would demand before supporting accelerated approval of a drug. Although the letter to Kessler intimated that saquinavir should not be eligible for approval until *completion* of the LST, Harrington moderated this stance at the hearing: "The answers don't have to be in by the time accelerated approval occurs, but it would be useful to have some kind of confidence greater than we have now that those answers would indeed be forthcoming." *Id.* at I-291 (Harrington). This was hardly an extreme position; after all, the accelerated approval rule itself stated that postmarketing studies "would … usually be … already underway" at the time of approval. 57 Fed. Reg. at 58,958 (codified at 21 C.F.R. § 314.510). Nonetheless, TAG seemed to continue to want at least preliminary evidence prior to accelerated approval; Harrington stated that approval would be appropriate only if and when the "surrogate markers show [clinical] benefit." EARLY AVAILABILITY, *supra* note [ ] at I-293 (Harrington).

[285] EARLY AVAILABILITY OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES, *supra* note 167 at II-36 (Cox).

[286] *Id.* at II-43 (Cox) (emphasis added).

Bill Bahlman challenged TAG's Cox: "Haven't you realized from your own experience that people respond very differently from [sic] individual drugs and … that personal choices and people making decisions for themselves is paramount[?]"[287] Delaney similarly contended: "No clinical trial, no number of clinical trials will ever predict what a drug is going to do in a single individual person. … [I]n the end it is still in every individual case between the doctor and a patient a degree of try it and see what happens."[288] Some witnesses emphasized the value of hope in and of itself. For example, HIV-positive Brie Salzman of the PWA Coalition of New York told the advisory committee that regardless of whether FDA's early access programs had extended her life, they "have given me hope. And that's really, really tremendously important … certainly more important to me than any mountain of hard data."[289]

Finally, TAG and its adversaries clashed over accelerated approval's impact on research. In TAG's view, premature accelerated approval would not only allow PWAs to make uninformed choices, but also undermine the possibility of ever obtaining the evidence necessary for patients to make informed ones. The TAG camp cynically doubted that Hoffman-La Roche would ever perform the post-approval studies required to determine if saquinavir offered any clinical benefit. Citing the same company's failure to complete the trials it had promised to conduct following the accelerated approval of ddC,[290] Harrington asserted that the AIDS community could not "depend on the good will of pharmaceutical industry sponsors."[291] The TAG witnesses further argued that in the absence of voluntary compliance, FDA did not have regulatory tools sufficient to *compel* sponsors to live up to their post-approval research commitments. The threat of expedited withdrawal of the NDA was of little practical use. Recalling the ddC episode, activist Carlton Hogan observed: "Roche didn't do the trial; what were you [FDA] going to do, pull the drug and take everybody in the country off it? No."[292]

In short, TAG and its allies believed that granting accelerated approval to saquinavir would inappropriately sacrifice the public benefits of scientific knowledge on the altar of personal choice. Cox expounded: "It's easy to construct a rationale allowing patients who are presently ill to make these terrible choices. It's less easy to construct a rationale for committing

[287] *Id.* at II-45 (Bahlman).

[288] *Id.* at 1–379.

[289] *Id.* at II-17.

[290] The company's failure to complete these trials was less clearly blameworthy than TAG suggested. See discussion of ddC's post-approval clinical program at *id.* 136–52.

[291] *Id.* at I-292 (Harrington); II-36-8, 41 (Cox); II-42 (Gonsalves), II-142 (Link).

[292] *Id.* at 1–108 (Hogan).; Letter (June 16, 1994), in Harrington, *supra* note 266 at 14.

patients who will be ill in five years to the same kind of ignorance."[293] Dennis Davidson, an unaffiliated HIV-positive witness, similarly opined:

> … [T]he notion that every citizen with HIV has a right to access new and reasonably safe therapies that show some promise of efficacy, however meager or ambiguous, is certainly appealing, given the cult of individuality which the American culture has so efficiently enshrined. It almost seems patriotic.
>
> However, new and perhaps more informative clinical trials, should they be held hostage to this demand[?]….
>
> … [P]erhaps the time has come to defer hypothetical benefit often couched in terms of rights of access to a … long-term benefit for all of us.
>
> … It may be harsh to frame this debate in terms of selfish individualism versus altruism, but demanding access for individuals without ensuring a process to benefit the group, becomes just that.[294]

