

# PEREG Lecture 05

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Alternatives to Public Interest and Capture:  
Reputational Models, Avoidance Models



# Problem in Existing Theories

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- All-or-nothing regulatory dichotomy: State is either entirely benevolent or captured (friendly to incumbent firms or is tollbooth “grabbing hand”).
- Theoretically, huge literature on bureaucracies that suggests that something else is going on
- Problems for empirical research: Djankov, et al.



# A STOCHASTIC PROCESS MODEL OF PRODUCT REVIEW

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Models derived from probability theory:

↖ used in sociology (Padgett, Spilerman)

↖ economics (Dixit, Jovanovic)

↖ political science (Padgett on budgetary process, Bendor and Heimann on organizational reliability)



## EXAMPLE: THE PROCESS OF DRUG DEVELOPMENT AND REGULATION

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1. R&D, then patent
2. “Investigational New Drug” (IND) Stage --
  - ↖ 3 phases of clinical testing for safety and efficacy ,  
governed by FDA regs.
3. New Drug Application (NDA) Review Stage
  - ↖ scientific review by FDA staff
  - ↖ Advisory Comm recommendation (sometimes)
  - ↖ FDA decision (approved, “not approvable”)

# A SIMPLIFIED REPRESENTATION OF THE PRODUCT APPROVAL PROCESS

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Imagine products arrive to regulator at exogenous rate, and are characterized by two parameters,

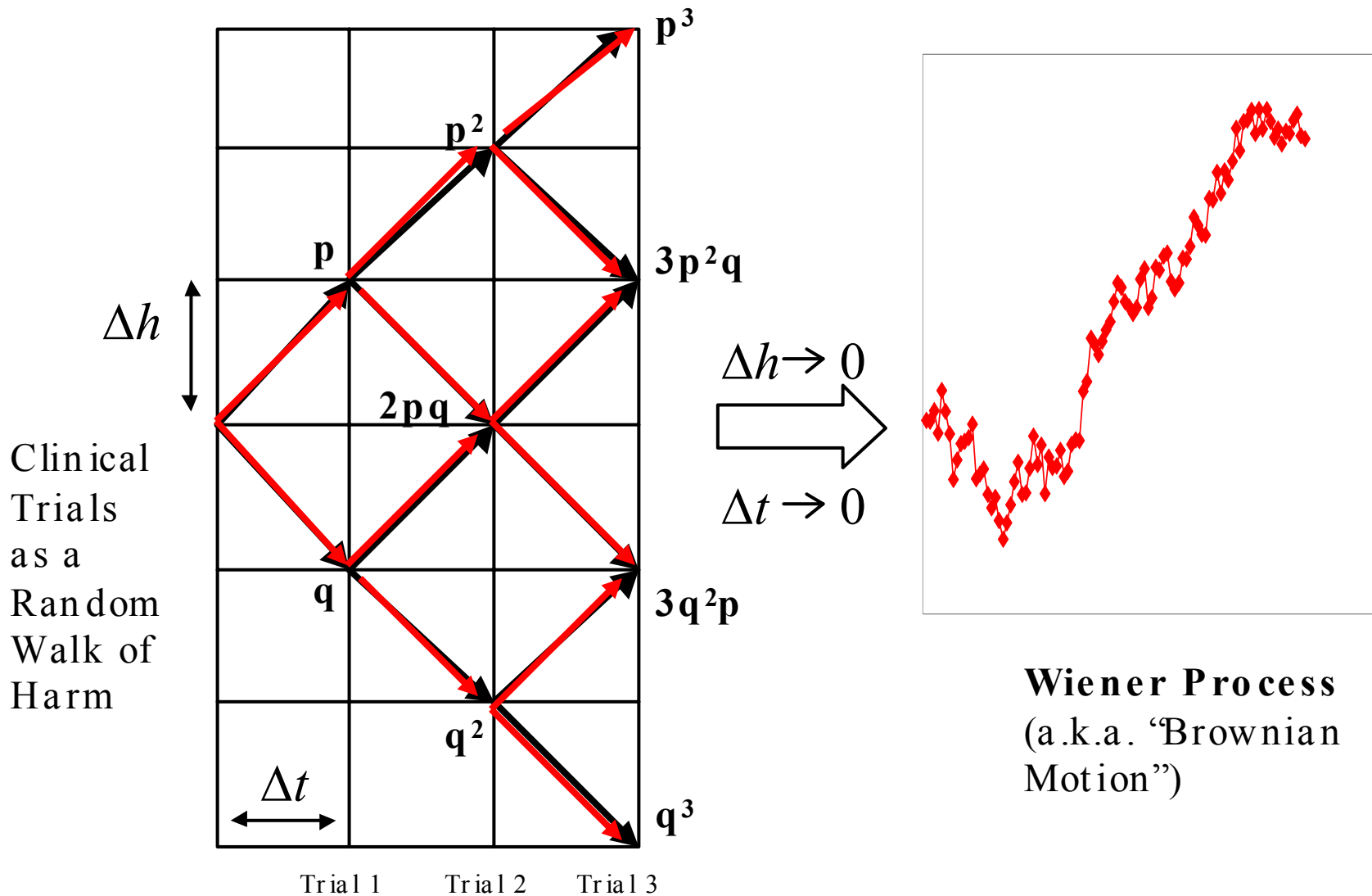
↖ QUALITY ( $\gamma$ ), known throughout

