HIV/AIDS Budget

Richard Klein
Office of Special Health Issues
Food and Drug Administration

Program	FY 2009 Actual Expenditures	FY 2010 Estimate
Human Drugs	*$36,643*	*$37,742*
Biologics	*$32,045*	*$33,006*
Medical Devices	*$2,506*	*$2,339*
Toxicological Research	*$102*	*$105*
Office of the Commissioner	*$3,355*	*$3,456*
Field Activities	*$22,187*	*$32,548*
Total HIV/AIDS	**$ 96,838**	**$109,196**

(Dollars in thousands)

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Human Drugs/Biologics
Therapeutics

- Work with sponsors (developers) of new products to assure that HIV clinical trials are well designed, scientifically sound, ethically conducted, and appropriately analyzed
- Work with the pharmaceutical industry and other researchers in the development of useful immune-based therapies, which may contribute to the body's own defense against HIV, and improve clinical outcome over drug therapy alone
- Provide technical assistance to HIV/AIDS researchers and manufacturers of medical treatments, and microbicides for prevention of HIV

Human Drugs/Biologics Therapeutics

- Review data collected from clinical trials related to HIV to establish evidence of safety and effectiveness of antiretrovirals and other therapeutics
- Collect and evaluate information on adverse events associated with marketed HIV/AIDS drug products (post market surveillance)
- Disseminate timely product information to the medical community and the general public when safety issues arise related to HIV therapies
- Work with the pharmaceutical industry, patients and physicians to provide information and a regulatory framework within which to allow access to promising investigational (unapproved) products when no practical, approved alternatives are available. Tens of thousands of AIDS patients have accessed promising, unapproved therapies for HIV through expanded access programs

Biologics
Diagnostic Testing and Blood Screening

- Assure that diagnostic and blood screening assays for HIV are sensitive and specific for the detection and/or quantification of HIV in blood and other body fluids, including urine and oral fluid
  - Diagnostic tests, such as enzyme immunoassay (EIA), chemiluminescent, Western Blot antibody, and Antigen/Antibody Combo tests, used to diagnose HIV exposure or infection in individuals (HIV 1, groups M and O, and HIV 2)
  - Patient monitoring tests, such as polymerase chain reaction (PCR) viral load and genotyping/resistance tests, used for prognosis and therapeutic management
  - Blood screening tests, including EIA, nucleic acid and PCR tests, used to detect blood collected from infected individuals, and prevent it from entering the blood supply
  - Tests for organ and tissue donors

Biologics
Diagnostic Testing and Blood Screening

- Evolving FDA guidance for blood banks
  - Recommendations for Management of Donors at Increased Risk for Human Immunodeficiency Virus Type 1 (HIV-1) Group O Infection
  - Guidance for Industry: "Nucleic Acid Testing (NAT) for Human Immunodeficiency Virus Type 1 (HIV-1) and Hepatitis C Virus (HCV): Testing, Product Disposition, and Donor Deferral and Reentry," intended to assist with testing, product disposition, donor deferral, donor notification, donor reentry, and lookback

Biologics
Blood Safety

- Help ensure the safety of the nation's blood supply by
  - minimizing the risk of infectious disease transmission and other hazards through registration and inspection of blood banks and other blood processing facilities
  - licensing and inspection of plasma centers, evaluating and licensing biologics manufacturing firms who make blood derivative products, such as clotting factor
  - developing necessary regulations, compliance programs, and guidelines to protect the blood supply in the United States

Biologics
Vaccines

- Work with industry and government developers of both preventive and therapeutic vaccines for HIV, including
  - Recombinant Live Vectors
  - Nucleic Acid-based vaccines
  - Inactivated HIV-1
  - Retroviral Vectors
  - Envelope Proteins/Peptides
  - DNA Plasmid
  - Core Proteins/Peptides.

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Medical Devices

- Surveillance and quality assurance of barrier products, including condoms, the female condom, dental dams, surgical and medical gloves, etc. In addition to monitoring the quality and integrity of these products, the agency works with sponsors to develop and test new materials (such as the non-latex condoms made of urethane plastic) and to label products for new uses, including development of tests for virus transmission through barrier products

- Review/approval of therapeutic devices, such as facial fillers for treatment of lipoatrophy related to HIV/AIDS

Medical Devices

- Ensuring proper device sterilization and disinfection in reprocessing of medical devices between patients by health care facilities to prevent transmission of AIDS/HIV

  - Organizing and presenting meetings/conferences about sterilization
  - Review of premarket submissions, compliance actions and/or equipment for reprocessing of devices, reusable devices
  - Regulatory laboratory testing of germicides, sterilizers and related products
  - Laboratory activities including research on the activation of the HIV virus by radiation and on the inactivation of microorganisms through the use of sterilizing or disinfecting agents
  - Conducting, planning, or consulting on epidemiology studies of the role devices or radiation play in the potentiation, transmission, prevention, detection, or treatment of HIV infection and closely associated conditions
  - Publication of information related to the above subjects

Guidance for Industry

Active development and refinement of *Guidance for Industry* for regulated products, such as:

- Fixed Dose Combination Products for HIV
- Labeling requirements for condoms
- Nucleic Acid Testing (NAT) for HIV, including product disposition and donor deferral and reentry

As well as Notices and meetings to collect public comment on proposed guidance, and presentations to educate affected industry

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Toxicological Research

National Center for Toxicological Research (NCTR)
provides peer-reviewed research based on needs identified by its Science Advisory Board, FDA product centers, other government agencies, industry, and academia.