Although some of TAG's opponents emphasized that sufficient data could be collected in clinical trials following accelerated approval,[295] at bottom they appeared to believed that if there was an irresolvable conflict between knowledge and access, the latter should prevail. Brenda Freiburg testified: "[T]he acquisition of more meaningful data is very important, but saving lives should always be our number one priority."[296]

As the advisory committee meeting drew to a close, the head of the FDA's Division of Antiviral Drugs remarked, "I can't recall a meeting with as broad representation and as much useful public commentary."[297] He gave no hint, however, as to whose approach would ultimately triumph—that of the TAG activists, who struggled to reconcile therapeutic choice with the acquisition of medical truth, or that of their rivals within the movement, who insisted that in the face of a dreadful malady like AIDS, patient autonomy trumped all other concerns.

In the end, the two sides fought to something of a draw. TAG's intervention doubtless had some impact. Even before the hearing had commenced, Hoffmann-La Roche had agreed to postpone its request for accelerated approval of saquinavir until the company performed an interim analysis of surrogate endpoint data from an ongoing phase III trial.[298] TAG would take credit for this delay, as well as for the company's establishment of a parallel track program to accompany the trial.[299] Nevertheless, the FDA

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[293] EARLY AVAILABILITY OF DRUGS FOR SERIOUS OR LIFE-THREATENING DISEASES, *supra* note 167 at II-36 (Cox).

[294] *Id.* at I-123-24 (Davidson).

[295] *Id.* at I-377 (Delaney).

[296] *Id.* at I-75 (Freiburg).

[297] *Id.* at II-313-13 (Feigal).

[298] *Id.* at I-154 (Soo).

[299] Harrington, *supra* note 266 at 10, 25.

did not otherwise embrace TAG's proposal. The agency granted saquinavir accelerated approval on December 7, 1995, fifteen months after the hearing, without demanding the commencement of an LST, let alone the presentation of data suggesting the drug's clinical efficacy.[300] Spencer Cox of TAG ascribed this action to "Corporate Cynicism, Savvy Schmoozing, and Relentless PR."[301]

CONCLUSION: LEGACY

By the turn of the millennium, the AIDS movement lost much of its vitality and visibility. Although internal divisions probably contributed to this decline, the primary reason was a much happier one: in 1996 and 1997, the FDA approved three additional protease inhibitors, all superior to saquinavir. These drugs became essential components in the cocktail therapies that made AIDS what it is for many patients today—a manageable chronic disease.[302]

Considered as a whole, the AIDS movement's FDA campaign was remarkably successful at instilling its shared goals and assumptions into America's "drug constitution." In their analysis of "administrative constitutionalism," Eskridge and Ferejohn emphasize that agencies' norm-generating actions are not the final word, but rather "trial balloons" subject to embrace or veto by Congress and other government actors.[303] In accordance with this model, the impact of AIDS activism is now clearly visible in the FDCA itself. The Food and Drug Administration Modernization Act of 1997 (FDAMA) added FDCA § 506, which expedites the approval of drugs for serious and life-threatening conditions.[304] This section partly codifies the FDA's 1988 Subpart E regulations (under the name "Fast Track") and also includes a liberalized version of the 1992 Accelerated Approval rule.[305] In the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), Congress revised section 506 to expand the eligibility for and advantages of Fast Track, to create a new expedited approval mechanism called "Breakthrough Therapy," and to grant

[300] 1995.12.07: FDA Approves First Protease Inhibitor Drug for Treatment of HIV, , http://archive.hhs.gov/news/press/1995pres/951207.html (last visited Oct 22, 2015).

[301] Harrington, *supra* note 245 at 29.

[302] These drugs were Norvir (ritonavir) (1996), Crixivan (indinavir)(1996), and Viracept (nelfinavir) (1997).

[303] ESKRIDGE AND FEREJOHN, *supra* note 9 at 33.

[304] Pub. L. No. 105-115, § 112, 111 Stat. 2296, 2309-10 (1997) (codified at 21 U.S.C. § 356).

[305] FDCA §506, 21 U.S.C. § 356.

the FDA greater flexibility and discretion to use accelerated approval for drugs intended to treat serious conditions.[306]

In addition, the FDCA now explicitly allows pre-approval treatment access. Section 561, also added by FDAMA in 1997, codifies the FDA's 1987 treatment IND rule as well the agency's longtime practice of granting access to individual patients.[307] In 2009, the agency revised the treatment IND rule itself to state that the evidence necessary to support widespread use of an investigational therapy for an immediately life-threatening disease will "ordinarily consist of clinical data from phase 3 or phase 2 trials, *but could be based on more preliminary clinical evidence*."[308] This regulation thus now effectively incorporates parallel track and its lower evidentiary standard into the treatment IND regime.

