Workshop on Transforming Di es into Products: Maximizing NIH's Le Catalyze Technology Transfer

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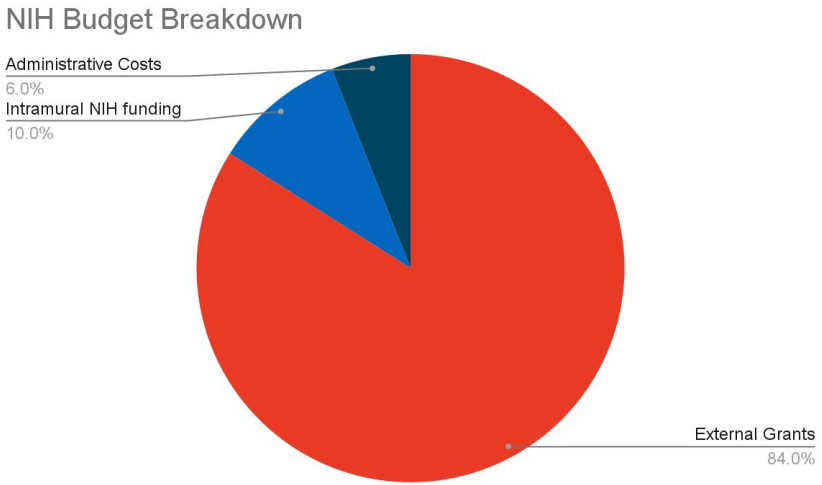
Why Universities?

$47.5 Million

Total NIH Budget

Of which 84% goes to external grants at universities, medical centers, and research institutions.



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Innovation at Universities has been a balance between access, affordability, and accolades.

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The Scientist's Story

By William Prusoff
March 19, 2001

Give this article

NEW HAVEN — I once helped create a drug that could enable millions of people to lead better and longer lives. At Yale University's pharmacology laboratory, my late colleague Dr. Tai-shun Lin and I developed d4T, an antiretroviral drug that now forms part of a "cocktail" used by people with H.I.V. and AIDS. The patent was held by Yale, which licensed it to Bristol-Myers Squibb for development. At great expense, Bristol-Myers took d4T through the necessary trials, then brought the drug to market under the name Zerit.

More recently, it became apparent that the drug Dr. Lin and I had developed was not reaching millions of desperately suffering people because they lacked the money to purchase it. However, Yale did hold the patent. The medical aid group Doctors Without Borders learned this and approached the university late last month. At the same time, a group of law students at the university became interested in the issue. The campus newspaper published an article about it on March 2, mentioning my role in developing d4T. A New York Times reporter called, and I said I thought d4T should be either cheap or free in sub-Saharan Africa. I believe Dr. Lin, were he still here, would agree.

BUSINESS

Research behind COVID-19 vaccines reaps close to $1 billion in royalties for Penn

Penn officials said they are plowing the money back into early-stage scientific research.

