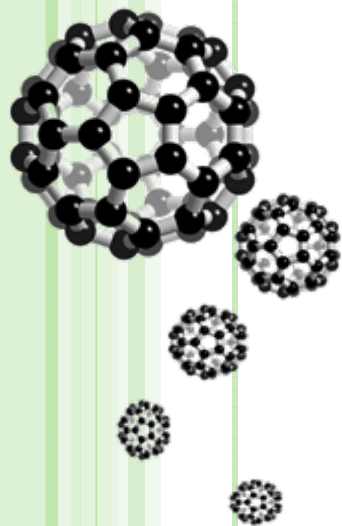


**Wendy R. Sanhai, Ph.D.**

**Senior Scientific Advisor  
Office of the Commissioner, FDA**

*AFIB THINK THANK: 04-27-09*

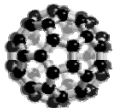


## Spectrum of Opinions



### Some Fundamental Questions as we go forward:

1. Do we have a critical public health need?
2. By consensus, can we have a vote to move forward?
3. Key questions this registry will answer...purpose/guidelines/parameters?
4. What Safety/Efficacy/Outcome measures?
5. Can existing efforts (registries/databases) answer these questions?
6. How much will this (new) registry cost?
  - Personnel; infrastructure; once built, how mtc? Report on outcomes?
7. Pilot? Small scale: implement incrementally?
8. Design elements: what data? Technical specifications?





**PREDICTIVE TOOLS**

- Evidence-based medicine
- New hypotheses...new trial designs

**Where we ought to be**

**REGISTRIES/DATABASES:**

- Product Requirements?
- Coverage Decisions?
- Measures of Benefits?

**NOW:**

- Administrative Burdens?
- Implementation Issues?
- What's available now/What's needed

## Context: FDA's Mission

“The FDA is responsible for **protecting the public health by assuring the safety, efficacy, and security** of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

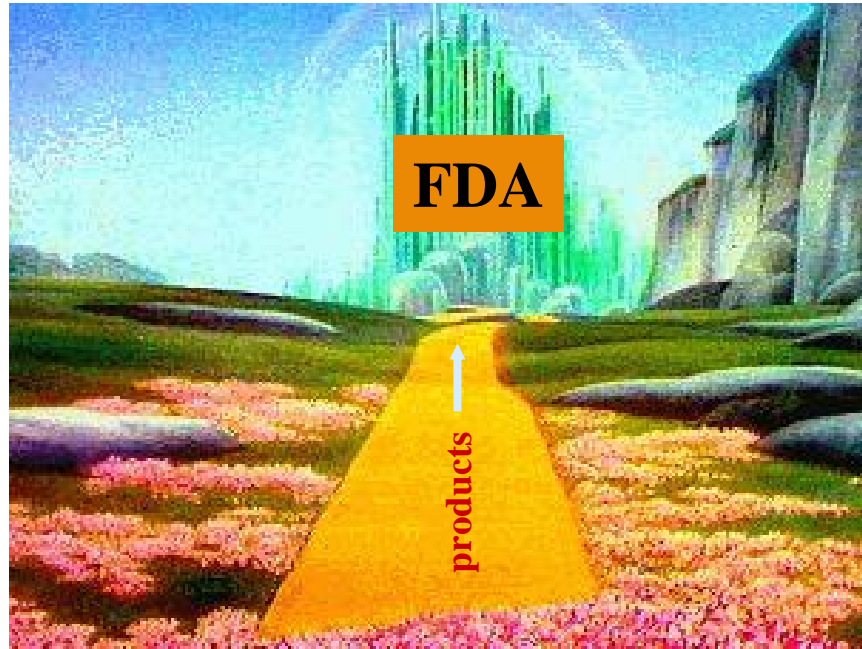
The FDA is also responsible for **advancing the public health by helping to speed innovations** that make medicines and foods more effective, safer, and more affordable; and **helping the public get the accurate, science-based information** they need to use medicines and foods to improve their health.”