The AIDS community also forged a widely-used model for direct involvement in FDA decision-making. Today, groups representing people with all sorts of diseases regularly seek to sway FDA drug approval decisions. Some of these organizations receive funding from the pharmaceutical industry, but many do not.[309] Advisory committee meetings are frequently crowded with patients, some of whom offer impassioned testimony. Moreover, thanks to the AIDS movement's efforts, patient representatives are now entrenched in the advisory committees themselves. In 1991, in response to demands of AIDS advocates, the FDA created a position for a Patient Representative on the Antiviral Drugs Advisory Committee for HIV.[310] Cancer patient groups soon requested similar representation. In 1996, the Clinton Administration provided that each FDA advisory committee reviewing a cancer-related therapy should include a patient representative "with experience in the specific malignancy" at issue.[311] Shortly afterward, the FDA announced that these representatives

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[306] Food and Drug Administration Safety and Innovation Act (FDASIA), Pub. L. No. 112-144, § 901, 902, 126 Stat. 993, 1082-88 (2012), codified at FDCA § 506, 21 U.S.C. § 356.

[307] Pub. L. No. 105-115, § 112, 111 Stat. 2296, 2365-67 (1997) (codified at 21 U.S.C. § 360bbb).

[308] 74 Fed. Reg. 40,900, 40,910-11, 40,945 (August 13, 2009); 21 C.F.R. 312.320(a)(3)(ii) (emphasis added).

[309] Susanna L. Rose, *Patient Advocacy Organizations: Institutional Conflicts of Interest, Trust, and Trustworthiness*, 41 J. LAW MED. ETHICS 680, 681 (2013) (between 30 and 71 percent of patient advocacy organizations receive funding from the pharmaceutical industry).

[310] U.S. Food & Drug Admin., Patient Representative Program, FDA.Gov, http://www.fda.gov/downloads/forconsumers/byaudience/forpatientadvocates/patientinvolvement/ucm14.

[311] Bill Clinton & Al Gore, Reinventing the Regulation of Cancer Drugs: Accelerating Approval and Expanding Access 9 (1996),

would have full voting privileges.[312] Now, patient representatives are voting members of a broad array of advisory committees considering drugs for many diseases.

The Food and Drug Administration Safety and Innovation Act of 2012 demonstrates how the patient-centered ethos of the AIDS movement continues to shape federal drug regulation. FDASIA added a new section 569C to the FDCA, titled "Patient Participation in Medical Product Discussion."[313] This provision obligates the FDA to "develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions."[314] To this end, it specifically instructs the FDA to encourage the participation of patient representatives, as "special government employees," in agency meetings with the sponsors of drug, device, and biologic applications.[315]

Another portion of FDASIA, the Prescription Drug User Fee Act (PDUFA V), binds the FDA to detailed performance goals for 2013 through 2017, set forth in a separate document.[316] These goals, which are part of a broader agency initiative called "Patient-Focused Drug Development," promise to move patients ever closer to the center of federal drug regulation.[317] The FDA commits not only to increasing its use of patient representatives in regulatory discussions about specific products, but also to holding four meetings per year with patient advocates regarding various disease areas—a number exceeded in both 2014 and 2015.[318]

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http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4191B1_01_03-Reinvent-Cancer-Drugs.pdf

[312] *Historical Overview Information—Cancer Patient Representative Program*, FDA Website, http://www.fda.gov/forconsumers/byaudience/forpatientadvocates/cancerliaisonprogram/ucm147019.htm

[313] FDASIA § 1137, 21 U.S.C. § 360bbb-8c (2012).

[314] FDCA 569C(a) (2012).

[315] FDCA 569C(a)(1) (2012).

[316] FDASIA § 101(b) (2012) (referring to goals identified in letters from the Secretary of Health and Human Services to the Chairmen of the relevant House and Senate Committees); U.S. Food & Drug Admin., PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 Through 2017, FDA.gov, http://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM270412.pdf (last visited May 14, 2014).