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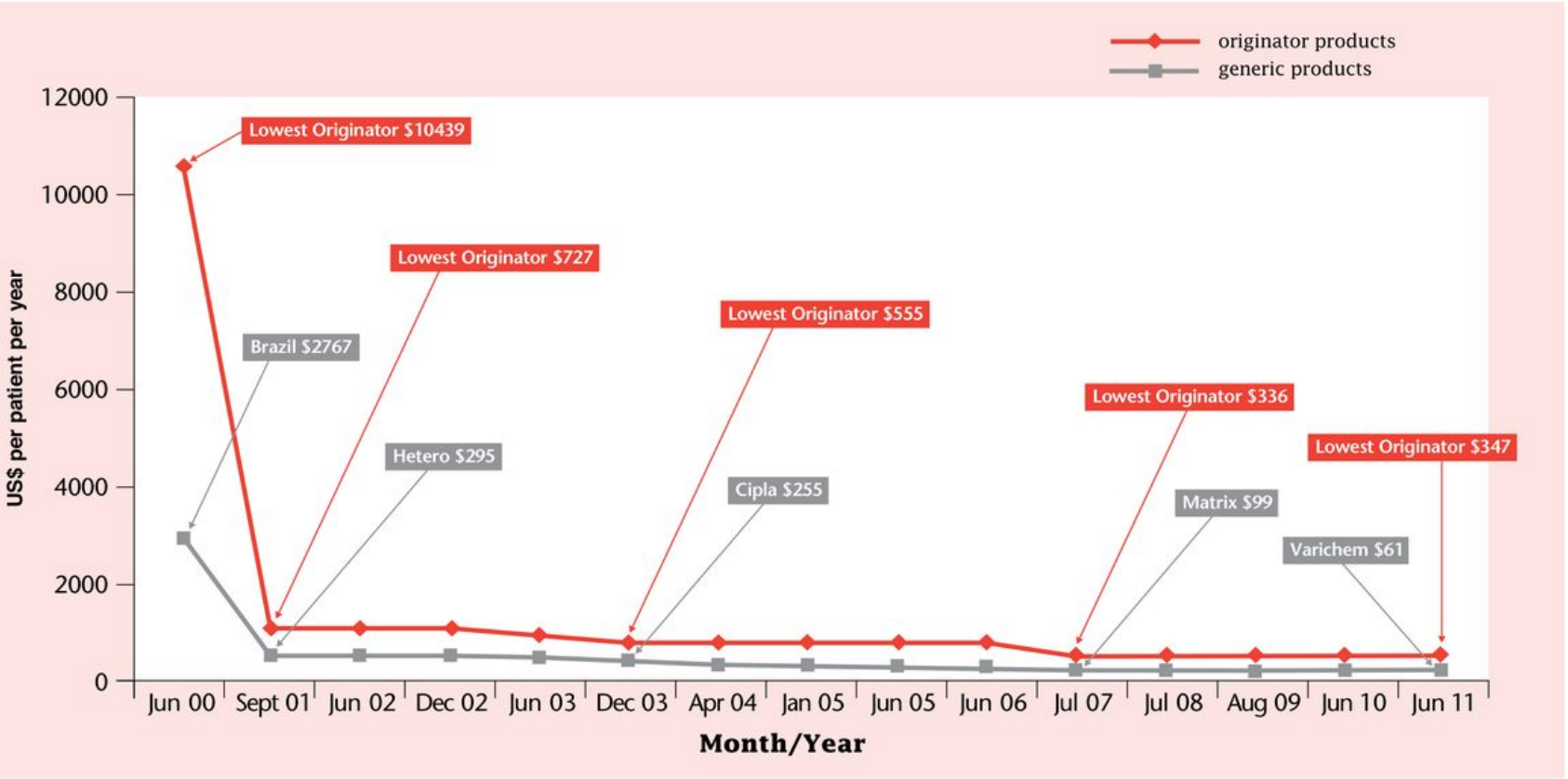

GRAPH 3: GENERIC COMPETITION AS A CATALYST FOR PRICE REDUCTIONS.

The fall in the price of first-line combination of stavudine (d4T), lamivudine (3TC), and nevirapine (NVP), since 2000.

Affordable Access Plan

- The AAP is contractual language, added to the terms of a licensing policy
- Requires the licensee to produce an “affordable access plan” and have it reviewed by the university when the product is approved.
- Plan can be accepted, rejected, or amended by licensor.
- Creates a check, and mentions licensing and partnerships as potential methods to ensure access and affordability.
- Applies to all health technologies.

Downstream Consequences

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BUSINESS

UCLA's effort to patent a costly prostate cancer drug in India hurts the poor, critics say

BY JAMES F. PELTZ
OCT. 22, 2017 7 AM PT

After scientists at UCLA created a breakthrough treatment for prostate cancer, it generated more than half a billion dollars for the university.

But deals struck with drugmakers also obligated university officials to help pursue patent protection for the drug around the world. Now, consumer activists claim that UCLA's efforts are propping up the drug's high prices — which can top $130,000 a year for a cancer patient in the U.S. — and keeping poor patients in less-developed nations from getting cheaper versions.

The university holds the patent on the chemical compounds its researchers developed that were used to create the drug called enzalutamide, which is sold under the name Xtandi.

PHARMALOT

STAT+

NIH rejects bid to cut a cancer drug's price by sidestepping patents

By Ed Silverman March 22, 2023 Reprints

ADOBE

In a long-awaited decision, the National Institutes of Health rejected a petition urging the agency to use a controversial provision of federal law to widen access to a cancer drug by forcing the manufacturers to license their patents.

