



Introduction to Homeland Security  
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Lecture 4A:

# The Bioshield Dilemma: Developing New Technologies At an Affordable Price

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## Introduction

The Need.

The Challenge: Patents Don't Work

The Story So Far: Three Proposals & Some Analysis

Cost Matters!

A Better Way to Design Incentives

From *Ad hoc* Proposals to Rational Design

The Neglected Disease Literature

Innovation Economics Literature

How to Get the Best Price

The Story So Far:  
BioShield I:  
Boosted Demand

BioShield I (2004):

Background:

Patents Don't Work

Strategy:

“Creating a BioDefense Industry”  
Mimicking Patents

Details:

\$5.6 bn. Appropriation  
DHS's “Boosted Demand” Strategy

Results:

(Disappointing)

The Story So Far:  
Bioshield I:  
Boosted Demand

Analysis:

Firms invest when...

$$(\text{Expected Reward}) - \text{Costs} > 0$$

This means we should offer  $(c + \varepsilon)$ , where  $\varepsilon$  is small.

The “Sunk Costs” Trap

Reassuring drugmakers.  
\$5.6 bn. is not enough!

The Story So Far:  
BioShield II:  
Wild Card Rights

BioShield II (2006?):

Wild Card Rights:

Extending rights on an *unrelated* patent by up to two years.  
Trading patents.

Analysis:

Using a Hidden Tax to Avoid the Cost Constraint

The Story So Far:  
Bioshield II:  
Wild Card Rights

Analysis, *ctd.*:

Background: Ordinary Patents

Patents are Not a “Free Lunch”

Making Knowledge Expensive.

Bad News: Reward can be much larger than  $(c + \varepsilon)$ .

Silver Lining: Reward never exceeds value to society!

Good News: Consumers pay systems seem fair.

Wild Cards

Wild cards permit *unlimited* overpayments.

More Bad News: Random people pay.

Good News: Wild cards may be unconstitutional  
Statute of Monopolies (1623)

## The Next Chapter: Advanced Purchase Commitments?

### Fixing BioShield I

#### Fixing Boosted Demand

Advanced Purchase Commitments (“APCs”).

BioShield II Mandate

S.B. 1628 (“Vaccines for the New Millennium”)

### The Bad News: What Price Should We offer?

What is  $(c + \epsilon)$ ?

What is “c”?

### The \$800m Pill.

J. DiMasi, R. Hansen, and H. Grabowski, “The Price of Innovation: New Estimates of Drug Development Costs,” *Journal of Health Economics* 22:151 (2003)

The Next Chapter:  
Advanced Purchase Commitments?

Is \$800m the Right Number?

**First Answer:** Congress thinks so...

**Second Answer:** *Do* drugmakers *actually* spend \$800m for each new drug?

The Controversy.

The \$800m ± \$115m Pill

Expect a 20 – 30% Overpayment On Average!

**Third Answer:** *Could* drugmakers spend less?

J. DiMasi, R. Hansen, and H. Grabowski, “The Price of Innovation: New Estimates of Drug Development Costs,” *Journal of Health Economics* 22:151 (2003)



The Next Chapter:

Advanced Purchase Commitments?

Firms invest when...

$$(\text{Expected Reward}) - \text{Costs} > 0$$

In a competitive market, firms will invest until . . .

$$(\text{Expected Reward}) - \text{Costs} = 0$$

The result is . . .

Racing, Duplication, &

“Competing Away the Profits.”

## The Next Chapter: Advanced Purchase Commitments?

### Implications

\$800m is **endogenous**, *i.e.* spending levels are set by existing patent incentives!

Congressional hearings tell us *nothing* about “c”

Could “c” be \$200m???