[317] U.S. Food & Drug Admin., Webinar: Background on FDA and Patient-Focused Drug Development, FDA.gov, http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm349133.htm (last visited May 13, 2014).

[318] http://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/ucm347317.htm

These initiatives enhancing patient involvement in drug development and approval are linked to a general understanding that victims of serious diseases generally demand freedom to assume greater risks for more uncertain benefits. As the FDA explained when announcing the commencement of its regular meetings with patient advocates: "A key part of regulatory decisionmaking is establishing the context in which the particular decision is made…. Patients who live with a disease have a direct stake in the outcome of the review process and are in a unique position to contribute to weighing benefit-risk considerations that can occur throughout the medical product development process.[319] This reassessment of the risk-benefit calculation, and who should make it, is also a legacy of the AIDS activists. Moreover, due largely to the AIDS movement's efforts, the FDA's view of its very mission has evolved. It now embraces the task not only of *protecting* the public health by preventing the sale of dangerous products, but also of *enhancing* the public health by ensuring access to potentially useful remedies.[320] Congress codified this expanded mission in the FDCA itself in 1997.[321]

To what extent have these developments actually led to the earlier availability of drugs for severely ill individuals? When answering this question, we must distinguish between post-approval and pre-approval access. The AIDS activists' impact is more obvious with respect to the former, doubtless in part because the pharmaceutical industry itself is fond of accelerated approval (and the profits it generates). Accelerated approval has now been an effective program for almost a quarter of a century. In the years immediately following the mechanism's 1992 creation, the FDA used it almost exclusively for AIDS therapies, including saquinavir and the three additional protease inhibitors mentioned above.[322] Starting in the late 1990s, under pressure from patient groups, the agency began using the procedure more frequently for drugs for cancer and other diseases. Today, more than 90 drugs have been approved under the accelerated approval system, approximately one-third for AIDS, one-third for cancer, and one-third for

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[319] 77 Fed. Reg. 58,848, 58,849 (Sept. 24, 2012).

[320] PETER ARNO FEIDEN, KARYN L., AGAINST THE ODDS: THE STORY OF AIDS DRUG DEVELOPMENT, POLITICS AND PROFITS 109 (1992).

[321] FDAMA, Pub. L. No. 105-115 (1997) added section 903(b) (now 1003(b)) to the FDCA, stating that FDA's mission is, first, to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner," and, second, to "protect the public health by ensuring that" these products are safe and effective. *See* FDCA § 1003(b), 21 U.S.C. § 393(b) (2006).

[322] By March 1997, the agency had granted accelerated approval to about a dozen AIDS-related drugs.

other illnesses.[323] The activists' influence (in conjunction with industry's) can also been seen in the common use and general success of other programs designed to speed the development, review, and approval of drugs addressing serious unmet needs, including the "fast track" and new "breakthrough therapy" designations.[324]

TAG's calls for caution have also had a permanent impact, however. The FDA has never used accelerated approval as frequently as the more fervent advocates of the procedure would like. As early as 1996, an article observed that TAG and its allies have "found the FDA to be an attentive audience" to their objections about "flooding the market with unproven 'remedies.'"[325] In the view of one scholar, whenever the FDA has yielded to demands to use accelerated approval more liberally, it has subsequently "revert[ed] to its cautious ways" under relentless pressure from the clinical research community, traditional consumer groups, and some legislators.[326] In 2012, a frustrated Congress amended section 506 of the FDCA to broaden the availability of accelerated approval and passed uncodified "Findings" and a "Sense of Congress" encouraging the FDA to employ the procedure more often.[327]

Apart from accelerated approval, the greater attention the AIDS movement brought to the "drug lag" contributed to a more fundamental change that dramatically increased the speed with which the agency reviews all drug applications. The Prescription Drug User Fee Act of 1992 ("PDUFA") established a system under which drug applicants pay user fees to the FDA to support the IND/NDA process, while the agency commits to

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[323] Office of the Commissioner, REPORTS - WHITE PAPER: FDA AND ACCELERATING THE DEVELOPMENT OF THE NEW PHARMACEUTICAL THERAPIES, http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm439082.htm (last visited Oct 27, 2015).

[324] Another FDA policy to expedite consideration of important new medicines is called Priority Review. See CDER Manual of Policies and Procedures 6020.3: Priority Review Policy (Apr. 22, 1996).

