

AIDS
ACTIVISTS
SHOWED US
THAT EVEN UNDER
THE MOST

BACK TO **BASICS**

HIV/AIDS ADVOCACY AS A MODEL FOR CATALYZING CHANGE

DIFFICULT
CIRCUMSTANCES
IT IS POSSIBLE TO
ACHIEVE
CHANGE

Working on this project was a labor of love for many people. We saw it as a unique opportunity to honor the contributions of so many gifted activists, and to offer up an analysis of the elements of the HIV/AIDS model so that those impacted by chronic and debilitating diseases other than HIV/AIDS could learn from it. From *HCM Strategists*, we'd like to thank Ronnie Tepp, Jeff Callis, and Terrell Halaska, and from *FasterCures*, we'd like to thank Cecilia Arradaza and Karen Rogers. Additionally, we'd like to thank Todd Olszewski. Of course, the paper is based on the

interviews with everyone who deserves our thanks and credit for their time but, more importantly, for their contributions. We also spoke to four other advocates: Peter Bell, of *Autism Speaks*; Susan Love, M.D., of the *Dr. Susan Love Research Foundation*; Mary Richards of the *Alzheimer's Association*; and Elizabeth Thompson of *Susan G. Komen for the Cure*.

We look forward to getting back to basics with all of our fellow advocates and catalyzing change.

—Michael Manganiello, *HCM Strategists*

—Margaret Anderson, *FasterCures*

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THE MOVEMENT

Change in the medical research paradigm

June 2011 marks the 30th anniversary of the discovery of HIV, the virus that causes AIDS. When the June 5, 1981 report by the U.S. Centers for Disease Control and Prevention (CDC) of the first five cases of AIDS was published,¹ it wasn't yet known that this would ultimately become a global pandemic. Today, 33.3 million people worldwide are living with HIV, and 30 million have died from AIDS.² Clearly, much has been accomplished to curb its spread and manage the disease.

People affected by HIV ultimately rallied together and created an advocacy movement that demanded change and got results. As a result of the efforts of the HIV/AIDS activists in the United States, HIV/AIDS has gone from being a death sentence to a chronic, manageable illness as long as access to medicines following diagnosis is assured. This movement fundamentally changed the medical research paradigm.

It changed how research is conducted, how drugs are approved, and how patients engage with all areas of the federal government, and even with the private sector.

Today, there are resources for research, treatment options, prevention efforts, federal care programs, and international efforts to ensure prevention and care are global priorities:

- The U.S. spends approximately \$3 billion in public funds each year on medical research for the treatment and cure of HIV/AIDS.³
- According to the U.S. Food and Drug Administration (FDA), there are now 33 drugs in seven classes developed and distributed by the 10 largest pharmaceutical companies in the world for the treatment of the disease.⁴
- According to the Centers for Disease Control and Prevention, in the U.S., investments in HIV prevention have paid off. The rate of new HIV infections has slowed from more than 150,000 in the mid-1980s to 55,000-58,500 per year now.⁵
- Congress reauthorized the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act in 2009

and appropriated \$2.2 billion for what is the largest federally funded program for people living with HIV/AIDS in the U.S. The original Ryan White Act was enacted in August 1990, and there have been four reauthorizations of this Act.⁶

- On the international front, the U.S. launched the largest commitment by any nation to combat a single disease in human history, creating the President's Emergency Plan for AIDS Relief (PEPFAR) in 2003.⁷

And while the problem is far from solved, and there is still an enormous amount of work ahead, people with HIV/AIDS are alive today because of these advances.

There is a vast archive of information documenting the HIV/AIDS advocacy movement. But there isn't a recent analysis of the tactics and strategies employed by the activists as it impacts medical research, to see whether it could be effective today.

Over the past several months, *FasterCures* and HCM Strategists conducted interviews with activists who started the movement, scientists responsible for directing the research, and federal officials who had power at both the Congressional and federal agency

CHANGE IS

levels to fund and change policy. This paper discusses — from the perspective of those interviewed — the components of the activists' advocacy model and the tactics and strategies they used to achieve success in their efforts. It focuses on the early efforts geared toward the federal agencies and policy process, and does not delve into the specifics of how HIV/AIDS activists engaged with the pharmaceutical industry. Perhaps of greatest interest to organizations looking to catalyze change today, this paper suggests how this model is relevant and provides a roadmap for approaching current challenges.

What struck us most was the power of the movement as a whole. The combination of the incredible force of each element and the drive behind every activist resulted in a movement that redefined not just the medical research paradigm, but also our national priorities.^{8,9,10}

The successes of the HIV/AIDS advocacy movement were the result of a unique moment in time when the illness and death of thousands of people catalyzed action. Despite the unique social and environmental circumstances that led to this perfect storm, this period of history provides a roadmap that is instructive for advocates today. It also provides hope and shows what is possible even in the face of seemingly insurmountable odds.

Change is possible. But in order to create change, the focused voices of advocates must be heard through the din. Individuals and organizations must do the hard work of becoming ready to question the status quo, and be smart enough to present well-founded alternatives. Strong leaders in government must pave the path and prepare to stay the course. Specific strategies with clear goals must be established in order to hold people accountable.

POSSIBLE



THE HISTORY 1981 - 2003



ACTIVIST ACTIONS

1981

JUNE 5, 1981

CDC reports first cases of rare pneumonia in young gay men in the June 5 MMWR, later determined to be AIDS. This marks the official beginning of the HIV/AIDS epidemic

1982

- CDC establishes the term Acquired Immune Deficiency Syndrome (AIDS)
- First U.S. Congressional hearings held on HIV/AIDS

> **Gay Men's Health Crisis established in New York City**

1983

- The Orphan Drug Act signed into law
- CDC adds female sexual partners of men with AIDS as risk group

> **"The Denver Principles" are issued**

1984

- Dr. Robert Gallo identifies HIV as the cause of AIDS

1985

- First International AIDS Conference held in Atlanta.

> **Ryan White is barred from school**

> **American Foundation for AIDS Research (amfAR) is founded**

> **Project Inform is founded**

1986

- President Reagan first mentions AIDS in public
- AZT begins clinical trials
- "Surgeon General's Report on AIDS" calls for education and condom use
- National Academy of Sciences criticizes U.S. response to AIDS; calls for \$2 billion investment
- Institute of Medicine calls for creation of National Commission on AIDS

1987

- First antiretroviral drug - Zidovudine or AZT - approved by FDA
- President Reagan makes first public speech about AIDS
- FDA establishes Treatment Investigational New Drugs (IND), which accelerates drug approval by two to three years
- NIAID established the AIDS Clinical Trials Group (ACTG)