↖ a danger ( $\mu$ ), which must be learned

IND Stage:  $\gamma$  estimated with certainty, clinical evidence about  $\mu$  generated.

NDA Stage: Agency learns about  $\mu$  through page-by-page review of clinical trial evidence.

**Figure 1: Convergence of Discrete to Continuous Review**



# LEARNING ABOUT PRODUCT DANGER

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Assume R learns about danger in a simple manner. Agency observes “harm”  $[X(t)]$ , a Wiener variable, and tries to infer danger ( $\mu$ ) through simple Bayesian average  $\hat{\mu}$

$$X(t) = \mu t + \sigma z(t)$$

A value to waiting: Waiting to learn more reduces agency’s uncertainty over  $\mu$ , or posterior var  $[S(t)]$ .

## THE APPROVAL PAYOFF (OR THE COST OF WAITING)

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So why doesn't R delay forever? It can't: consumers (patients) and firms want approval.

*Approval Payoff (A)* is politically weighted number of consumers without alternatives, further weighted by political clout of submitting firm

↖ re FDA, a function of the *prevalence* and the *political salience* of a disease, plus firm influence.

Previous approvals also matter. Once consumers adopt a product, they drop out of “demand pool.”

# THE AGENCY'S PROBLEM

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Intuitively: R wants to approve the product to maximize the sum of “payoff” from approval (A) and loss from realized danger ( $\mu$ ) of the product.

Formally: Stop the stochastic process  $\hat{\mu}$ , given a terminal payoff A.

SO: The agency just stops the review when  $\hat{\mu}$  falls below A, right?

NO

# Agency's Problem

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$$\begin{aligned} \max E e^{-\delta(t_{app})} \left\{ A - E_{\hat{\mu},t} \int_t^{\infty} e^{-\delta(y-t)} \mu^*(y, \omega) dy \right\} \\ = E e^{-\delta(t_{app})} \left\{ A - \delta^{-1} \mu^*[t_{app}, \omega] \right\}, \end{aligned} \quad (5)$$