[325] Matthew Lovell, *Second Thoughts: Do the FDA's Responses to a Fatal Drug Trial and the AIDS Activist Community's Doubts About Early Access to Drugs Hint at a Shift in Basic FDA Policy?*, 51 FOOD DRUG LAW J. 273–294, 274 (1996); See also Sheila R. Shulman & Brown, Jeffrey S., *The Food and Drug Administration's Early Access and Fast-Track Approval Initiatives: How Have They Worked?*, 50 FOOD DRUG LAW J. 503–532, 516 (1995) (stating that under pressure from AIDS patients, FDA's emphasis "is less on speeding the availability of new compounds than it is on establishing therapeutic value).

[326] Jacob W. Stahl, A HISTORY OF ACCELERATED APPROVAL: OVERCOMING THE FDA'S BUREAUCRATIC BARRIERS IN ORDER TO EXPEDITE DESPERATELY NEEDED DRUGS TO CRITICALLY ILL PATIENTS 2 (2005), https://dash.harvard.edu/handle/1/8852155.

[327] FDA SAFETY AND INNOVATION ACT, 126 Stat. 993-1132 1083–86 (2012) (Findings; Sense of Congress, and Amendment of FD&C Act 506).

improved performance goals in the operation of this process.[328] Congress enacted this law because of FDA complaints about budget pressures and industry frustration with NDA backlogs, but also, as Representative Henry Waxman emphasized, because "the public will benefit by getting access to lifesaving drugs sooner."[329] During hearings on PDUFA reauthorization in 1997, Jeff Bloom of the AIDS group Project Inform, appearing on behalf of a coalition of over a hundred organizations for patients with serious and life-threatening diseases, declared: "[T]he single most important step Congress can take to help patients is to move quickly and revise and extend [PDUFA]."[330] With such fervent support from patient groups, PDUFA was renewed that year and three subsequent times at five-year intervals.[331] The implementation of user fees has slashed the median number of months FDA takes to review and approve NDAs for new molecular entity drugs from 23.0 months in 1993 to 9.8 months in 2012.[332]

Whether the AIDS movement has helped make NDA approval easier, as well as faster, is less clear. But the FDA now must deal with "freedom of choice" rhetoric whenever it is reviewing the NDA for a product intended to treat an otherwise incurable condition. And in a few prominent instances, the patient choice argument has prevailed. For example, in response to protests by sufferers of irritable bowel syndrome, the FDA in 2002 permitted the return to the market of Lotronex®, a drug earlier withdrawn because of occasional severe side effects.[333] In September 2016, under fierce pressure from patient advocates, FDA granted accelerated approval to a treatment for Duchenne muscular dystrophy, despite the vociferous objections of agency staffers and a negative advisory committee vote.[334]

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[328] Pub. L. No. 102-571, 106 Stat. 4491-4505 (1992).

[329] 138 CONG. REC., H9098 (daily ed. Sept. 22, 1992). *See generally* Bruce N. Kuhlik, *Industry Funding of Improvements in the FDA's New Drug Approval Process: The Prescription Drug User Fee Act of 1992*, FOOD DRUG LAW J. 483–503, 483–91 (1992).

[330] *Reauthorization of the Prescription Drug User Fee Act and FDA Reform: Hearing Before the Subcomm. on Health & Environment of the H. Comm. on Commerce*, 105th Cong. 103 (1997) (statement of Jeff Bloom).

[331] FDA Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (1997); Prescription Drug User Fee Amendments of 2002, Pub. L. No. 107-188, 116 Stat. 594, 687-694 (2002); FDA Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823, 825-42; FDA Safety and Innovation Act of 2012, Pub. L. No. 112-144, 126 Stat. 993, 996-1008 (2012).

[332] HUTT, MERRILL, AND GROSSMAN, *supra* note 108 at 749–50.

[333] *See* Denise Grady, *U.S. Lets Drug Tied to Deaths Back on Market*, N.Y. TIMES, June 8, 2002, http://www.nytimes.com/2002/06/08/us/us-lets-drug-tied-to-deaths-back-on-market.html.

[334] Sabrina Tavernise, *FDA Clears Debated Drug That Patients Lobbied For*, N.Y. TIMES, Sept. 19, 2016, at B1.