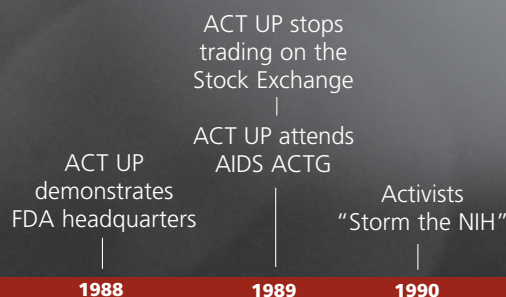
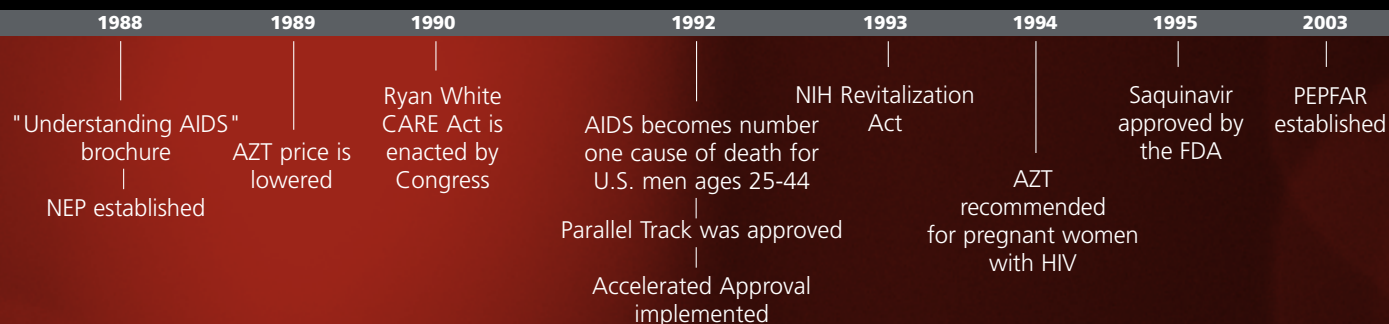
> **AIDS Coalition to Unleash Power (ACT UP) established in New York**

1988

- U.S. Surgeon General and CDC mail brochure, "Understanding AIDS," to all U.S. households; first and only national mailing of its kind

> **ACT UP demonstrates at FDA headquarters in protest of slow pace of drug approval process**

- First comprehensive needle exchange program (NEP) established in North America



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FDA. 2009. "HIV/AIDS Historical Timeline 1981-1990," <http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/HIVandAIDSActivities/ucm151074.htm>, accessed June 7, 2011.

The Henry J. Kaiser Family Foundation. 2001. "The Global HIV/AIDS Timeline," <http://www.kff.org/hivaids/timeline/hivtimeline.cfm>, accessed June 7, 2011.

1989

- Fifth International Conference on AIDS in Montreal
- > ACT UP demonstrates, calling for a significant change in AIDS treatment research
- > ACT UP members invited to discuss Parallel Track with Anthony S. Fauci, M.D.
- Fauci endorses Parallel Track policy
- > ACT UP stops trading on the Stock Exchange floor
- > AIDS activists protest at U.S. headquarters of Burroughs Wellcome
- Burroughs Wellcome lowers the price of AZT
- Ganciclovir approved by FDA for treatment of CMV retinitis in patients with AIDS
- > ACT UP members attend AIDS Clinical Trials Group (ACTG) meeting

1990

- 6th International AIDS Conference, San Francisco, CA. **To protest U.S. immigration policy, domestic and international non-governmental groups boycott the conference. Last international AIDS Conference to be held in the U.S.**
- > Activists "Storm the NIH"
- The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act is first enacted by Congress

1992

- AIDS becomes number one cause of death for U.S. men ages 25 to 44
- Parallel Track policy expands availability of investigational drugs to people with AIDS/HIV-related diseases without satisfactory alternative therapy and who cannot participate in controlled clinical trials
- Accelerated Approval allows approval of drugs based on surrogate endpoints that reasonably predict that a drug provides clinical benefit

1993

- Congress enacts the NIH Revitalization Act, giving the OAR primary oversight of all NIH AIDS research; requires research agencies to expand involvement of women and minorities in research
- > First annual "AIDSWatch" held in Washington, DC to lobby for increased AIDS funding

1994

- U.S. Public Health Service recommends use of AZT by pregnant women to reduce perinatal transmission of HIV
- AIDS becomes leading cause of death for all Americans ages 25 to 44; remains so through 1995

1995

- First protease inhibitor, Saquinavir, approved by the FDA

2003

- President's Emergency Plan for AIDS Relief (PEPFAR) established

KEY ACCOMPLISHMENTS

Specific medical research successes of the HIV/AIDS movement

What were some of the specific successes of the HIV/AIDS movement? What is different today because of their accomplishments?

The changes spurred by activists not only effectively delivered medical solutions to HIV/AIDS patients quickly, but they also paved the path for a more effective medical research and development paradigm that is responsive to patients' needs.

We recognize that the battle with HIV/AIDS is far from over, however we spotlight here some of the key accomplishments. These milestones transformed the research system, improved the regulatory paradigm, and garnered political will needed for funding support.

Transformed the Medical Research System through Patient-Driven Clinical Trial Designs

When the National Institutes of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID) first created the AIDS Clinical Trials Group (ACTG) in 1987, it featured promising research programs and protocols that some felt were not specifically designed to meet the needs of people living with HIV/AIDS. This propelled activists to organize a protest

known as "Storm the NIH" on May 21, 1990, and demand more treatments for the opportunistic infections that affect people living with HIV/AIDS, and more representation for women and people of color in clinical trials.¹¹

Following this, national and local community advisory boards were formed within the ACTG and other NIH-funded clinical trials networks. These provided people with HIV/AIDS activists a defined role in the design, implementation, and evaluation of clinical trials.¹² ACTG is now the largest HIV clinical trials organization in the world. It supports the most expansive network of both clinical and translational investigators and trial units researching HIV/AIDS.¹³

The notion that patients and advocates can actually shape clinical trial design had implications far broader than ACTG. This approach to clinical trials opened the path to regulatory process improvements.¹⁴ This includes creation of the Parallel Track policy, implementation of accelerated approval, the removal of obsolete restrictions on study entry criteria, the inclusion of all affected or infected groups in clinical trials, and to studies of interventions to prevent and treat HIV's opportunistic infections and cancers.

"Storm the NIH" protest helped shape clinical trial design to be more patient-driven.

1987
NIAID CREATES AIDS CLINICAL TRIALS GROUP (ACTG)

Improved the Regulatory Paradigm through Expanded Access Mechanisms

Accelerated drug approval is among the hallmarks of the HIV/AIDS movement, and considered by many to be among its most important achievements.¹⁵ By focusing efforts on creating specific programs with mechanisms that expedited the research and development process and ensured broad access to therapies,¹⁶ advocates were able to redefine the regulatory process and make new drugs widely available to patients in need as quickly as possible.

