BERKELEY CENTER
FOR HEALTH TECHNOLOGY

Incentivizing R&D through Innovation Prizes

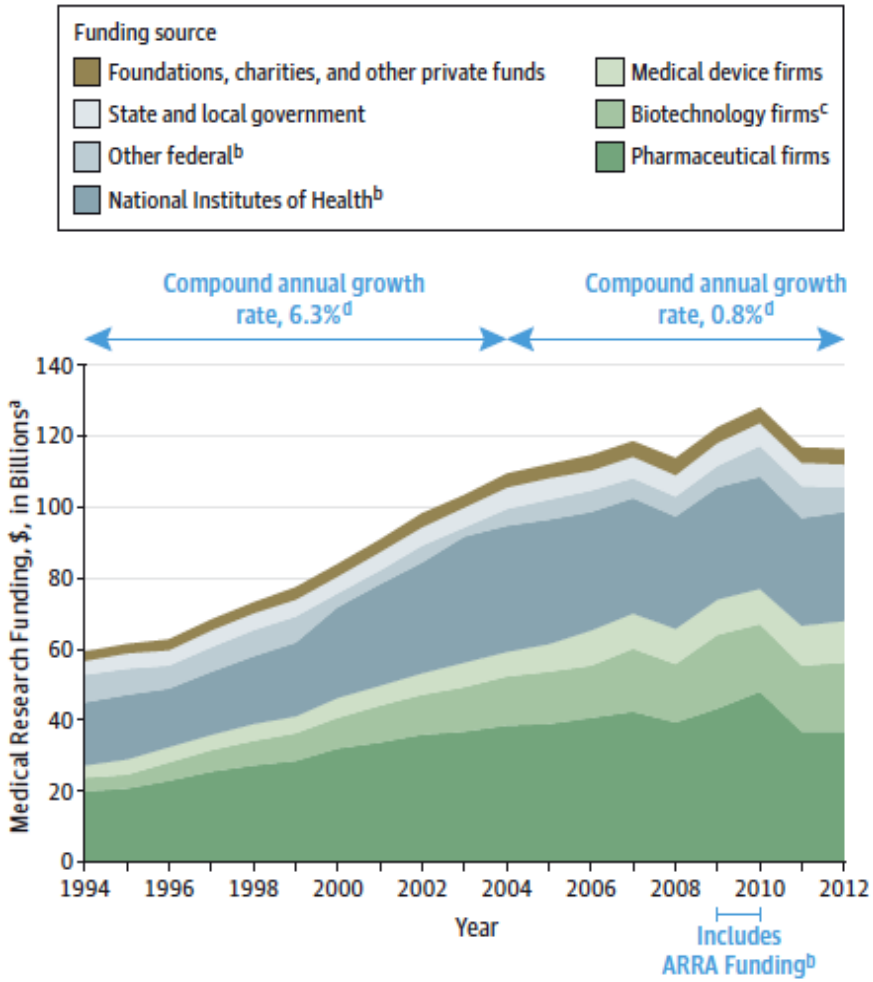
PH222A
2019

Overview

- Funding innovation for low-cost tests and treatments
- Prize funding and other pull mechanisms
- Challenges of TB diagnosis and treatment in developing countries
- Prizes for treatment of antibiotic resistant infections
- Prizes for TB Diagnostic Tests

Funding for Pharmaceutical R&D

- Pharmaceutical R&D financed largely by industry profits, based on special institutional features designed by public policy
  - Patent protections allow innovators to price their products at monopolistic rather than competitive levels
    - Publicly subsidized health insurance permits patients to afford drugs priced at these high monopolistic levels
- Creates incentive for industry to focus R&D resources on tests & treatments that can generate high prices and profits