Taking Stock

# The Bioshield Dilemma

## Three Stalled Ideas...

## Taking Stock

“[Private sector drug companies] will not say what package of incentives would be sufficient to persuade them to take up biodefense work . . . While I understand these fears, we simply have to know what it would take in the way of incentives to establish a biodefense industry. If the incentives in BioShield or BioShield II are not sufficient, we need to know what incentives are sufficient . . . And only the industry can give us a clear answer to these questions. We cannot have a dialogue on these urgent questions without the government listening and the industry speaking.”

Sen. Joseph Lieberman

Testimony Before Senate Judiciary and HELP  
Committees, Oct. 6, 2004.

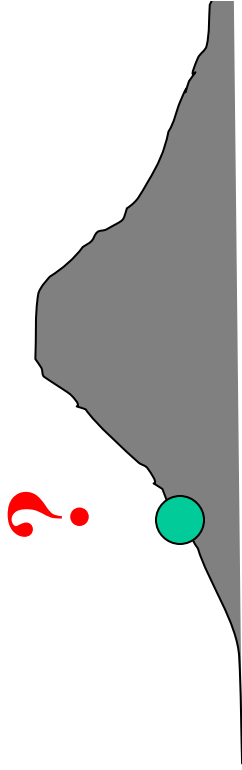
Taking Stock

The Bioscience Dilemma:

**Cost Matters!**

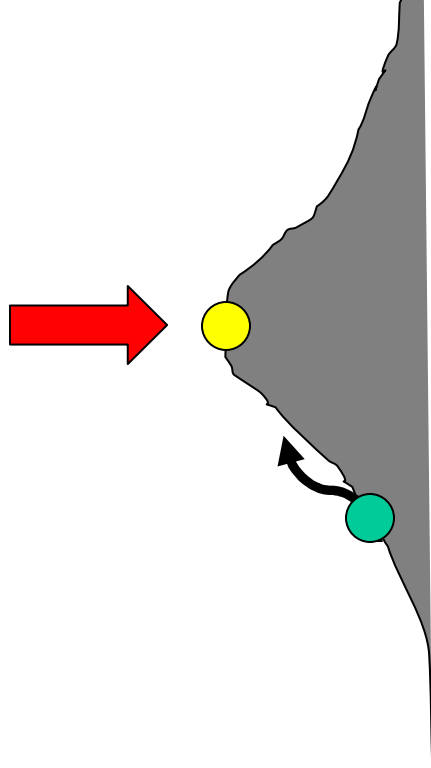
What Went Wrong?  
Innovation Economics & A New Direction

# What Went Wrong?



# What Went Wrong?

“Local Optimization”