Treatment Investigational New Drugs (IND)

The FDA issued final regulations in May 1987 establishing the treatment IND. This provided severely ill patients, including HIV/AIDS patients, with investigational drugs for the treatment of serious and life-threatening illnesses for which there are no satisfactory alternative treatments. A treatment IND may be granted after sufficient data have been collected to show that the drug “may be effective” and does not have unreasonable risks.¹⁷ Physicians can access a drug directly from a pharmaceutical company as soon as it has treatment IND status.¹⁸

This new mechanism was approved just in time to deal with the impending demand for zidovudine, or AZT, a type of antiretroviral drug used for the treatment of HIV/AIDS. With the new approach, more than 5,000 people were able to access AZT soon after completion of a single controlled clinical trial that showed efficacy.¹⁹

Parallel Track


Unsatisfied with waiting for HIV drugs to be released, AIDS activists collaborated in 1992 with the head of NIAID to create a system of their own: a “Parallel Track” program. This program allowed drugs that were currently in the clinical trial pipeline, but not yet through trials, to be available to patients. Special programs distributed the Parallel Track drug didanosine (ddI) for free, instead of through pharmacies. By implementing this alternative means of moving drugs through clinical trials—later called “expanded access”—ddI was made available in less than two years to more than 23,000 people who had proven unresponsive to AZT.²⁰

Accelerated Approval

Building on the Parallel Track policy, the FDA

“PARALLEL TRACK” PROGRAM

Unsatisfied with waiting for HIV drugs to be released, AIDS activists collaborated in 1992 with the head of NIAID to create a system of their own: a “Parallel Track” program.



developed Accelerated Approval procedures that same year that allowed pharmaceutical companies to be able to market new drug and biological products that (1) had been studied to treat serious or life-threatening illnesses and (2) “provided meaningful therapeutic benefit to patients over existing treatments (e.g., ability to treat patients unresponsive to, or intolerant of, available therapy, or improved patient response over available therapy).”²¹

While clinical trials were still underway, careful planning with the FDA made it possible for the agency to approve drugs well ahead of schedule as long as the company agreed to complete certain clinical trials after the drug had been granted Accelerated Approval.

This quickly became, and remains, the standard for HIV/AIDS drug development as it provided people with HIV/AIDS access to products sooner, and incentivized pharmaceutical companies to work in AIDS, initially the only place they could get Accelerated Approval.

Garnered Political Will to Support Federal Investment in Research and Care

In addition to systemic and regulatory changes, activists played a key role in creating the political will needed to increase the federal investment in research at NIH and later in care through passage of the Ryan White CARE Act.

Funding for AIDS research at the NIH increased from \$5.6 million in Fiscal Year 1982 to \$1.61 billion in Fiscal

Year 1998. By 1998, AIDS research represented 12 percent of the entire NIH budget.²²

In 1990, Congress passed the Ryan White CARE Act, and provided an initial \$200 million for services to people with HIV. By 1994, Congress had allocated \$632 million through this Act,²³ and by 2005, the program was allocated \$2.1 billion.²⁴ Total federal spending on HIV/AIDS increased dramatically, currently totaling 27 billion in fiscal year 2011.²⁵ These funds were spent on prevention, research, care and assistance, and international programs carried out by agencies such as the NIH’s Office of AIDS Research (OAR), NIAID, and Centers for AIDS Research.

WHAT ARE THE ELEMENTS OF THE MODEL?

This section of the report lays out — in the words of the activists who led the effort and the policy makers who implemented the changes — the elements of the HIV/AIDS advocacy model. The advancements we have seen since the identification of the HIV virus in 1981 point to perhaps the most successful public policy change model ever seen. In the interviews we conducted, five key elements rose to the top:

- 1 **ATTENTION**
- 2 **KNOWLEDGE & SOLUTIONS**
- 3 **COMMUNITY**
- 4 **ACCOUNTABILITY**
- 5 **LEADERSHIP**

ATTENTION

Creating the political will to transform policies



“The political theater was important because we needed to use theater to communicate directly with the American people, and that would result in connecting through the American people to Congress and to the Administration.”

MARK HARRINGTON became an activist with ACT UP in 1988. He is also a co-founder and current executive director of the Treatment Action Group.

When people think about HIV/AIDS advocacy in the U.S. in the late 1980s and early '90s, the demonstrations, or the theater, are often what many people point to as its legacy. This theater was born out of fear, frustration, and anger. Activists' strategy to get attention ultimately helped to change public opinion and create the political will to transform policies.

The activism was built on a framework of civil disobedience efforts that had originated with Gandhi at the outset of the South African campaign for Indian civil rights and had been used by labor organizations, women's rights groups, the civil rights movement, anti-war movements, gay rights organizers, and in anti-Apartheid efforts. HIV/AIDS activists personalized these precedents, and invented new tactics.^{26, 27} This in turn spawned a movement that created a new model of advocacy in this country, and its street soldiers were a critical component of this model.

HIV/AIDS activists organized and engaged in civil disobedience to get the nation's attention. It was an all-out 'our bodies are on the line' exercise. Never before had this country seen thousands of sick people laying their bodies down on Wall Street. Or chaining themselves to the fence of the FDA. Or storming the NIH. "You have to be able to inspire people at a level of civil disobedience," noted Jim Curran, M.D., who was then the director of HIV/AIDS at the CDC. "Throwing condoms in St. Patrick's Cathedral, I mean, who does these kinds of things? They were not afraid to get arrested."

In the mid-1980s, AZT was shown to slow the progression from HIV to AIDS. The drug was approved by the FDA in March of 1987, 25 months after the first signals that it was active against HIV in the laboratory. This is one of the shortest periods of drug discovery to approval ever.²⁸ For the thousands of people living with HIV across the country, the drug provided hope that a treatment breakthrough had finally been achieved.

However, this hope quickly turned to outrage as the high cost of the new drug made it inaccessible to the many who desperately needed it.

Formed in response to this growing outrage over the lack of government activity on AIDS, as well as the lack of treatment and funding, the AIDS Coalition to Unleash Power (ACT UP) was created in 1987 and became one of the first groups to effectively channel the fear and anger of activists.

“We were dying, and we looked like we were dying,” said Larry Kramer, the founder of ACT UP. “We had spots and we couldn’t walk, and they saw that. And we were fighting for our lives, for our friends who were there with us who were dying like flies all around us, so we were motivated.” HIV/AIDS activists were masterful in their ability to utilize the media and demonstrations to put a human face on the disease. They mounted demonstrations that offended people and made policy makers and federal officials uncomfortable. They wanted the public to see them, and to understand the consequences of inaction at the federal level. They wanted people to be angry and afraid, too, motivating the public to action in their fight.

Jim Eigo, an activist who began working with ACT UP shortly after the group was founded, recalled that “a critical mass of people with AIDS realized their bodies were not just the site of a disease. They had also become the site of a social struggle. They sat in the middle of Wall Street, the center of capitalism, and said, ‘All right. This is my body— disease and all. Take it. Deal with it.’” Kramer said that “what makes activism work is anger and fear, and I do not think it can work without that. I don’t think any of those organizations in Washington understand that because, for whatever reason, they’re constrained. They can’t be angry, and they can’t show their fear. The fear is among the patients, and somehow you have to be able to capture that or to put it in a bottle and bottle it and use it.”

The activists were strategic in their use of theater to get attention, employing different strategies for different audiences and for different challenges that needed to be solved. The mindset was first to get attention focused on the issue, then focus on the solutions. For example, the demonstrations at NIH were focused on ensuring the inclusion of people living with HIV/AIDS in the research programs and protocols carried out by the newly-created ACTG and other networks at NIH.



“You have to be able to inspire people at a level of civil disobedience”

JAMES CURRAN, M.D., is the current dean and a professor of epidemiology at the Rollins School of Public Health at Emory University in Atlanta, Ga. He is also co-director of the Emory Center for AIDS Research. In the 1980s, Curran coordinated the task force on acquired immune deficiency at the CDC and then led the HIV/AIDS Division.