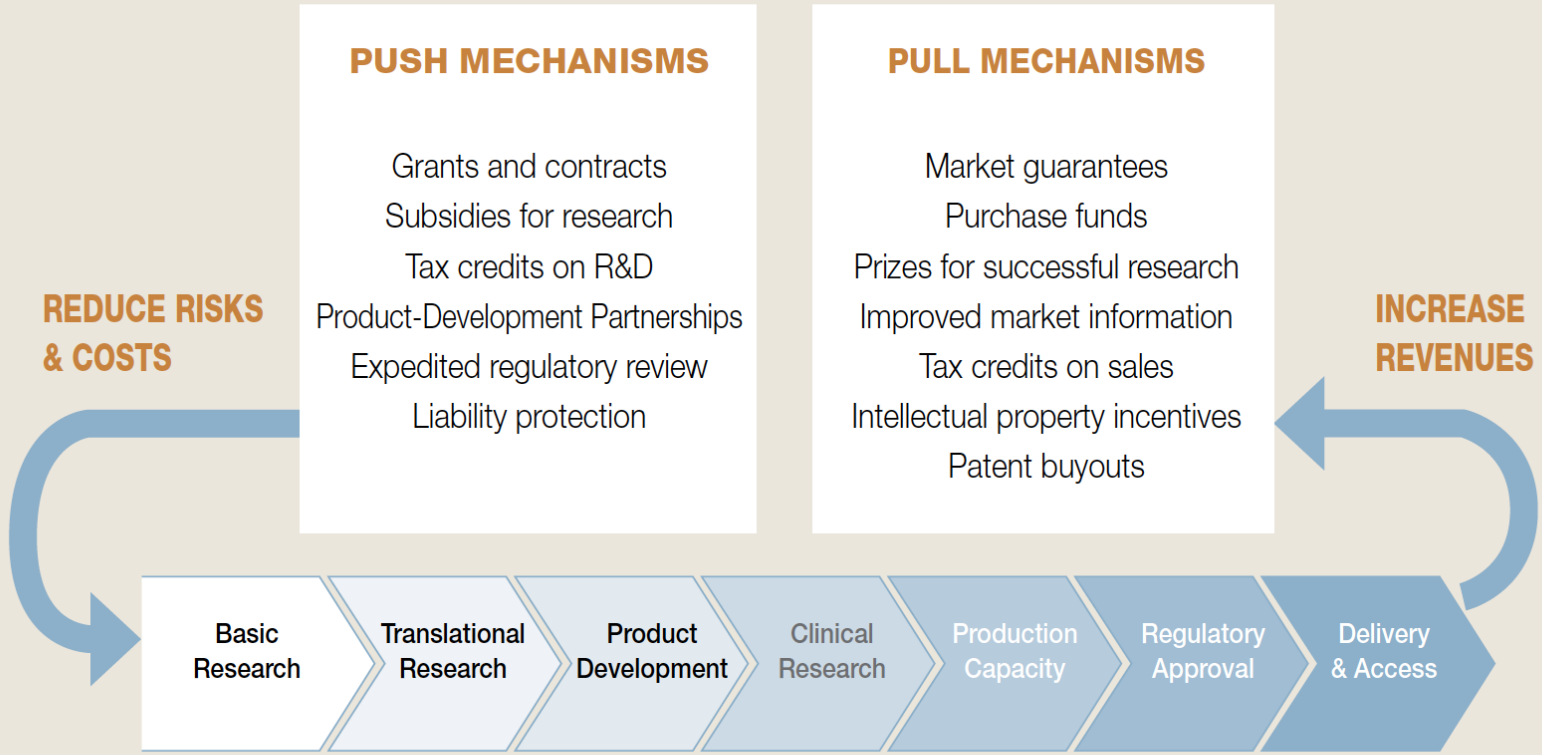
Source: Sustaining Innovation While Ensuring Affordability For Specialty Pharmaceuticals, 2018- UC Berkeley

Importance of Alternative Mechanisms to Fund R&D

- The developing world has a great need for new, affordable drugs, vaccines and tests for tuberculosis and Chagas
  - Treatments for some diseases (e.g., Chagas) are not researched because the illnesses are only prevalent in low-income nations that cannot afford to pay high prices
  - Others (such as TB) are prevalent in both rich and poor nations, but the tests and treatments used in rich nations are too expensive and/or require an extensive infrastructure of supply and provision
- This has prompted interest in alternative funding mechanisms that substitute for (or supplement) prices
- These funding sources can either subsidize the R&D (push mechanisms) or increase payments and revenues for the treatments (referred to as pull mechanisms)
- These alternatives are important for low-income nations but are of interest in rich nations seeking lower prices