# R&D and the Future



**Personalized Medicine**

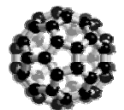


**Safety Assessments**  
**Simulation Modeling**

**Validated Predictive & Evaluative  
Research Tools/Tests**

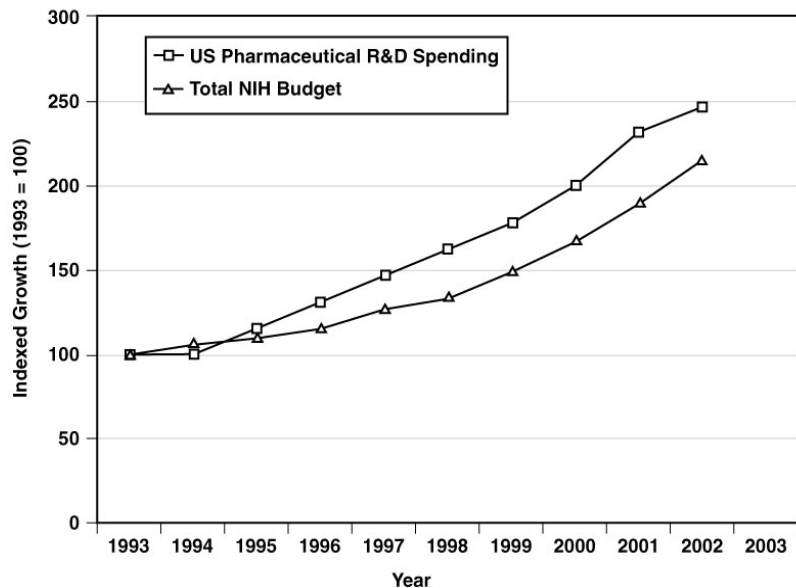
**★ Validated for intended use/s**

**Regulatory Guidances and  
Standards**

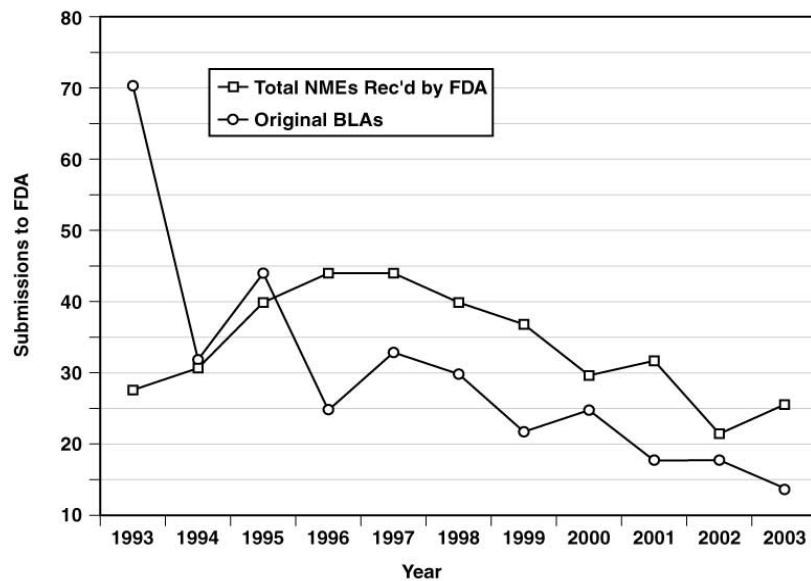


# TRENDS IN BIOMEDICAL RESEARCH

### 10-Year Trends in Biomedical Research Spending

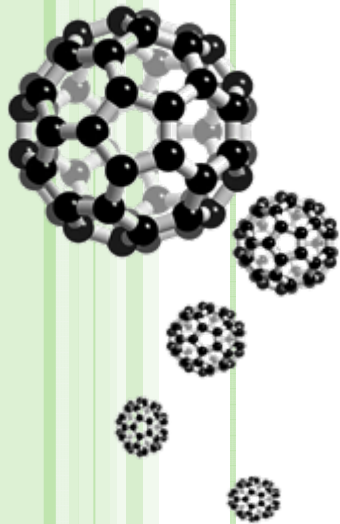


### 10-Year Trends in Major Drug and Biological Product Submissions to FDA



# WHY USE A PPP BUSINESS MODEL?

- Share the risks and benefits
- Guidance on industry standards: R&D and manufacturing
- Leveraging expertise and infrastructure
- Developing a transparent product development pathway
- Lowering the cost to each partner:
  - Sharing administrative expenses