As part of this effort, the activists blanketed the NIH campus with tailored leaflets detailing specific demands. The 1990 “Storm the NIH” demonstration was planned after the activists learned about a bureaucratic issue that was slowing down the clinical trials. Mark Harrington remembers Anthony S. Fauci, M.D., NIAID director inviting him and a few other activists to the ACTG meeting in November 1989 where he learned of the issue. “We weren’t welcomed by the federal officials or the scientists... We brought the news of this bureaucratic issue back to ACT UP in New York, and the activists were outraged and decided to do the ‘Storm the NIH’ demonstration in May 1990.”

Harrington noted that the real transition for the HIV/AIDS movement occurred between 1988 and 1990, framed by two specific demonstrations — the October 1988 demonstration at the FDA and the May 1990 demonstration at the NIH. Eigo referred to the demonstration at the FDA as “something of a sea change.” More than 1,000 activists participated, and he noted that “this was the first international recognition that we got, that this was a movement... and nobody could look at it and think these are just activists in the streets mouthing off because we had

all the papers... that were not only coherent, [but] people in the NIH, and National Cancer Institute were now quoting our papers.” Added Harrington: “The theater was important because we needed to use the theater to communicate directly with the American people, to Congress, and to the Administration.”

Fauci described how activists progressed from focusing on the enormity of the problem of the HIV/AIDS epidemic to specific problems to specific solutions and opportunities. He said, “So, when ACT UP first started, they were saying that ‘you the federal government,’ ‘you the U.S.’... are not paying enough attention to a problem that is gradually exploding into something that is going to be beyond your imagination. So it was pure attention getting for the big issues, and that is what they did. They got attention, they disrupted things, they demonstrated. Then they started to concentrate on much more specific and granular issues beyond the fact that this is a big problem. They insisted that we rethink how we did clinical trials; they pointed out that the rigidity of the FDA is unacceptable when you have a disease with no treatment... [and] the rigidity of the trials makes it impossible for them to participate.”



NYTIMES PHOTO: JOHN SOTOMAYOR/THE NEW YORK TIMES/REDUX

“We were fighting for our lives, for our friends who were there with us who were dying like flies all around us, so we were motivated.”

LARRY KRAMER, FOUNDER OF ACT UP

WHAT WE HAVE LEARNED

It is impossible to move someone to action without first getting his or her attention. The early years of HIV/AIDS activism were characterized by mass demonstrations and other actions designed to get attention. Today, most of the American public probably believes that the theater was the beginning, the end, and the driving reason behind the success of the HIV/AIDS movement. When individuals and organizations say things like “we need to be more like ACT UP,” what they are often referring to is the mass mobilization and the theater. However, this was only one critical piece of the model.

HIV/AIDS activists showed us that getting attention sometimes requires making people feel uncomfortable. Today, organizations are working to execute on multiple goals and may shy away from actions that make decision makers uncomfortable. Instead, they focus on building relationships and engaging in activities that make decision makers feel safe. They develop sophisticated strategies focused on how to work within the system and the rules, without challenging the notion that the system and the rules as constructed may not be in their best interest. And for individuals who don't have organizations to work through, challenging the status quo may seem like a Herculean task.

Have we become complacent? In many instances, organizations meet with their elected officials, are invited to meetings at federal agencies, are asked to sit on advisory boards, and are often part of “the process.” And yet the level of frustration about the speed of getting new treatments and cures is growing.

Access and face time do not mean you have decision makers' attention and, in some instances, it only means that they can 'check the box' about consulting

with the community without having really listened. They have met with and listened to the advocate and their outreach is done. That is NOT getting their attention.

It is ironic that in today's increasingly connected society with 24/7 news cycles, new tools to communicate, and an explosion of advocacy organizations, getting the attention of the public as well as policy makers and regulators might actually be more challenging. There are more ways to get attention and to communicate today, yet it is harder to be heard.

In the end, HIV/AIDS activists were successful in getting the attention of, and ultimately being heard by the American public and decision makers. They were skilled at the development and execution of activities targeted at specific audiences — something that the sheer volume of information today makes even more critical.

Organizations need to analyze their communications strategies. We are not advocating blocking the Brooklyn Bridge or chaining advocates to the fences surrounding federal agencies. We are suggesting that a new level of urgency is needed to make decision makers understand the consequences of inaction or of accepting the status quo. The message needs to be delivered not by the organizational executives or the cadre of scientists. Their message has to be delivered by the informed stakeholder or patient. HIV/AIDS activists fought for a seat at the table. Where organizations have the ability to get that attention again is by putting their advocates back at the table.

KNOWLEDGE & SOLUTIONS

Shaping the discussion and getting answers



“It wasn’t that they were simply advocates. It was that they really were contributors and that they really brought a very sophisticated understanding.”

MARGARET A. HAMBURG, M.D., is the current commissioner of the FDA, a position she has held since 2009. From 1986 to 1988, Hamburg served in the U.S. Office of Disease Prevention and Health Promotion, and from 1989 to 1990 she was assistant director of NIAID at NIH.

The activists not only got attention effectively, they also did their homework and knew what to ask for. Tony Fauci recalls that when ACT UP started, activists had to capture the attention of the people in charge. Fauci remembers clearly the transition between the purely attention-focused activities and the demonstrations that were timed and designed to put the spotlight on specific problems concerning scientific or regulatory issues. The theater was becoming inextricably linked to the substance. HIV/AIDS activists began to put the focus on the way clinical trials were designed and the rigidity of the FDA. “In order for them to gain any kind of credibility for that, they had to start educating themselves, and that is where they made the transition from a theatrical group that gained your attention to a group that has your attention and is now discussing very important and thought-out issues with you,” remembered Fauci.

Many who were in the federal government in positions of leadership during the HIV/AIDS emergence pointed to pivotal moments when their perception of the activists changed. This transformation opened the door and established a new model for advocacy that included the ‘patient expert’ who could challenge the status quo and, as Maureen Byrnes, a former Senate appropriations

“If you just take away the theatrics and look at what they were talking about... it became clear that though they weren’t always factually correct, most of the time they were... they really got it right and came up with some alternatives.”

ANTHONY S. FAUCI, M.D., is director of the NIAID at the NIH and oversees an extensive research portfolio devoted to preventing, diagnosing, and treating infectious and immune-mediated diseases, including HIV/AIDS.

subcommittee staff director, states, “[they] pushed as hard as possible for what they wanted.”

Fauci recalls walking across the NIH campus and picking up one of the leaflets that had been dropped by activists. He read the specifics of the demands, and remembered thinking that “if you just take away the theatrics and look at what they were talking about... it became clear that though they weren’t always factually correct, most of the time they were.” And he notes that in the parts they got right, “they really got it right and came up with some alternatives. They asked reasonable questions, such as ‘Why have we accepted for decades that the regulatory process excludes this and says you must do that?’”

The activists got smart and pushed for specific changes in the system and in policies that challenged the status quo. “[The activists] were able to make us think in some new ways,” remembers Margaret Hamburg, M.D., who was assistant director at NIAID from 1989 to 1990, “to rethink some of the models that existed because the truth is some of the models were simply legacies of how things had been done but didn’t mean that that was the only way things could be done.”