Push and Pull Mechanisms for Promoting R&D

Figure 2.1. Push and pull mechanisms for health research and development



Source: Adapted from International AIDS Vaccine Initiative

Comparison of Funding Mechanisms

	Prices & Profits	Research Grants	Tax Incentives	Innovation Prizes
Advantages	• Has be very successful in promoting innovation including for illnesses afflicting disadvantaged populations (HIV, HCV) • Reduces pressure on taxes (given taxpayer resistance) • Competition spurs risk-taking; capital markets (investors) willing to bear considerable risk	• Can be targeted at questions in basic science, with spillover benefits for many disease areas • Supports nation's life sciences ecosystem, an important part of the modern economy • Can be targeted at areas of high visibility to policymakers	• Political advantage over grants, do not need appropriation each year • Offer high value to startup firms that cannot fund research from profits because they lack profitable products • Can be targeted to domains of special concern (e.g., orphan illnesses)	• Pays only for successes (in contrast with grants and tax incentives) • Can increase interest among participants thru recognition & glory • Can raise funds from philanthropist and crowd-sourcing, reducing reliance on taxes • Do not require specifying path to desired end
Disadvantages	• Incentivizes R&D in profitable areas • High prices limit access in high income as well as low income nations • Creates incentives for payers to create obstacles to patient access (prior authorization, cost sharing)	• Must sustain taxpayer support in the face of competing priorities & budgetary fatigue • Subject to congressional whims ('wars,' 'moonshots,' 'imperatives') • Funding agencies subject to capture by politically-potent recipient orgs	• Reduced tax revenues indirectly require additional taxes be raised, expenditures on other programs be reduced, or budget deficit be allowed to increase • Targeted cuts could reward most those firms that have aggressively domiciled patents in low-tax nations	• Require clear success criteria, limits use for early stages where goals are unclear but ambitious; Milestone payments mitigate this problem • Exclude developers unable to fund R&D upfront (e.g., startups) • Difficult to ascertain optimal prize size

Source: Sustaining Innovation While Ensuring Affordability For Specialty Pharmaceuticals, 2018- UC Berkeley

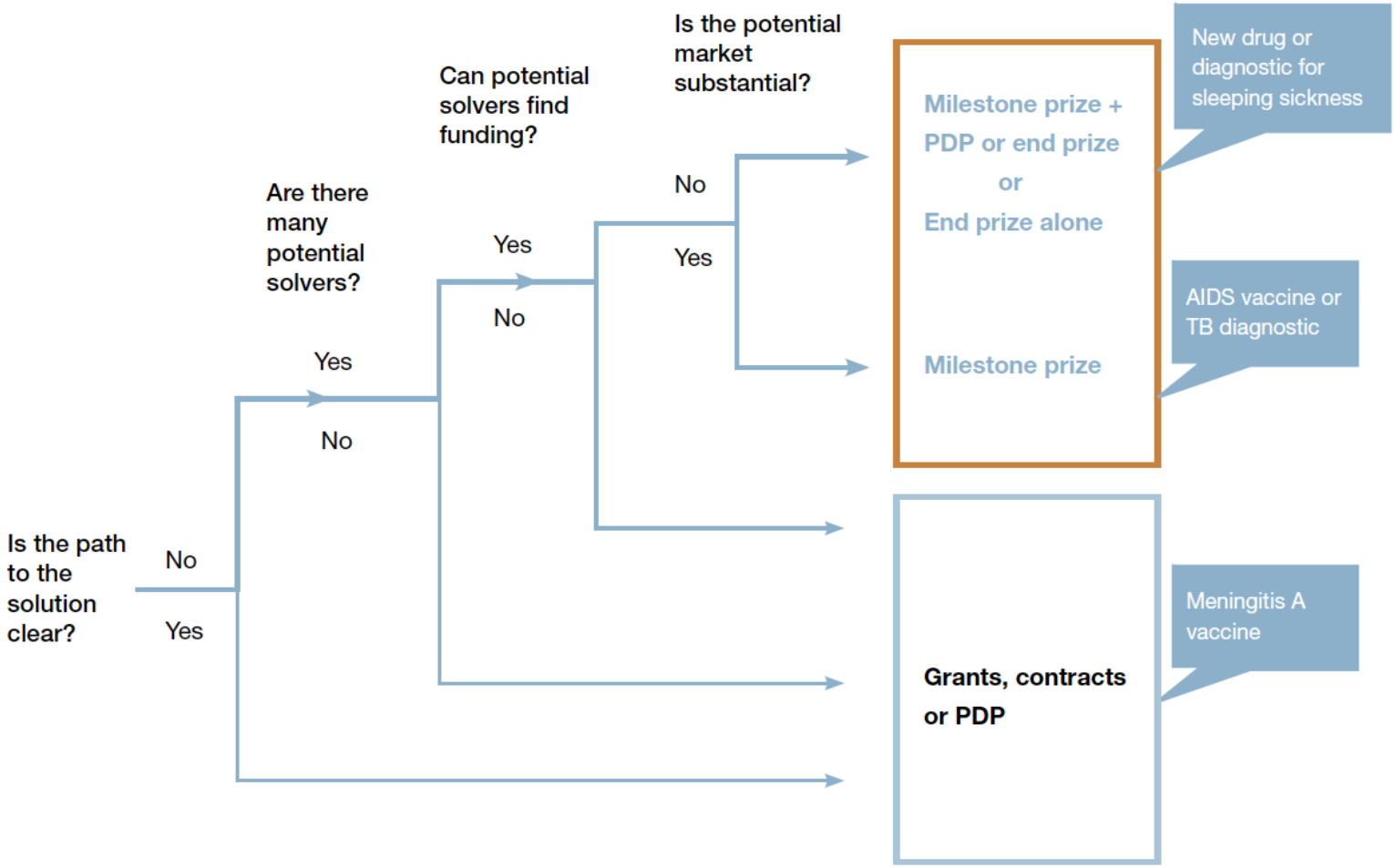
Advantages and Disadvantages of Prizes as Funding for R&D

