The History of FDA's Role in Preventing the Spread of HIV/AIDS

It was not so long ago that an AIDS diagnosis was interpreted as a death sentence. But in the past 30 years, medical breakthroughs have transformed this once fatal disease into a treatable chronic condition. In addition to individual antiretroviral drugs, preventive medications, fixed dose combination drugs, and monoclonal antibodies have revolutionized the fight against the AIDS epidemic. So far, FDA has approved 32 antiretroviral drugs, 1 pharmacokinetic enhancer and 21 fixed dose combinations to treat HIV/AIDS patients. Thanks to these therapeutic advancements, after a year of antiretroviral treatment a 20-year-old patient diagnosed with AIDS has a life expectancy of 78 – nearly the same as the general population!

Yet even as we are better prepared to combat the spread of AIDS than ever before, AIDS remains a global threat. As we reflect on the enormous progress in the treatment of HIV and AIDS, we must remember that these accomplishments are the shared work of scientists, industry, regulators, patients, and advocates. The AIDS crisis has demanded that a broad range of stakeholders with diverse perspectives and talents work together to develop effective therapies, redesign investigational studies, expedite the drug review process and increase access for as many patients as possible. This exhibit, assembled in 2018 to commemorate the 30th anniversary of World AIDS Day and FDA's Division of Antiviral Products, documents the success of their efforts.

AIDS Fraud

In the early years of the AIDS Crisis, when researchers were struggling to identify the virus that was causing this rapidly expanding epidemic, patients were inundated with misinformation about the cause and treatments of the disease. Fraudulent AIDS “cures” – from Vitamin C and hydrogen peroxide, to imitation nonoxynol-9 spermicides such as Lubraseptic – preyed on patients’ fear and desperation and their eagerness to take a proactive role in preserving their health. During this period, FDA took action against numerous fraudulent cures that claimed therapeutic benefits in treating or preventing HIV and AIDS.

HIV Test Kit

On March 4, 1985, the year following the identification of the Human Immunodeficiency Virus (HIV) as the cause of AIDS, Health and Human Services Secretary Margaret Heckler announced FDA’s decision to license the first test for the virus. The test was designed to detect antibodies to the virus, an indication that the patient had been exposed, though other symptoms of the disease may or may not yet have developed. The license permitted the manufacturers to distribute the test to the nation’s 2300 blood banks and plasma centers.

ACTUP Protest at FDA Headquarters

In 1988, hundreds of AIDS activists organized by the AIDS Coalition to Unleash Power (ACTUP) surrounded the FDA Parklawn headquarters building to protest what they perceived as an obstructionist drug approval process that was preventing access to possibly useful treatments … and costing patients their lives. The ACTUP protest publicized patients’ concerns to improve access to emergent therapies and pushed FDA to promulgate new accelerated approval regulations to accompany new treatment regulations for Investigational New Drugs implemented in 1987, both of which enabled desperately ill patients access to promising new therapies.

AZT (zidovudine)

In March of 1987, FDA approved zidovudine (AZT) as the first antiretroviral drug for the treatment of AIDS. The high cost of the drug inhibited access for many patients and prompted Congress to authorize $30 million in emergency funding to states to pay for low income patients’ treatment with AZT – a precursor to the AIDS Drug Assistance Program launched in the 1990s. Later in 1987, FDA authorized the sale of male condoms to include HIV prevention as an indication for use, marking a major stride in public health communication and safe sex and HIV/AIDS transmission.

Founding of DAVP

In 1988, seven years after the AIDS Crisis began, FDA created a new Division of Antiviral Products (DAVP) in the Center for Drug Evaluation and Research (CDER). Under the leadership of its first director, Dr. Ellen Cooper, DAVP was given the principal responsibility of reviewing applications for antiviral and antiinfective drugs to treat HIV/AIDS. This infrastructural change signified a growing number of new drug applications (NDAs) for HIV/AIDS, as well as the agency’s commitment to expedite access and spur innovation.

Patient Engagement

In 1987, the AIDS quilt was assembled for the first time on the national mall in Washington, D.C., a testament to the widespread cultural impact of the AIDS Crisis. By the 1990s, AIDS activists organized thousands of supporters together for AIDS Walks in cities around the nation. This movement pushed FDA to involve patients in the policy making process. The new Office of AIDS and Special Health Issues was tasked with building relationships with patient communities, and FDA created an initiative to include at least one patient representative on every advisory committee.

PEPFAR Drugs

Under the President's Emergency Plan for AIDS Relief (PEPFAR), a five-year, $15 billion commitment launched in 2003 that involved several federal agencies, host country governments, and other participants, FDA began to review and grant full or tentative approval on an expedited basis of applications for HIV/AIDS drugs, particularly pediatric preparations, for distribution only in resource-limited nations. The program continues to this day, and CDER recently granted the 211th approval or tentative approval of an HIV/AIDS drug under PEPFAR.

Atripla

FDA's approval of Atripla in July of 2006 marked a watershed in HIV treatment. Prior to that, HIV patients were typically prescribed three different antiviral medications administered as separate pills. Gilead Science's Atripla combined these drugs – efavirenz, emtricitabine and tenofovir – into a single fixed-dose combination pill. Instead of a "cocktail" of multiple medications, HIV treatment could now be simplified into a once-daily single tablet regimen.

Truvada for PrEP

Truvada, Gilead Science's combination of tenofovir disoproxil fumarate and emtricitabine, was first approved as a treatment for HIV in 2004, and quickly became a staple of HIV/AIDS pharmacopeia. Eight years later, it earned new significance in the history of AIDS treatment when it was also approved for pre-exposure prophylaxis (PrEP), making Truvada the first drug marketed as an HIV prevention method. Since then, many public health campaigns have sought to increase awareness about Truvada for PrEP among at risk populations, and to encourage its use in conjunction with other safe sex practices, such as condom use.

Trogarzo

In March of 2018, FDA approved the first monoclonal antibody treatment for HIV. TaiMed Biologics USA's Trogarzo (ibalizumab-uiyk) offers a treatment option to the small percentage of HIV-1 positive patients that are multidrug resistant, providing "significant benefit to patients who have run out of HIV treatment options," according to Jeff Murray, M.D., deputy director of the Division of Antiviral Products.

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