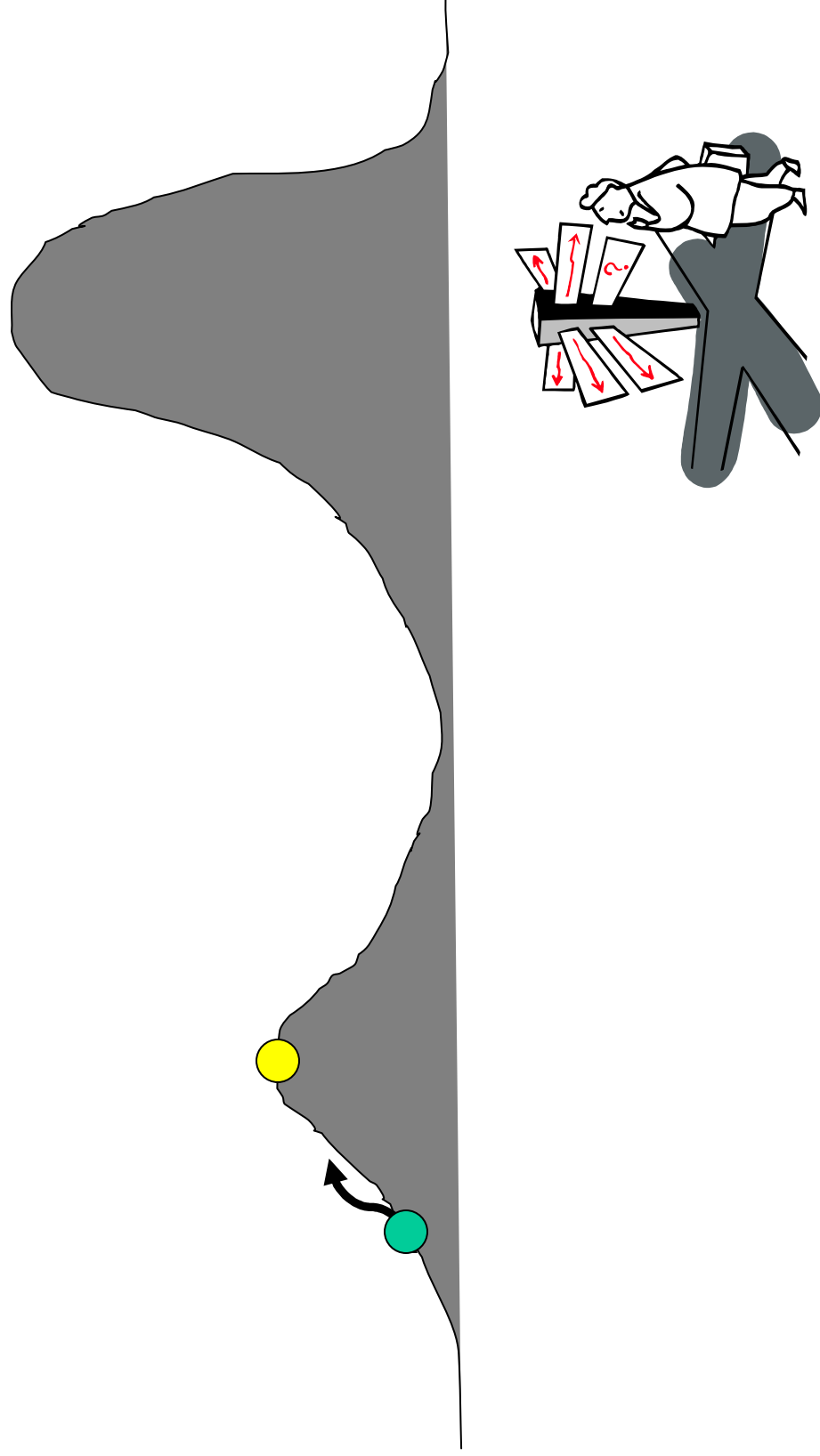


*Ad hoc improvements*



What Went Wrong?

Local Optimization has Drawbacks





## Is Local Optimization Good Enough?

**Congress' Assumption:** The private sector (*i.e.*, patent-like solutions) are the best solution for every R&D problem.