The AIDS movement also had a significant permanent impact on the availability of *unapproved* drugs. Between 2009 and 2014, the FDA cleared more than 99 percent of the expanded access INDs and protocols it received, for a total of nearly 6,000.[335] While impressive, this number is not as dramatic as it might appear at first glance, however. More than 96 percent of the expanded access INDs and protocols that the FDA has recently permitted have been for *single* patients. The bulk of the others have been for "intermediate-size patient populations." In 2013-14, for example, the FDA cleared only 12 full-size treatment INDs and protocols.[336] A dozen major early access programs per year far exceeds the number available prior to the late 1980s, but it is fewer than one might expect in light of patient demands.

The number of treatment INDs is not limited by any hesitation on the part of the agency to permit them. To the contrary; during the same period, the FDA *received* only 12 requests for such programs.[337] The true constraint is thus a lack of industry interest in pursuing treatment INDs. But the FDA itself plays a central role in dampening corporate participation in early access programs through its severe restrictions on charging for unapproved drugs.

In 2003, the cancer-focused patient advocacy group Abigail Alliance filed a suit alleging that the FDA's charging restrictions and its evidentiary standard for treatment use of investigational drugs violated patients' substantive due process rights under the 5th Amendment to the U.S. Constitution. The organization contended that terminally ill patients have a right to purchase experimental therapies after the completion of phase 1 safety trials, and to do so at a price that allows manufacturers to profit from the sale. The U.S. Court of Appeals for the D.C. Circuit rejected the claim.[338] The current version of the FDA's treatment IND regulations, revised in 2009, continues to mandate that sponsors obtain agency approval

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[335] FDA website, "Expanded Access INDs and Protocols 2009-14," http://www.fda.gov/newsevents/publichealthfocus/expandedaccesscompassionateuse/ucm443572.htm

[336] http://www.fda.gov/newsevents/publichealthfocus/expandedaccesscompassionateuse/ucm443572.htm

[337] http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/INDActivityReports/UCM430188.pdf

[338] *Abigail Alliance for Better Access to Developmental Drugs v. Crawford*, 495 F.3d 695, 697 (D.C. Cir. 2007) (en banc). Abigail Alliance is named after Abigail Burroughs, who died of cancer at age 21 in 2001 after failing to gain access to two experimental drugs that FDA later approved. I will discuss this case extensively in my forthcoming book, YOU CAN CHOOSE YOUR MEDICINE: FREEDOM OF THERAPEUTIC CHOICE IN AMERICAN HISTORY AND LAW.

before charging for investigational drugs and to limit any permitted charges to the amount required for the recovery of direct costs. Moreover, the 2009 amendments to the rule clarified an earlier ambiguity by specifying that recoverable direct costs do *not* include the expenses of research and development.[339]

The agency's stringent charging policy is intended to preserve sponsors' financial incentive to complete their clinical research and apply for NDA approval.[340] The rule's effect—combined with other factors, such as drug supply challenges, tort liability exposure, and the possibility that treatment access will slow down or derail the NDA approval process—is to reduce the pharmaceutical industry's interest in participating in large expanded access programs.[341] As a practical matter, therefore, the government's demand for data still constrains therapeutic choice in many instances. And this situation is doubtless agreeable to TAG members, who today describe themselves as "science-based treatment activists working to expand and accelerate vital research …."[342]

The country's amended "drug constitution" thus continues to reflect TAG's reformist approach rather than a more radical unraveling of FDA gatekeeping power. But when TAG's founders view the current activities and demands of many patient activists and their libertarian and industry allies, they must sometimes fear that when they stormed the FDA in 1988, they, like Dr. Frankenstein, created a monster they can no longer control.

In December 2016, with the overwhelming support of both industry and patient advocacy groups, Congress passed and President Obama signed the 21st Century Cures Act, a law intended to "accelerate the discovery, development, and delivery of" medical products.[343] Along with providing a

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[339] 21 C.F.R. § 312.8(c).

[340] 74 Fed. Reg. 40, 872, 40,883-85 (August 13, 2009) (codifed at 21 C.F.R. Part 312). The rule states that a sponsor who wishes to charge for expanded access must provide FDA with "reasonable assurance that charging will not interfere with developing the drug for marketing approval," including "[e]vidence of sufficient enrollment in any ongoing clinical trial(s)" and "[e]vidence of adequate progress in the development of the drug for marketing approval." 21 C.F.R. § 312.8(c).