- Research on lactic acidosis, a fatal outcome of extreme mitochondrial toxicity especially in women on antiviral treatment, to provide critical information to FDA for the development of guidelines to plan new treatment strategies to reduce the frequency and severity of antiretroviral-related toxic effects in women, particularly in pregnant women
- Carcinogenicity studies in mice of antiretroviral drugs, used for the prevention of mother-to-child transmission of HIV-1 infected pregnant women to determine the long-term consequences of administration of the drugs to what are essentially disease-free individuals

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Office of the Commissioner

- Patient Representative and Consultant Programs
  - Recruitment, training and education
- Community Outreach
  - Meetings/conferences
- Communication
  - HIV/AIDS web site
  - FDA HIV E-list
    - safety updates, approvals, meeting notices, guidance documents, opportunities to comment
  - Telephone and e-mail communication related to HIV/AIDS (patients, physicians, nurses, insurance carriers, press)

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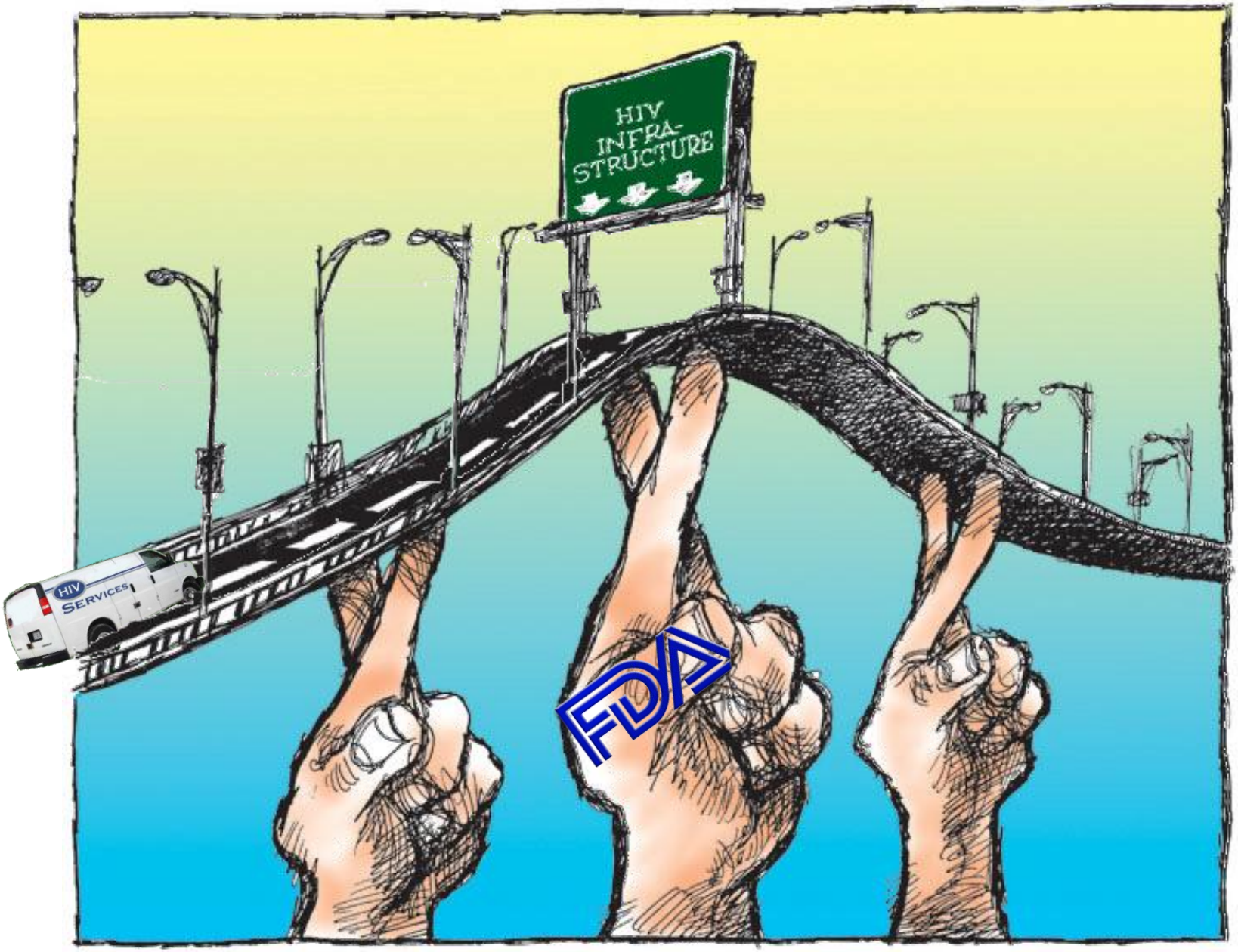
Field Activities
Regulatory Affairs

- Inspection of clinical trial sites and study records
- Audit of Institutional Review Boards (IRB)
- Inspection of medical product manufacturing facilities
- Blood bank establishment inspections


HIV
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SERVICES
FDA