- Prizes reward successful innovation, not merely investments
- Can be targeted to worthy conditions or populations
- Permit a wide range of funders and co-funders ('crowd sourcing'), thereby reducing pressure on government taxes
- Prize are not linked to volume of sales, removing incentive for over-marketing
- Corporate acquisitions and licenses serve as incentive for startups, and are linked to success at each stage
- But success worthy of the prize needs to be defined in advance. Payers may opportunistically find grounds not to award prize, once the desired product exists
- Some source of funding must be found for the prizes

Source: Sustaining Innovation While Ensuring Affordability For Specialty Pharmaceuticals, 2018- UC Berkeley

When to Use Innovation Prizes

Figure 5.1. Decision tree for prizes for health product development



Source: Prizes for Global Health Technologies, 2011- Center for Global Health R&D Policy Assessment

Determining Optimal Prize Size

- Prizes should be large enough to motivate a sufficient number of product developers to invest in the required R&D but not larger than the expected benefit of the new product
  - Participation can be motivated by factors besides prize size, including favorable publicity and desire to solve social problems
- For-profit developers considering a prize on commercial grounds weigh expected investment (cost of R&D) against potential reward (prize size). They consider the risks:
  - *Technological risk*: developer may not be able to develop specified product or reach the milestone. Most product-development efforts fail
  - *Competitive risk*: other product developers will win and then R&D investments by non-winners are wasted.
  - *Cost of capital*: can be very high for small firms unable to finance R&D from cash flow
  - *Opportunity cost*: potential return from investing scarce resources, including staff, in other projects

Examples of Innovation Prizes

Figure 2.3. Examples of prize models and objectives

Prize Model	Objective	Approach
AMC ADVANCE MARKET COMMITMENTS for vaccines	Augment inadequate markets for new vaccines in poor countries	Create a donor-subsidized market for new vaccines that meet agreed specifications
Medical Innovation Prize Act of 2007	Align medical innovation to public health need; promote access by bringing prices close to costs	Reward new products according to health benefit; enable generic production from regulatory approval
PRIZE4LIFE	Overcome scientific barriers to new treatments for ALS; make R&D faster and more efficient	Use milestone prizes to stimulate early-stage innovation and to make trials easier
XPRIZE FOUNDATION	"Unlock" a market for point-of-care TB tests in developing countries	Use a prize to overcome technological barriers and attract attention to the field