[341] Benjamin R. Rossen, *FDA's Proposed Regulations to Expand Acccess to Investigational Drugs for Treatment Use*, 64 FOOD DRUG LAW J. 183–224 (2009); Jerome Groopman, *The Right to a Trial: Should Dying Patients Have Access to Experimental Drugs?*, NEW YORKER, 2006.

[342] Treatment Action Group Mission Statement, available at http://www.treatmentactiongroup.org/mission

[343] http://docs.house.gov/billsthisweek/20161128/CPRT-114-HPRT-RU00-SAHR34.pdf . Over 250 patient groups joined industry in supporting the initial version of the bill in 2015. Letter from 251 patient organizations to leadership of House Committee on Energy and Commerce (June 18, 2015), available at

generous $4.8 billion increase in funding for the National Institutes of Health,[344] the statute extensively amends the FDCA. Many of the law's FDA-related provisions reflect the spirit of AIDS activism in the late-1980s and early-1990s. For example, 21st Century Cures requires the agency to issue guidance regarding the use of "patient experience data" in regulatory decisionmaking, including ("if appropriate") their use as part of the risk-benefit assessment in drug approval.[345] It directs the agency to programmatically evaluate and issue guidance concerning the potential use of "real world evidence" (that is, data "from sources other than randomized clinical trials") to support the approval of new indications for existing drugs.[346] The new law also requires manufacturers to publicly declare their expanded access policies with respect to drugs for serious conditions.[347]

On June 11, 2015, TAG's Gregg Gonsalves and Mark Harrington, along with former FDA Commissioner David Kessler, wrote an op-ed piece for the *New York Times* blasting an earlier version of the legislation, which was largely similar to the bill that later passed. Their column warned that the law threatened to "lower the standards for approval of many medical products" and thus undermine "the essential responsibility that drug companies have to patients and the American public: … to show that new drugs [are] safe and effective under the usual criteria required by the agency."[348] Their protests went largely unheeded, however. The 21st Century Act ultimately passed by overwhelming margins in both the House (392-26) and Senate (94-5).

Most of the drug provisions in the 21st Century Cures Act are soft mandates; they encourage the agency to consider, rather require it to make, significant changes to the drug approval process. Moreover, the law limits the possible extent of these changes in important ways.[349] The statute is thus a mere incremental measure compared to what is being attempted at the state level. Since 2014, thirty-one states have enacted "right to try" laws

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http://energycommerce.house.gov/sites/republicans.energycommerce.house.gov/files/114/Letters/251PatientGroupsSupportCures.pdf

[344] *Id.* § 1001.This funding was an important reason why the law attracted the support of many Democrats skeptical about its other provisions.

[345] *Id.* § 3002.

[346] *Id.* § 3022.

[347] *Id.* § 3032.

[348] Gregg Gonsalves Harrington Mark & David A. Kessler, *Don't Weaken the F.D.A.'s Drug Approval Process*, THE N.Y. TIMES, June 11, 2015, http://www.nytimes.com/2015/06/11/opinion/dont-weaken-the-fdas-drug-approval-process.html (last visited Oct 30, 2015).

[349] For example, the "real world evidence" section clearly states that it does not alter the current standard of evidence for drug approval, "including the substantial evidence standard" in section 505(d) of the FDCA. § 3022.

based on a model bill disseminated by the libertarian Goldwater Institute.[350] These statutes—which are almost certainly preempted by federal law—essentially codify the remedy Abigail Alliance sought unsuccessfully in court; that is, they allow physicians caring for terminal patients with no treatment alternatives to prescribe, and companies to charge for, unapproved drugs that have cleared phase I trials.[351]

The Goldwater Institute has ties to the American Legislative Exchange Council (ALEC), a pro-business organization that exploits the "low policy capacity" of busy, part-time state lawmakers by providing them with model bills and supportive materials.[352] The proliferation of state "right to try" laws is thus, in and of itself, a dubious measure of public enthusiasm for such measures. In 2014, however, no less than 78.4 percent of Arizona voters supported such a law when it was put to a statewide referendum.[353] Moreover, in September 2016 California Governor Jerry Brown, a liberal Democrat, signed bipartisan "right to try" legislation in that state. Such events suggest that a broad swath of Americans remains powerfully devoted to the idea of therapeutic choice for desperately ill individuals.