  - Sharing R&D expenses (billions!)



# Basic Steps in Developing PPPs with FDA

*(not comprehensive! not consecutive!)*

Start with the Public Health Need, SCIENCE!  
Identify Priorities for multiple stakeholders

Identify gaps/avoid duplication  
Hold expert workshop, Identify partners etc.

- Leverage resources/expertise
- Identify partners: define roles/responsibilities
- Co-develop: proposals, budgets, timelines etc.
- Implement joint projects
- Share data in public domain

## Some Benefits

**PRIVATE PARTNERS: Know-how, Tools, Project Selection, Go/No Go Decisions**

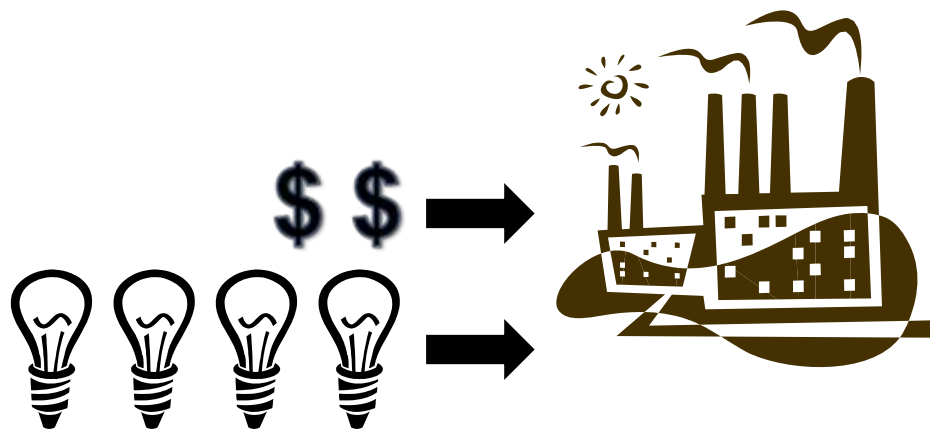
**ACADEMIA: Best Practices, Publications, Patents, Additional Grants**

**FDA: Guidances, Standard-setting, Evaluative Tools, Clinical Data**

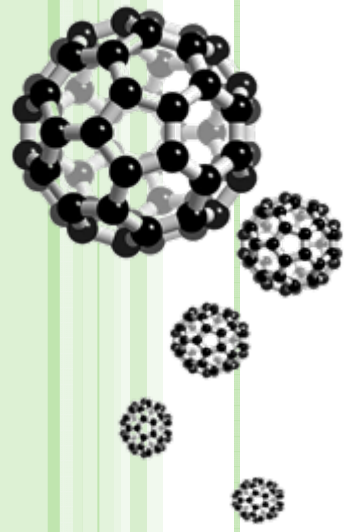
**Patients: faster, safer and cheaper medical products!!!!**