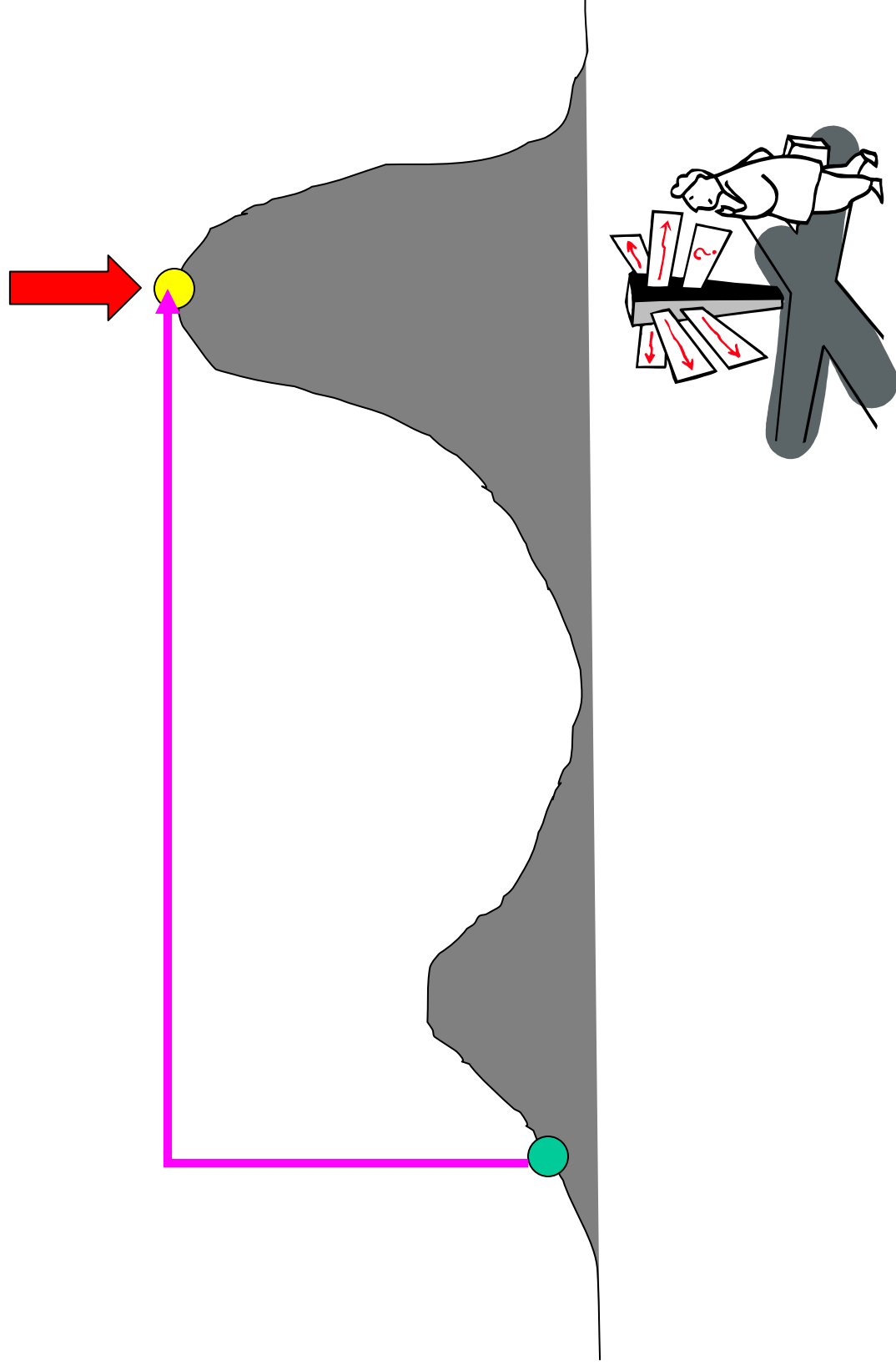
### **Congress' Evidence:**

Ideology & Beltway Analogies

### **A Common Sense Objection:**

Patents have *never* been the only mechanism.

# “Global Optimization”



Doing Better...

## A Language for Thinking Globally

Innovation Economics:

**There is no “dominant” incentive mechanism!**

Equivalently:

Be agnostic!

All incentives have strengths and weaknesses!

All solutions are flawed!

Fit the solution to the R&D problem!

## A Language for Thinking Globally

### Idealized “Perfect” Tools:

Patents

Grants

Prizes

Contracts

Open Source

### Social Obstacles:

Eliciting Information

Moral Risk on Sponsor Side

Moral Risk on Researcher Side

Efficient Access

**Cost**

Doing Better...

## **Analysis:**

Drug Discovery is a pipeline with ~ 12 distinct steps.

For each point along the drug discovery pipeline...

**Step 1:** What are the Principal Social Obstacles?

**Step 2:** Pick an Incentive Mechanism

**Step 3:** Identify & Manage Areas of Weakness?

Management *vs.* Incentives...