Gregg Gonsalves has publicly condemned the state "right to try" laws.[354] In a 2014 letter to the *Washington Post*, he explained:

> Two decades ago, [AIDS activists] worked closely with the Food and Drug Administration to streamline access to new medications, but we learned quickly that, as patients, we needed more than access; we needed answers about what these new drugs were doing in our bodies. Unfortunately,

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[350] Thomas M. Burton, *White House Backs Drug Law for Terminally Ill Patients*, WALL ST. J., Feb. 8, 2017, at A3; Goldwater Institute Right to try Model Legislation, available at http://scienceblogs.com/insolence/files/2014/10/GoldwaterInstituteRighttoTryModel.pdf. *See also* Rebecca Dresser, *Symposium: Science Challenges for Law and Policy: The "Right to Try" Investigational Drugs: Science and Stories in the Access Debate*, 93 TEX. LAW REV. 1631 (2015); Paul Howard, *Hail Mary Medicine (reviewing Darcy Olsen, The Right to Try (2014))*, WALL STREET JOURNAL, November 13, 2015, http://www.wsj.com/articles/hail-mary-medicine-1447375941 (last visited Nov 18, 2015).

[351] Some of the laws would also immunize physicians and drug companies from tort liability.

[352] Alexander Hertel-Fernandez, *Who Passes Business's 'Model Bills'? Policy Capacity and Corporate Influence in U.S. State Politics*, 12 PERSPECTIVES ON POLITICS 582, 583, 584 (2014). On the Goldwater Institute's links to ALEC, see A REPORTER'S GUIDE TO THE GOLDWATER INSTITUTE: WHAT CITIZENS, POLICYMAKERS,, AND REPORTERS SHOULD KNOW ([2013]).

[353] Arizona Terminal Patients' Right to Try Referendum, Prop. 303 (2014). Results available at https://ballotpedia.org/Arizona_Terminal_Patients'_Right_to_Try_Referendum,_Proposition_303_%282014%29

[354] Matthew Perrone, *Former FDA Foe Now is in Its Corner*, BOSTON GLOBE, August 12, 2014, at B7.

> conservative think tanks took advantage of desperate patients to push their own agenda—deregulation of the FDA, weakening the agency's ability to vet new agents and give us the very answers we required.
>
> History is repeating itself with right to try laws.[355]

Gonsalves' warning has had little if any effect, however, in slowing the wave of state legislation.

Does the proliferation of "right to try" statutes augur a further, dramatic liberalizing of the country's federal "drug constitution"? A truer test will occur as Congress considers federal "right to try" legislation.[356] Unlike the preempted state laws, a federal statute—depending on how it is framed—could have immense practical implications. President Donald Trump and Vice President Mike Pence have expressed support for such a law.[357] Following the opening of the 115th Congress in January 2017, "right to try" bills were quickly introduced in both the Senate and the House of Representatives.[358] These bills are ambiguous with respect to manufacturers' authority to charge for experimental treatments. The success and details of any federal "right to try" law will hinge largely on American citizens' awareness of the destructive effect that the sale of unapproved drugs could have on the clinical research enterprise.[360] Americans value their medical freedom, but they presumably value the advance of medical knowledge, as well. They might be willing to curb the former to extent necessary to ensure the latter. But perhaps not. The very fact that this is a close question is another legacy of the AIDS movement of the late 1980s and early 1990s.

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[355] Gregg Gonsalves, Letter to the Editor, *Going Around FDA Will Not Serve Patients' Interests*, WASH. POST, May 21, 2014, at A14.

[356] Such bills have periodically appeared—and failed—since the mid-1990s. *See, e.g.*, Terminally Ill Access to Treatment Act of 1996, H.R. 3149, 104th Cong. (1996); Compassionate Freedom of Choice Act of 2012, H.R. 6342, 112th Cong. (2012); Right to Try Act of 2015, H.R. 3012, 114th Cong. (2015).

[357] Thomas M. Burton, *White House Backs Drug Law for Terminally Ill Patients*, WALL ST. J., Feb. 8, 2017, at A3.

[358] Trickett Wendler Right to Tray Act of 2017, S. 204, 115th Cong. (2017) (introduced Jan. 24, 2017); Right to Try Act of 2017, H.R. 878, 115th Cong. (2017) (introduced Feb. 6, 2017).

[360] The state "right to try" measures generally mandate that the drug in question "remain under investigation in a clinical trial," but this requirement falls well short of ensuring that drug sponsors are vigorously pursuing a complete clinical research program and ultimate FDA approval.