# THE VALUE OF WAITING TO APPROVE

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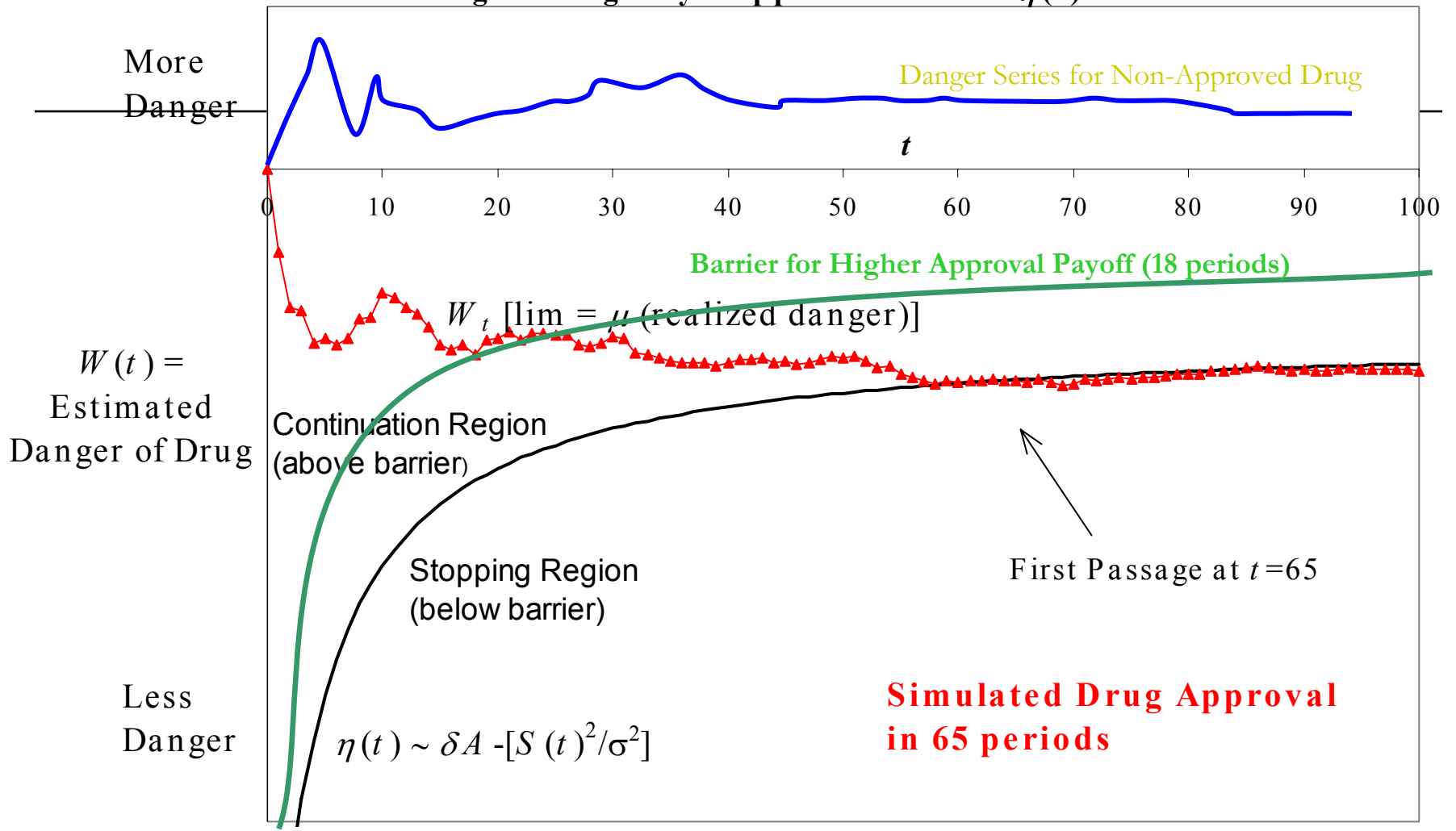
Delay is a way of getting more information about a risky (irreversible) decision.

FDA can recall a dangerous drug, but recall can't undo the reputational damage from its mistake.

**Best Rule:** Approve product when estimated danger is less than approval payoff AND value of waiting.

**BUT:** Value of delay not constant; it depends upon worth of information to be learned by waiting.

**Figure 2: Simulated First Passage of the Danger Process  $W(\mu, t)$  through the Agency's Approval Barrier  $\eta(t)$**



# Disease Politics and Order of Entry Effects

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R's Cost of Waiting = *Approval Payoff* (A)

= politically weighted ( $\psi$ ) number of patients ( $L$ ) without alternatives ( $1 - \gamma$ ), also weighted by clout ( $\lambda$ ).