Source: Prizes for Global Health Technologies, 2011- Center for Global Health R&D Policy Assessment

Application: New Treatments for Antibiotic Resistant Infections

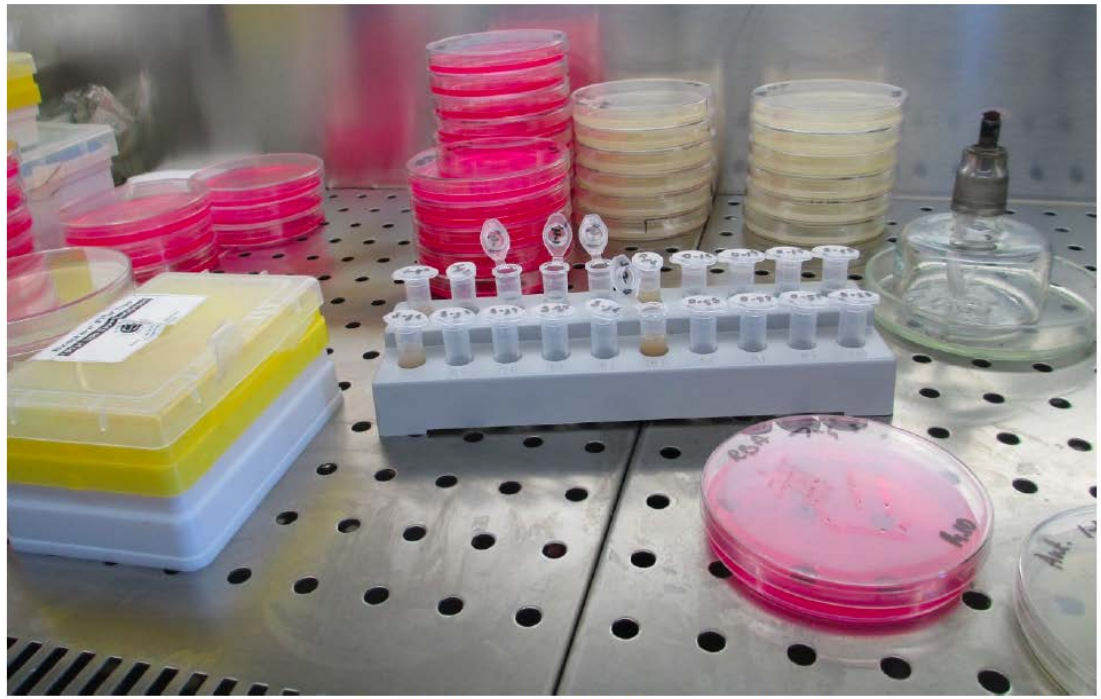
- Funding

Proposal:

$2B prize for new antibiotics for drug-resistant infections, plus generic pricing for each dose

Lawmakers propose $2B prize fund for new antibiotics—if developers waive exclusivity

by *Phil Taylor* | Apr 13, 2017 8:40am



A new bill intends to stimulate R&D into drugs for serious and life-threatening bacterial infections.

A bill tabled by senior Democrats would set up a $2 billion prize fund that will try to encourage the development of more effective antibiotics for serious infections.

Tucked away in the wide-ranging Improving Access to Affordable Prescription Drugs Act, the antibiotic research clause calls for "up to three" prizes for products that " provide added benefit for patients over existing therapies in the treatment of serious and life-threatening bacterial infections demonstrating in superiority trials."