# Step 1: What are The Principal Social Obstacles?

## Social Challenge

Basic Research	Moral Risk Eliciting Information
Early Phase Drug Discovery	Moral Risk Eliciting Information
Pre-Clinical & Human Testing	Cost
Manufacturing	Cost

Step 2:  
Pick Incentives  
(Current Solution)

	<u>Social Challenge</u>	<u>Patent System</u>
Basic Research	Moral Risk Eliciting Information	Grants, Prizes, Patents (Universities)
Early Phase Drug Discovery	Moral Risk Eliciting Information	Patents (Biotech)
Pre-Clinical & Human Testing	Cost	Patents (Big Pharma)
Manufacturing	Cost	Patents (Big Pharma)

## Step 2: Pick Incentives

### Possible Replacements:

Patents → Grants, Prizes

### Comment:

Controls agency problems

Allows researcher discretion

Makes information freely available for later use.

Patents → Contract Research

Controls costs



Step 2:  
Pick Incentives  
("Bioshield 4")

Social  
Challenge      Patent  
System      Bioshield  
4

Basic Research	Moral Risk Eliciting Information	Grants, Prizes, Patents (Universities)	Grants Prizes (Universities)
Early Phase Drug Discovery	Moral Risk Eliciting Information	Patents (Biotech)	Grants Prizes (Virtual Pharma)
Pre-Clinical & Human Testing	Cost	Patents (Big Pharma)	Contract R&D (Virtual Pharma)
Manufacturing	Cost	Patents (Big Pharma)	Contract R&D (Virtual Pharma)

Step 3:  
Identify & Manage  
Areas of Weakness

	Social <u>Challenge</u>	Bioshield 4	<u>Evidence</u>
Basic Research	Moral Risk Eliciting Information	Grants Prizes (Universities)	Pre-1980 System
Early Phase Drug Discovery	Moral Risk Eliciting Information	Grants Prizes (Virtual Pharma)	Can Government Pick Winners?
Pre-Clinical & Human Testing	Cost	Contract R&D (Virtual Pharma)	Drug Company Outsourcing
Manufacturing	Cost	Contract R&D (Virtual Pharma)	Drug Company Outsourcing, March of Dimes, Avian Flu

## Step 3: Identify and Manage Areas of Weakness

### Can Government Pick Winners?

#### Theory:

*Not About Competence*  
Defunding Failure

#### Practice:

Fort Detrick, March of Dimes, Pasteur Institute  
Private-Public Partnerships (Neglected Diseases)

#### Should We Try It?

20 – 30% is a large number!  
Making Contact With the Evidence

## Conclusion

The case for Virtual Pharma.

We've Learned Some Jargon & Some Truths:

There is **No Dominant Incentive System**

Patents are *Not* Costless

R&D Costs are Endogenous

The **Optimal Level of Patent Protection is Unknown**

A Final Comment

“What, Exactly, Was So Great About “The Greatest Generation?””

## Readings

### Innovation Theory (Short Version):

S. Maurer, “Innovation Incentives,” available at <http://www.cs.washington.edu/education/courses/csep590/04au/lectures/>

### Innovation Theory In-Depth:

S. Scotchmer, *Innovation & Incentives* (MIT Press 2004)

### Bioshield I:

Available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108\\_cong\\_public\\_laws&docid=f:publ276.108.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=108_cong_public_laws&docid=f:publ276.108.pdf)

## Readings

### Bioshield II Legislation:

The text of the Senate’s Bioshield II legislation is available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109\\_cong\\_bills&docid=f:s975is.txt.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=109_cong_bills&docid=f:s975is.txt.pdf)

### Lieberman Testimony

“Creating a BioDefense Industry: Bioshield II” (Oct. 6 2004), available at <http://lieberman.senate.gov/newsroom/reports/bioshieldtestimony0604.pdf#search='creating%20a%20biodefense%20industry'>