The focus of the petition was the cost of the Xtandi prostate cancer drug, which has a list price of between $160,000 and $180,000. The medicine was developed at the University of

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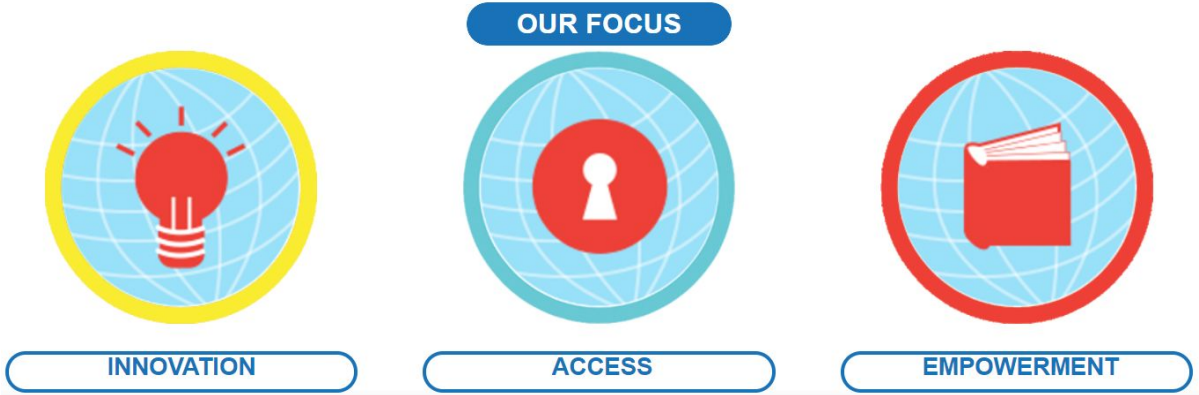
EQUITABLE TECHNOLOGY ACCESS FRAMEWORK (ETAF)

Every health technology developed by publicly-funded research or at a publicly-funded institution (hereinafter "publicly-funded research institution" "PFRI") with the potential for further development into a medicine, vaccine, medical device, procedure and system[1] (hereinafter "health technology") should be transferred with a concrete and transparent strategy to make affordable versions equitably available for patients. This document acts as a framework for this process to be adapted based on the context. Technology transfer is complex and occurs through different modalities, hence each case will be unique. PFRIs should therefore implement concrete Global Access Strategies that adhere to all of the following 3 Goals.

Goals of ETAF

1. **Improve Global Equitable Access**
   a. Affordable + Accessible to ALL
2. **Promote Further Development of Health Technologies**
   a. Ensure intellectual property doesn't act as a barrier to further research
3. **Improve Transparency in Health Technology Transfer**



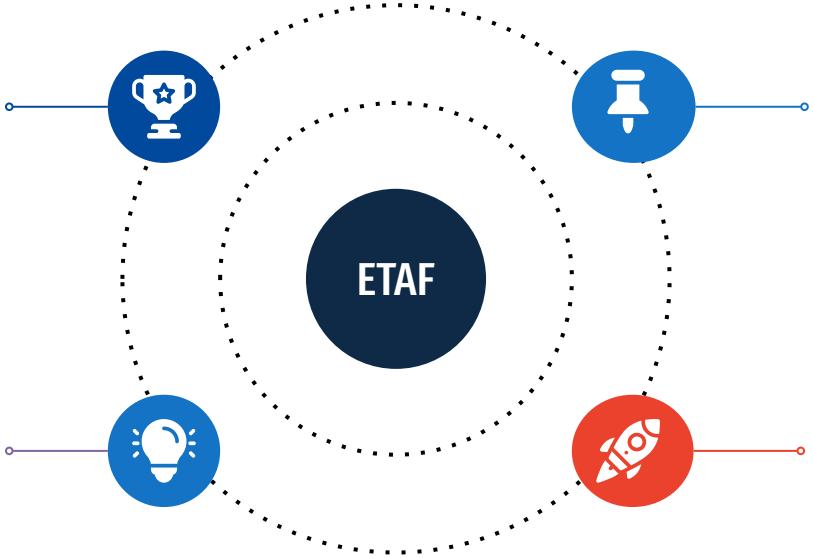
ETAF Modalities

Licensing

PFRI grants exclusive or non-exclusive license to third party

Spin-Off Companies

PFRI creates a company to develop research into a product



Product Development Partnerships

PFRI collaborates with third party to develop a product from research

Commissioned Research

Third party commissions university to do research on a specific issue

Concerns over licensing policy at the university level

- **Leverage** - can a university license really have leverage over access, especially with more complex compounds?
- **Commercialization -** How to ensure these policies are not risking commercialization strategy.
- **Willingness to Enforce -** University pressures are at the whim of administrations, with turnover and varying priorities.
- **Contractual Obligations**

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The NIH can and should lead the way on affordable access provisions/reasonable pricing to:

- Level the playing field
  - Create space for university licensing innovations
  - Amplify impact across NIH investment portfolios
  - Create a true public return on investment - based on access, affordability
- Improve transparency of NIH licensing:
  - Make licensing agreements transparent (or more transparent)
  - Use REPORTer and ClinicalTrials.gov to their full potential
  - Report the costs of clinical trials

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