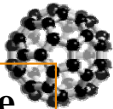
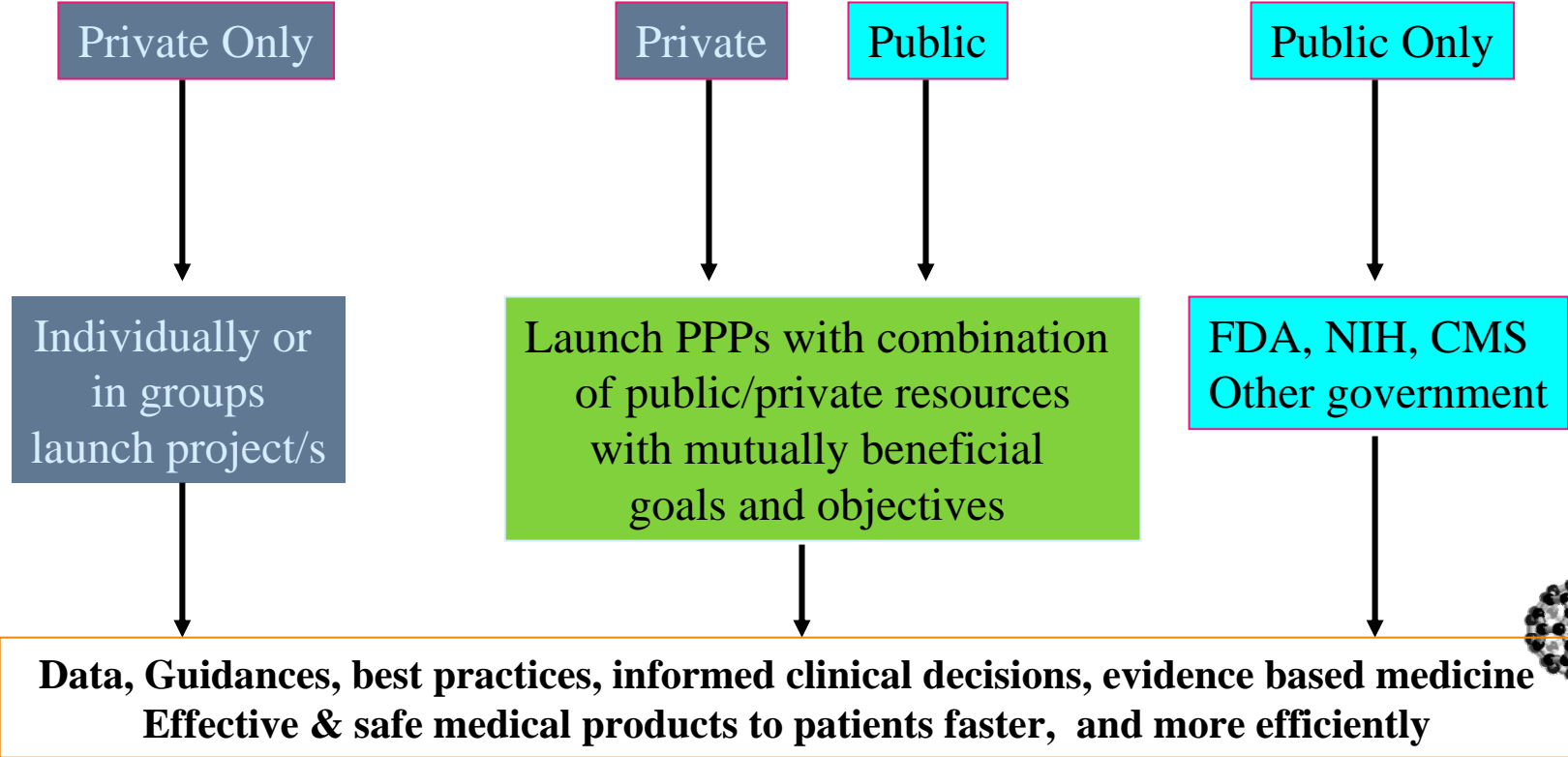