“I remember that [Fauci and I] were invited to speak at an ACT UP meeting in the Village, and just the two of us went. We felt very vulnerable going in and not knowing quite what would happen.” Going into in ACT UP meeting in New York — into the lion’s den — “wasn’t comfortable,” Hamburg remembers. “But we were able to have a real discussion, and in doing that, established a different relationship, a different level of trust.” For Hamburg, the advocates had become contributors, and were helping shape the direction of future efforts.

By the time the HIV/AIDS activists had earned a seat at the table, they possessed the knowledge to justify their participation. David Kessler, M.D., commissioner of the FDA at the time, remembers being “enormously struck and impressed that the activists at the table had as much scientific sophistication as the other members.”

They were able to articulate their demands in the language of the others around the table because, as Byrnes notes, “they respected the scientific imperative.” Their argument was framed, she recalls, as ‘we need to understand it [HIV/AIDS]. We need to get those answers. But, we also recognize that people are dying of opportunistic infections... and while you are trying to figure out the



“[I was] enormously struck and impressed that the activists at the table had as much scientific sophistication as the other members.”

DAVID KESSLER, M.D., was commissioner of the FDA from 1990 to 1998. He is currently a professor of pediatrics, epidemiology, and biostatistics at the School of Medicine, University of California, San Francisco.

virus, please continue to invest in treatments that will deal with the opportunistic infections.”

The activists got smart by attending scientific meetings, reading the literature, and talking to the scientists about what was going on with clinical trials. They also stumbled across one woman named Iris Long who took them under her wing and served as a mentor. Larry Kramer remembers meeting Long — a housewife from Queens who was also a biochemist — for the first time. “She came to an ACT UP meeting and said ‘you really don’t know anything. You don’t know about the system. You don’t know about the drugs. You don’t know about the science. You don’t know how the government works. You don’t know the FDA from the NIH. You’re just out there yelling and screaming.’” She offered to teach this to anyone who wanted to learn, and a group of advocates, including Jim Eigo, took her up on the offer. From this, a group of highly informed advocates emerged.

Mark Harrington looked back to how a statistician named David Byar, M.D., was instrumental in educating a group of activists about clinical trial design. “At the [ACTG] meeting in November of 1989,” recalls

Harrington, “we met a bunch of statisticians who were working on ACTG trials, and we joined a group of theirs called the Statistical Working Group.” Byar and his colleagues took the activists under their wing and, as Harrington recalls “they taught us a lot about trial design and helped us understand how we could get what we wanted and the FDA could get the answers they wanted, too. There was a very durable kind of alliance [that developed] between us and [that group of] statisticians, and it helped us a lot in the work we did over the next five years.”

HIV/AIDS activists showed us that it is critical to be part of the discussion to achieve meaningful change. To accomplish that, organizations must do the hard work of getting their advocates smart – being intelligent enough to be the translators of disease, to understand the science, to know the system, and to challenge the status quo effectively.

Gregg Gonsalves, who became a member of ACT UP in 1990, remembered that the organization provided a framework for activists in other countries. “I think what happened at the end of the century was the globalization of AIDS activism, basically the model took off

“It basically exploded all over the world, and it is less around scientific, technical knowledge than knowing intellectual property frameworks and legal things about how generic drugs are approved.”

GREGG GONSALVES, co-founder of the Treatment Action Group and International Treatment Preparedness Coalition.



But if patients are to engage in the most productive way – if there is going to be an ‘inside strategy’ – patients must do the hard work of getting smart, and organizations should develop programs and invest resources to help them do that.

in other places like India and Russia. It basically exploded all over the world, and some of it is less around scientific, technical knowledge than knowing intellectual property frameworks and legal things about how generic drugs are approved. It became another set of technical expertise.”

WHAT WE HAVE LEARNED

Clearly, one of the legacies of this movement was the fundamental shift in how patients and disease organizations interact with the federal government and Congress. Agencies have created advisory panels and have carved out representation for patients, and they talk publicly about the important role and perspective of the patient. Yet, the conversations among patients and organizations representing them about the length and time frame to get to treatments is growing, and the major complaints are that the patient voice is not being heard and taken into account, and that progress is too slow.

Over the past few decades, organizations have focused energy on raising money, funding research, building internal scientific expertise — all things that have helped to accelerate the pace of research in many areas. But where the backsliding has occurred is having the actual patient seated at the table with scientists, policy makers, private industry, and regulators pushing for specific changes and demanding accountability. We have reverted back to the old paradigm, but instead of patients deferring to doctors and scientists, they now defer to the organizations and scientists representing their interests. The gold standard should be to have both internal scientific

expertise and a group of patients who can speak both to the science AND the urgency needed to make change. It will be a commitment for organizations to devote the human and financial resources needed to train their advocates. That undertaking, however, is essential to make real change occur.

Disease-based organizations are skilled at putting a face on a specific disease, and their activities have grown substantially over the years. Patients make valuable contributions and are organized around annual Congressional lobby days, events in Members’ districts, and fundraising efforts. They are given talking points about the organization’s priorities and a brief training with some background on the issues. But if they are to engage in the most productive way, they must do the hard work of getting smart, and organizations should develop programs and invest resources to help them do that. Harrington proved that a few dozen people — not a few thousand — who are smart enough to question the status quo can be instrumental in catalyzing change. And the breast cancer community has shown, through programs like Project LEAD of the National Breast Cancer Coalition, that efforts like this can work. For those individuals who don’t have established organizations to turn to for support, HIV/AIDS activists showed us that you can do it on your own. In the beginning, they were smart enough to know what they didn’t know. They went to scientific meetings, did their own research, created manuals for others to learn from, focused on the task at hand, and listened to people like Long and Byar who could help make them smarter.

COMMUNITY

Working together for the same cause



“ACT UP started in 1987 when a critical mass of people with AIDS realized their bodies were not just the site of a disease. It had also become the site of a social struggle.”

JIM EIGO is a writer and AIDS activist. He began working with ACT UP shortly after the group was founded in 1987.

In the 1980s, tens of thousands of individuals were struggling with the stigma associated with having HIV/AIDS. With the formation of ACT UP in 1987, the community began to build a structured setting for HIV/AIDS activists to come together and speak out in a unified voice. Says Larry Kramer, “We had a lot of committees, and we met every night of the week. There was always a meeting you could go to.” And for Kramer, these meetings provided a forum that encouraged activists to get together and to get to know each other, and gave everyone involved a sense that they “were all working together for the same cause.”

Just as important as the structure was the added sense of community that resulted. Kramer believes that one of the reasons that ACT UP was so successful was that it was social. He says, “It was a good time, which is something else that people should be aware of, that you should make whatever you are doing enjoyable. It helps cement brotherhood. And that’s important—brotherhood—in all of this.” For individuals struggling to deal with the fear and anger associated with HIV/AIDS, the social aspect of ACT UP created a community of like-minded individuals that provided reassurance to all participants that they were not alone.

TURNING THE CAUSE INTO A
MOVEMENT
1987

“You have to be angry. Anger is a very healthy emotion.”

LARRY KRAMER, FOUNDER OF ACT UP

For Jim Curran, M.D., it was this collective identity that played a vital role in sustaining the activist movement over time. Says Curran, “You had an overwhelming new health problem, and you had a community that could deal with it... The gay community accepted people with HIV with much less stigma than society did. You had affected, infected, and non-infected gay people who took up the cause with an incredible amount of passion and understanding.”