Prize Proposal Description

- $

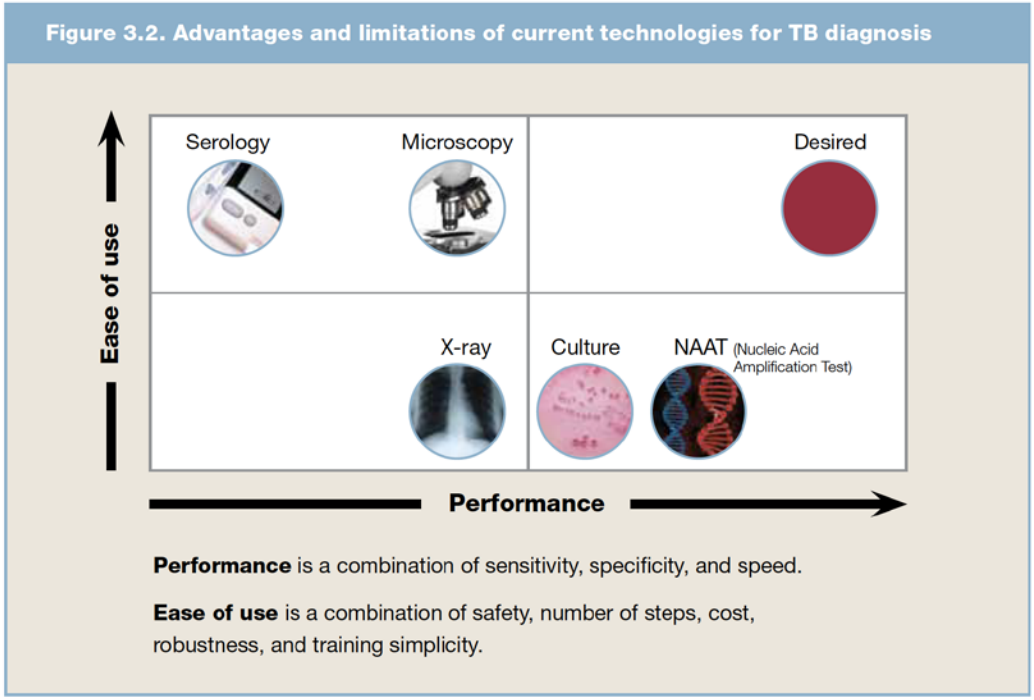
Source:

Application: Low-Cost Test for Tuberculosis

- Tuberculosis (TB) claims 2 million lives every year, mostly in low-income countries. It is resurgent in the US for drug users, prison inmates.
- Progress controlling disease because of inadequate drugs, vaccines, and diagnostics.
- Symptoms of TB resemble those for other illnesses, and hence it diagnosis is important in order to target treatment. There is need for rapid, point-of-care (POC) tests that can be used in lower levels of health system and give results while patient waits

Available Diagnostics for TB are Unsatisfactory

- Most common TB diagnostic: sputum smear microscopy
  - Cheap and highly specific but is insensitive (many false negatives)
  - Performs poorly in children and patients with HIV
  - Requires at least simple laboratory and trained technician and typically takes several days to return results
    - Rural settings where patients travel long distances, diagnosis delay means many patients do not return for results and do not begin treatment
- A new, more sensitive test that could be used in remote areas and returned results quickly could prevent as much as 36% of deaths, saving hundreds of thousands of lives every year



Source: Adapted from WHO, *Diagnostics for Tuberculosis: Global Demand and Market Potential*, 2006

Source: Prizes for Global Health Technologies, 2011- Center for Global Health R&D Policy Assessment

Obstacles to Improved TB Diagnostics

- Lack of need in high-income countries and lack of ability to pay in low- and middle-income countries
- Growing markets in the emerging economies (China, India), coupled with the interest among rich-nation donors, could make TB diagnostics attractive to industry
- Need to develop and validate biomarkers for infection and for particular strains of infection
- Need extends beyond the test itself to the infrastructure of supply, analysis, treatment, and patient monitoring
- Tests must be adapted to difficult environments, where there may be no refrigeration, no reliable running water, no reliable electricity, and few adequately trained staff

Source: Prizes for Global Health Technologies, 2011- Center for Global Health R&D Policy Assessment

X Prize Foundation Proposal

- $20M prize to create rapid, accurate, POC TB diagnostics
  - Up to four purses of $5M each if products shown in clinical trials to meet minimum technical criteria
- (In-Kind) Support to Teams:
  - Access to sample banks (~$300K–500K)
  - Subsidized clinical trials (~$2.5M–5M)
  - Aggregation of demand
- Contestants retain IP and includes no licensing provision
  - Contrast with ‘de-linkage’ proposals where prizes would be awarded contingent on recipient transferring/licensing IP to a patent pool
  - De-linkage sees prizes as substitute for prices and profits whereas X-Prize Foundations sees them as complements
- Awardee is not required to supply product at specified price

Source: Prizes for Global Health Technologies, 2011- Center for Global Health R&D Policy Assessment