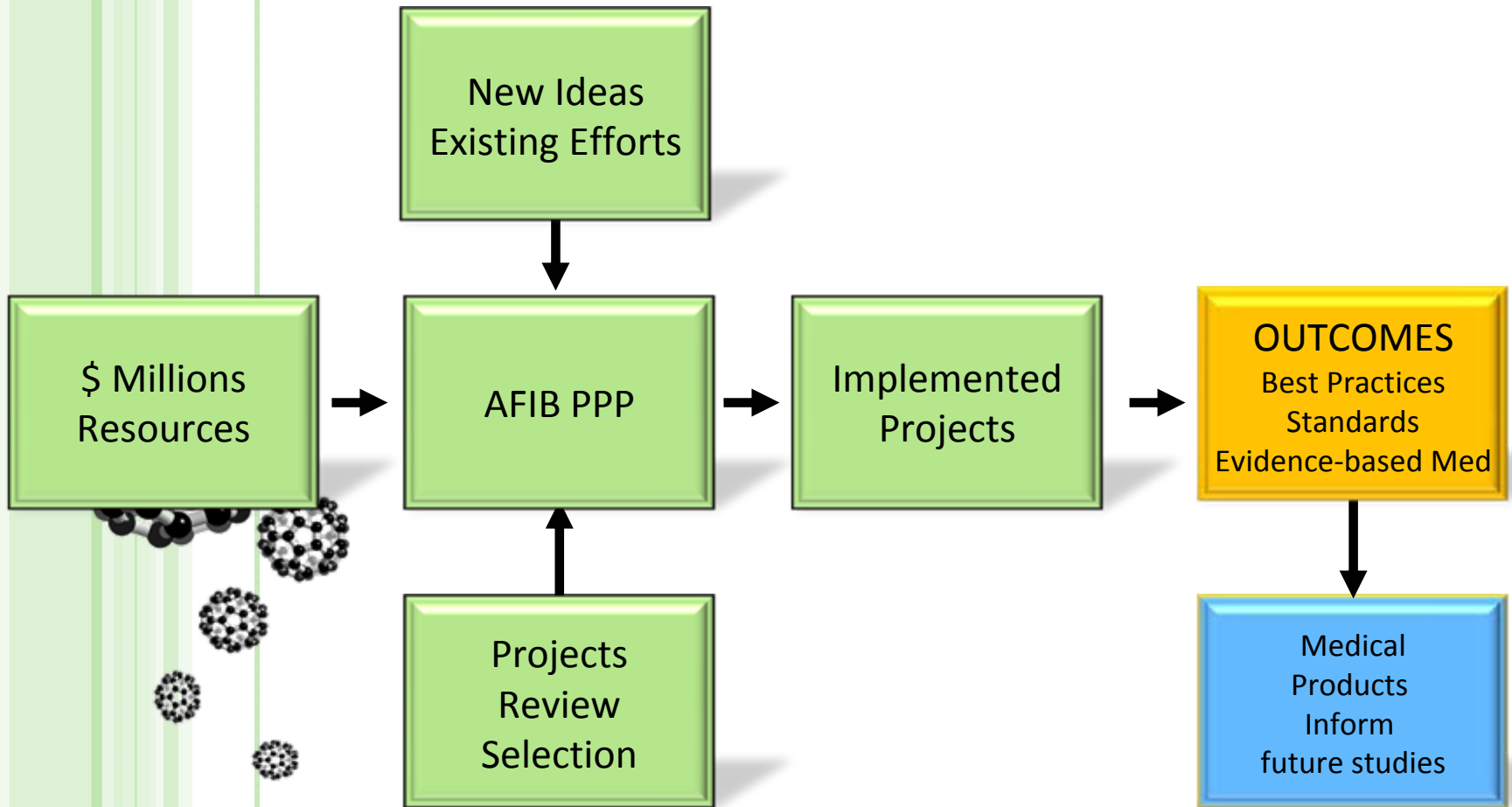
# PPP FINANCIALS



# BASIC COLLABORATIVE FUNDING PARADIGM



# FLOW OF RESOURCES



**Thank You!!**

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