Many of the activists were young and dying, and each was angry at a system that they felt was failing them every step of the way. For Kramer, it was the ability of activists to focus this outrage that made them so successful — something he believes that many advocacy groups today have been unable to do. Says Kramer, “You know, you have to be angry. Anger is a very healthy emotion.”

For Brenda Lein, a member of ACT UP in San Francisco, the fact that so many of the people who were dying of the disease were young led to an increased sense of injustice. Says Lein, “People who are young feel invincible. People who are young feel like they shouldn’t be dying. They feel entitled to life,

as well they should, and it’s easier for them to stand up and say, ‘This is wrong.’”

For Lein, however, the success of HIV/AIDS activism was about more than just the anger. She says, “For people who were angry, [ACT UP] was great to have a place to put your anger.” But she adds, “...an individual can’t sustain themselves for the long-term when they’re rooted in anger... We needed an alternative to anger as well.” Referencing her work with Martin DeLaney, AIDS activist and founder of Project Inform, Lein says, “While Larry Kramer was advocating that people start taking lessons at the shooting range and getting out in the street and being aggravated and angry, what Martin offered as an alternative was a message of hope.” According to Lein, DeLaney was able to “turn desperation and fear into hope and action.”

While ACT UP certainly created a unified community that ultimately became a powerful force for HIV/AIDS activism, the sense of community and brotherhood that existed within ACT UP was not limited only to members of ACT UP. Says Curran, “They weren’t really operating with ACT UP totally on their own.

FELLOWSHIP

A connected community ensured interaction among activists, doctors, nurses, and researchers. Creating a sense of fellowship requires time, resources, and unrelenting courage.

“You had affected, infected, and non-infected gay people who took up the cause with an incredible amount of passion and understanding.”

JIM CURRAN, M.D., is the current dean and a professor of epidemiology at the Rollins School of Public Health at Emory University in Atlanta, Ga. He is also co-director of the Emory Center for AIDS Research.

In other words, you’d have an international AIDS meeting, you’d have all sorts of activists demonstrating by the pharmaceutical company booth and lobbying Tony Fauci or other people, but it wasn’t without a lot of people in the AIDS community agreeing with them.” The presence of a connected community outside of ACT UP itself ensured that interaction occurred not only among activists within ACT UP, but also among doctors, nurses, and researchers outside of the movement.

WHAT WE HAVE LEARNED

Building a community around a specific disease or issue serves multiple purposes. The HIV/AIDS example showed that it is a way to bring people together to focus their fear and anger, to create a ‘safe haven’ so that people don’t feel alone and judged by society, and to create solidarity and ‘brotherhood.’ The meetings organized by ACT UP are legendary. Building a community was a significant component to the success of the HIV/AIDS activists. It was raised in every interview conducted. It was how they turned a cause into a movement.

Today, there are many ways to build a community, and it still serves similar purposes. While it is easier to

connect people and to disseminate information, it seems harder to make meaningful connections. What should be learned from the HIV/AIDS experience is that regardless of the tools and strategies used to connect people and build a community, individuals and organizations need to find their own version of the ACT UP meetings. Those meetings were critical in sustaining and focusing the advocates during a time when it was difficult to find hope, and it gave others the shoulders they needed to stand on to call for sweeping changes to the system. Recreating the meetings, in whatever form, will not happen by just having an advocate sign up to support your cause on Facebook. The sense of community achieved by HIV/AIDS activists cannot be replicated solely by bringing advocates to Washington, D.C., once a year to educate federal officials. What has to be created, either in person or cyberspace, is a sense of fellowship where advocates understand they are not alone. This clearly takes time, resources, and unrelenting follow-up.

Of all the elements that contributed to the success of the HIV/AIDS movement, this formation of fellowship is the one that needs to be adapted most specifically to a cause.



“People who are young feel invincible. People who are young feel like they shouldn't be dying. They feel entitled to life and it's easier for them to stand up and say, ‘This is wrong.’ ”

BRENDA LEIN is a board member of the Foundation for AIDS and Immune Research. A member of ACT UP San Francisco, she worked with Martin DeLaney, AIDS activist and founder of Project Inform.

ACCOUNTABILITY

Implementing an ‘inside and outside’ strategy



“There were the real nerdy geeks who just salivated over becoming experts on the most obscure minutia of immunology and virology. And then there were a few big picture people like me.”

PETER STALEY joined ACT UP in New York shortly after its founding in 1987, and headed its fundraising committee for three years. In 1988, he left his Wall Street job to become a full-time AIDS activist, joining ACT UP's Treatment & Data Committee.

By the late 1980s, the HIV/AIDS community effectively mobilized and generated attention focused on the problem. They also developed a pipeline of activists who were steeped in the science and the policy. In addition, they had skilled strategists who could sit at the table and participate in conversations with advocates, scientists, and policy makers to help craft solutions to their demands and issues raised in the meetings.

ACT UP quickly became sophisticated and created committees to delegate work and enable people to specialize in different areas. The Treatment and Data Committee was created to focus on the science. In the beginning, the primary focus was on collecting information about where the clinical trials were being conducted. Mark Harrington recalls that there were about 20-40 people within the committee. Over time, these advocates joined forces with Project Inform on the West Coast and created a network of about 100 people nationwide. Says Harrington, it was this group that always “kept alive this idea that [activists] needed to be training and mentoring newer activists so they could be science and policy literate and develop [their own] relationships.”

FIRST INTERNATIONAL RECOGNITION

What started as a demand to change the system moved toward ‘this is *how* you must change the system.’

MORE THAN

1,000
ACTIVISTS

Getting attention led to getting smart, which led to being able to develop specific demands and an overarching strategy. Once that happened, activists were able to hold people accountable for making their requests and recommendations a reality.

“What ACT UP did so well,” recalls Peter Staley, “is that it had both an outside and an inside strategy.” As part of their inside strategy, clearly defined roles were created. Staley recalls that “there were the real nerdy geeks who just salivated over becoming experts on the most obscure minutia of immunology and virology. And then there were a few big picture people like me.” This combination of expertise created a powerful force. Jim Eigo refers to this strategy as a “two-handed model.” He says that “we who were working on the inside never could have done what we did if we couldn’t deliver bodies in the streets. But bodies in the streets wouldn’t have gotten the regulatory reform in 14 months that people have been trying elsewhere to do over decades.”

Staley, one of the leading strategists, noted that “just having a strategist in the room [wouldn’t] do much good. If I didn’t have people like Mark [Harrington] or Gregg [Gonsalves] in the room, I wouldn’t be able to

negotiate, to get down into the nitty-gritty,” says Staley. “I was never in the category of the Mark Harringtons or Gregg Gonsalveses that could sit down and have a scientific conversation with Tony Fauci, but I could have a very hard talk with Fauci on strategy and management.”

Tony Fauci acknowledges that this inside-outside strategy was very powerful, put a human face on the disease, and ultimately was successful in convincing policy makers that more money needed to be invested in research. Says Fauci, “[When] I was pushing for more money for AIDS research, and they were out demonstrating in their districts...it was very helpful.”