Bangladesh, Barbados, Bolivia, and Suriname (BBBS) Prize Proposal for TB Diagnostic

- Similarities to X Prize: targets Dx for use in peripheral settings in developing countries; a two-stage evaluation of candidate products, and subsidy of clinical trial costs
- Differences to X Prize:
  - $100M grand prize plus series of small prizes of various types
  - Affordability and access standard
  - Winner required to grant licenses for all patents and know-how needed for competitive supply of the product to licensing pool
  - Performance in HIV+ patients potentially in required criteria
  - Proposes governments as main source of funding
- No rich nations or NGOs stepped to fund this prize
- No developer expressed interest

Source: Prizes for Global Health Technologies, 2011- Center for Global Health R&D Policy Assessment

Firm-Reported Factors for TB Diagnostic Prize

Figure 3.7. Factors influencing prize participation, by type of firm

Type of Firm	Technological competence	Revenue threshold for conventional markets	Total prize amount	Prize structure	Other benefits
New start-ups	Developing relevant platform or biomarkers	$20M/year	$5–10M too small	Strong preference for milestone	Recognition, technology validation
Established small to mid-size firms	Have relevant platform or biomarker	$20M/year, maybe less if costs are low	$5–10M might be attractive in some situations	Strong preference for milestone	Recognition
Large firms	Have relevant platform	$50–$100M/year	$5–10M too small to be commercially interesting	Perhaps prefer end prize if public relations benefits are stronger	Positive publicity from global health initiative

Source: Prizes for Global Health Technologies, 2011- Center for Global Health R&D Policy Assessment

[HOLD] Qualcomm Tricorder XPRIZE

- $10 million global competition to incentivize the development of innovative technologies capable of accurately diagnosing a set of 13 medical conditions independent of a healthcare professional or facility, ability to continuously measure 5 vital signs, and have a positive consumer experience
  - $10 million Grand Prize possible
  - $4.7 million Prize Purses Awarded
  - $5.3 million dedicated to Post-Prize Programs at UCSD and Mozambique
  - $1 million Additional Milestones totaling were awarded:
    - Lab Test Demonstration Milestone of $50K to 5 teams
    - Human Qualification Milestone of $375K each to 2 teams
  - Launched in 2012, winner announced April 2017

Source: https://tricorder.xprize.org/prizes/tricorder

[HOLD] Qualcomm Tricorder XPRIZE - Outcomes

- Qualcomm Foundation committed $5.3M in post-prize programs, primarily funding clinical testing as well as the development of IT infrastructure to support device data transfer and storage into a cloud environment
- The Roddenberry Foundation has committed $1.6M to fund a combined effort in Mozambique and the Qualcomm Institute at UCSD. Program will connect healthcare providers to the technologies to more rapidly and accurately diagnose Tuberculosis (TB) and hypertension
- A specific collaboration to provide the devices for use to a hospital in Mozambique

Source: https://tricorder.xprize.org/prizes/tricorder

[HOLD] Qualcomm Tricorder XPRIZE - Winner

- DxtER™, Basil Leaf Technologies
- Diagnostic engine based on analysis of actual patient data
- Developed algorithms for diagnosing 34 health conditions
  - Some of these conditions include: diabetes, atrial fibrillation, chronic obstructive pulmonary disease, urinary tract infection, sleep apnea, leukocytosis, pertussis, stroke, tuberculosis, and pneumonia
- Development of DxtER also involved the creation of a collection of non-invasive sensors, custom-designed to collect data about a person's vital signs, body chemistry, and biological functions
- System pulls together data from a patient's personal and family medical history, physical exam, and multiple sensors to make a quick and accurate assessment

Source: http://www.basilleaftech.com/dxter/

Summary: Prize for Drug-Resistant Conditions

- Most

Summary: Prize for Tuberculosis Test

- Tuberculosis has historically not attracted much industry investment due to perceived lack of profitability
- Innovation prizes such as X Prize and the BBBS Proposal have attempted to spur industry investment in R&D for low-cost tests and treatments
- Challenges facing prizes for even this obvious candidate highlight challenges facing prize mechanisms, and underscore their use as supplements rather than substitutes for prices/profits, research grants, tax incentives