The perception of HIV/AIDS activists was to many Americans their ability to, in dramatic ways, get the attention of a nation. However, the reality is that their success was the direct result of a strategy that utilized “getting the attention” of the decision makers and the public as only one tool in their tool chest. Fauci’s inverted pyramid is a simple, yet elegant, way to look at this strategy. He notes that at the top of the inverted pyramid “everybody could demonstrate and get your attention. A lesser number of people can get your

RELATIONSHIPS

“[Activists] needed to be training and mentoring newer activists so they could be science and policy literate and develop [their own] relationships.”

MARK HARRINGTON is co-founder and current executive director of the Treatment Action Group.

attention and point out the illogical nature of what you are doing. Then a lesser group of people can help you in the design of clinical trials, and an even smaller group of people can actually help you out with the science.” The techniques and methods used at each succeeding level constantly fed the strategy as a whole. By the time you reach the inverted tip of the pyramid you are catalyzing change.

WHAT WE HAVE LEARNED

The activists were successful because they were smart enough to adapt as they learned. As the activists gained more knowledge, their demands became more targeted. It started as a demand to change the system. As they gained more expertise, they said “this is how you must change the system.” And Fauci states that “what I think was unique about them was that combination of theater to get your attention and their phenomenal analysis of things that actually make logical sense.”

Every organization and individual can have a different definition of success. What is important is not how it is defined, but that it is defined. It involves having a long-term vision with benchmarks to measure

progress along the way. And integral to success is holding people accountable.

Holding people accountable seems like such a simple thing, but in reality it is often where organizations and individuals asking for change can fall short. Holding the relevant parties accountable was a key component of the activists’ strategy, and it is as important today as it was during that time. Vigilance is hard work and never-ending, but losing attention and focus risks wiping away progress.

There is a big difference between following up on a request and being vigilant. The HIV/AIDS activists were specific in their demands and vigilant in their follow-up. People knew that they would be holding policy makers’ and regulators’ feet to the fire until they took specific actions. They didn’t get tired and go home, move on to the next issue, or take no for an answer and agree to disagree.



“What I think was unique about them was that combination of theater to get your attention and their phenomenal analysis of things that actually make logical sense.”

ANTHONY S. FAUCI, M.D., Director, NIAID at NIH

LEADERSHIP

Inspiring and motivating people to act on a shared vision



“Activist leaders, regular people who had leadership forced upon them, took their skills and passion and built a movement.”

MAUREEN BYRNES was staff director of the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies for Senator Lowell Weicker from 1986 to 1988, and she served as executive director of the National Commission on AIDS from 1989 to 1991.

This movement, like any successful movement, has a long list of leaders who were instrumental in its success. Vision, the ability to inspire and motivate thousands of people to become activists, adaptability, and vigilance are all hallmarks of the leaders of the HIV/AIDS activist movement.

Mark Harrington acknowledges that they were lucky to have leaders in Congress and in the federal agencies whose goals aligned with those of the advocates. “We had Senator Ted Kennedy and Congressman Henry Waxman and Congressman Ted Weiss who were pushing the federal government every year from the outbreak of the epidemic. We had a young and ambitious director [of NIAID, Tony Fauci], and he will definitely go down in history for what he has done, and we had the FDA turning into an enlightened agency under David Kessler.” And Maureen Byrnes notes that members of Congress, such as Senator Lowell Weicker, chairman of the Senate Labor, Health and Human Services Appropriations Subcommittee in 1986, were leaders in “giving the NIH the money it needed to study the virus.”

And there were leaders in the activist movement — among them a novelist (Larry Kramer), a Wall Street

DO THE RIGHT THING

What the HIV/AIDS movement shows us is that you need strong leadership on the outside to stand up and demand that government leaders do the right thing so that leaders on the inside have a greater likelihood of success.

executive (Peter Staley), a housewife and former biochemist from Queens (Iris Long) — regular people who had leadership forced upon them who took their skills and passion and applied it to building a movement.

WHAT WE HAVE LEARNED

HIV/AIDS activism shows us that leadership must occur at all levels. The activists demonstrated that leadership can arise organically, or individuals can be forced or cajoled into becoming leaders. These leaders had the ability to keep the rank and file motivated and engaged. Each element of the model required different leadership skills, and leaders emerged to fill the need of each element of the strategy. And they worked together, enhancing the strength of the whole.

The different administrations during this time period were cornered into leadership positions by public and expert opinion. At the NIH, FDA, and CDC it was a combination. Natural leaders arose because there was an impending public health catastrophe on the horizon, and there were compassionate and visionary people at the helm. In some instances, however, heads of federal agencies became leaders because their peers had paved the way and taken the risks.

Maureen Byrnes recalls that there were leaders in the key federal agencies in the mid-1980s who stood up and told the truth about what was going on when asked by Congress — during a time when the White House had not said anything about HIV/AIDS. She remembers federal officials testifying before Congress and how they were “brave and courageous to forthrightly tell the truth about a public health epidemic.”

Leadership from the White House, industry, and the federal agencies never would have happened if it had not been for the strategy employed by the leaders of the movement itself. The tens of thousands of Americans who had HIV/AIDS became a movement that put a human face on the epidemic. This movement helped to provide cover, ammunition, and purpose to leaders in critical positions so they could stand up and change the system.

What the HIV/AIDS movement shows us is that you need strong leadership on the outside to stand up and demand that government leaders do the right thing so that leaders on the inside have a greater likelihood of success.

CHANGE THE SYSTEM

The tens of thousands of Americans who had HIV/AIDS became a movement that put a human face on the epidemic. This movement helped to provide cover, ammunition, and purpose to leaders in critical positions so they could stand up and change the system and be true leaders.

TODAY'S REALITY

Understanding what can and cannot be replicated

To understand whether or not the HIV/AIDS advocacy model can be replicated today, it is important to examine what is unique about the HIV/AIDS epidemic, the ensuing response, and the era in which it took place. Today's environment is very different from that of the 1980s and 1990s.

At the time that the disease was characterized and first described in a scientific publication — in the CDC's 1981 *Morbidity and Mortality Weekly Report* (MMWR)²⁹ — many things were different, including, but not limited to, the communication tools available, the lack of patient advocate models to turn to, the economics of medical research in general, the federal budget, the specific nature of infectious disease epidemiology and epidemics, and the science of HIV/AIDS.

Technological advancements have shaped the way we connect and communicate, the way news is disseminated, and the way we build “communities.” The discovery and ultimate widespread utilization of the Internet and other communication tools were several years away when the HIV/AIDS epidemic began. Activists described fax machines working nonstop for weeks at a time. Today, we have news coverage and analysis at all hours across a variety of multimedia outlets, rather than only in the morning papers and on the evening news. News travels at warp speed. “Opinion” sharing happens in real-time through a myriad of social networking tools.

Tools like Facebook, Twitter, and YouTube allow individuals to spread messages instantaneously —

and the breadth of information shared is astounding — from seemingly mundane personal updates to the world-changing calls-to-action that helped to facilitate the recent uprisings in the Middle East. Our information mindset has changed. And so has the culture of involvement and engagement. There is a new generation used to being supremely connected, to getting all of their information in a click, and to turning to their personal networks for just about everything.

Because the epidemic hit before these tools were available, HIV/AIDS advocates utilized information dissemination that emphasized face-to-face communication and regularly established meetings to both share information and establish and solidify relationships. There were no apps for that. Even more difficult is the ability to compare HIV/AIDS activists' success in getting attention through mainstream media versus the ability to sustain interest and attention amidst today's information din.

There is power in having advocates share their personal story, and that clearly made a difference in terms of what was accomplished with HIV/AIDS. It is possible to turn to that period of history and point out the favorable outcomes that resulted from it. The HIV/AIDS activists really had no models to point to. If in fact the most effective advocates are patients — what about diseases for which patients themselves are in less of a position to advocate because of the swiftness of the disease or the debilitating effects — like pancreatic cancer or Alzheimer's? What lessons are applicable to the caregiver advocacy community?

What they left behind as a legacy is a model of advocacy that, when taken as a whole and adapted to today's environment, can be as powerful and effective today as it was in the mid-1980s and early 1990s.

The fact that HIV/AIDS was a previously unknown infectious disease that was spreading rapidly heightened attention and generated a movement to find treatments and effective prevention strategies — immediately. How can urgency be created for action on other diseases that have been long-identified, where there remains dissatisfaction with the pace of research and quality of life?

There have also been remarkable scientific advances that have defined the past three decades. We know more about biology than ever before. We've sequenced the human genome and are beginning to use this knowledge to develop therapies that target specific disease mechanisms and are tailored to respond to each person's unique needs. But we also know, unlike many other diseases, HIV/AIDS has a surrogate marker, the CD4 count.

Another critical element so different from 30 years ago is the federal budget. The current debates around the federal budget deficit could significantly impact medical research, and budget constraints are dictating national priorities. Did the relative availability of resources impact the response to the HIV/AIDS epidemic, or was it that it was an infectious disease with life-threatening consequences?

Today's pharmaceutical business model and the many factors that impact how drugs are developed and delivered to patients is also different. Many concur that the business model for the development of new treatments is uncertain. What this means for a

patient-driven movement to get new therapies is also unclear. Today we have both patients and disease organizations as actual investors in research through the venture philanthropy model. This has allowed certain disease areas to benefit from the focus that these groups can bring — in directing scientific priorities, in bringing resources, and bringing patients into the research process. This model did not exist in the 1980s and 1990s.

Finally, the FDA's organizational structure and budget has grown in the past 30 years, and so have the demands on the agency. Today's FDA budget is roughly two and a half times what it was in the early 1980s, but at the same time, responsibilities have also grown exponentially. Between 1996 and 2009, more than 50 legislative acts have added new responsibilities to the FDA, many in the form of unfunded mandates.

Simply transposing the elements that made the HIV/AIDS movement successful to our current reality may not work exactly the same, but today's patient advocates have much to gain from taking the lessons of this model to better inform and shape existing efforts to ensure the best possible outcomes.

CONCLUSIONS

Going back to basics

The activists who led this movement acknowledge that there was no master plan at the beginning. They were individuals who were not brought together by choice but rather by a crisis, and they banded together out of desperation and fear. They charted their own course, focused a nation's attention on a specific disease, created the political will, and forged relationships with policy makers and regulators that resulted in saving the lives of millions of people. But many died along the way.

What they left behind as a legacy is a model of advocacy that, when taken as a whole and adapted to today's environment, can be as powerful and effective today as it was in the mid-1980s and early 1990s. The contribution of the activists in helping to transform HIV/AIDS from a death sentence to a more chronic disease (and at the same time transform how several federal agencies approach medical research) has been recognized by many. But they also helped millions more, across diseases and issues, by creating a roadmap for catalyzing significant public policy change.

Today, we see scientific expertise being built within disease organizations, broad-based grassroots networks expanding throughout the country, patients gaining a presence on federal advisory panels, and relationships with senior federal officials and within Congress becoming stronger. This is all progress. But this will only get us part of the way to significant public policy change. To cross the finish line, to succeed in forcing the broad sweeping changes that are needed to make change in so many areas, the HIV/AIDS activists showed us that you need to go back to basics.

The HIV/AIDS movement was born out of fear and anger. Its legacy can be traced back to the initial pursuit of a simple question — *where are the clinical trials being conducted in New York City?* Everything else — the history and changes — grew out of that question. Through the pursuit of the answer, people like Jim Eigo, Iris Long, and others discovered that there were serious problems with the way trials were being designed and conducted. “[We] could pretty quickly see that we would never get anything done before everybody was dead if it went on like [the initial trials],” remembers Eigo. The rest is history.

What is the key question that your individual group must ask that can spark a movement? And once you have identified the question, don't rely on someone else to give you the answer - find it yourself. Get smart. Adjust the strategy as needed. Hold people accountable. Use the roadmap these activists left us. Real change is hard. But these activists showed us that even under the most difficult circumstances, it is possible to achieve change.

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MAUREEN BYRNES is a member of the Council on Foreign Relations and currently works as an independent consultant with a particular focus on public health and human rights issues. In the 1980s, Ms. Byrnes worked with Senator Lowell Weicker as the staff director of the U.S. Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies. Later she served as the executive director of the National Commission on AIDS.

JAMES CURRAN, M.D., M.P.H., is the current dean and a professor of epidemiology at the Rollins School of Public Health at Emory University in Atlanta, Ga. He is also co-director of the Emory Center for AIDS Research. In the 1980s, Dr. Curran coordinated the task force on acquired immune deficiency at the Centers for Disease Control and Prevention (CDC) and then led the HIV/AIDS Division.

JIM EIGO is a writer and AIDS activist. He began working with ACT UP shortly after the group was founded in 1987.

ANTHONY S. FAUCI, M.D., is director of the National Institute of Allergy and Infectious Diseases (NIAID) at the National Institutes of Health. He oversees an extensive research portfolio devoted to preventing, diagnosing, and treating infectious and immune-mediated diseases, including HIV/AIDS. Dr. Fauci also directs an NIAID laboratory and has made many scientific contributions to the fight against HIV/AIDS.

GREGG GONSALVES is a treatment activist. He was a founding member of the Treatment Action Group, and also worked with the Gay Men's Health Crisis and ACT UP New York.

MARGARET A. HAMBURG, M.D., is the current commissioner of the Food and Drug Administration (FDA), a position she has held since 2009. From 1986 to 1988, Dr. Hamburg served in the U.S. Office of Disease Prevention and Health Promotion, and from 1989 to 1990 she was assistant director of NIAID at NIH.

MARK HARRINGTON became an activist with ACT UP in 1988. He is also a co-founder and current executive director of the Treatment Action Group.

DAVID KESSLER, M.D., was commissioner of the Food and Drug Administration from 1990 to 1998. He is currently a professor of pediatrics, epidemiology, and biostatistics at the School of Medicine, University of California, San Francisco (UCSF).

LARRY KRAMER is a playwright, author, and activist. He was a co-founder of the Gay Men's Health Crisis (GMHC) in 1982, and founded the AIDS Coalition to Unleash Power (ACT UP) in 1987.

BRENDA LEIN was a member of ACT UP in San Francisco in the late 1980s and early 1990s. She was the director of Project Inform's Project Immune Restoration and is currently president of the board for the Foundation for AIDS and Immune Research (FAIR).

PETER STALEY joined ACT UP in New York shortly after its founding in 1987, and headed its fundraising committee for three years. In 1988, he left his Wall Street job to become a full-time AIDS activist, joining ACT UP's Treatment & Data Committee (T&D).

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