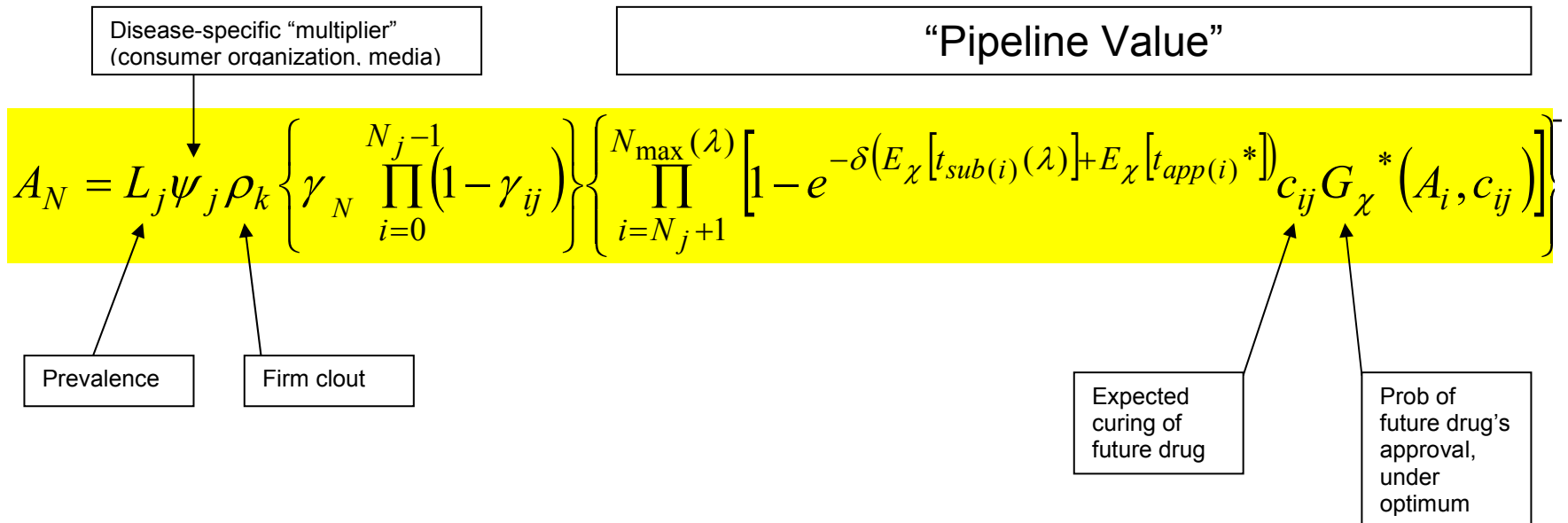
⌞ Organized disease sufferers and their advocates can increase FDA's cost of waiting, and media can amplify these effects

⌞ Previous approvals also matter. Drug adopters drop out of “demand pool.”

$$\gamma_{N_j} L_j \times (1 - \gamma_{1_j}) \times (1 - \gamma_{2_j}) \times \cdots \times (1 - \gamma_{N-1,j}) = L_j \gamma_{ij} \prod_{i=0}^{N_{i-1,j}} (1 - \gamma_{ij})$$

$$A = A(i, j, k, \gamma) = (1 + \lambda_k) \psi_j L_j \gamma_{ij} \prod_{i=0}^{N_{i-1,j}} (1 - \gamma_{ij})$$

# Past Drugs, Future Drugs and the Approval Payoff



Agency conditions present decisions on:

- (1) present politics
- (2) past decisions
- (3) future (expected) decisions on the pipeline of drugs

# Repeated Regulation – Learning from History

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$$\mu'_{ik} = \mu_i + \xi_k, \quad \mu_i \sim N(m, s), \quad \xi_k \sim N(0, 1).$$

$$\hat{\xi}_k[\tau] = \left[ \left\{ \frac{1}{N_k} \sum_{i \in [N_k \sim M_k]} \hat{\mu}_{it} \right\} + \left\{ \frac{1}{N_k} \sum_{i \in [M_k]} \mu_i \right\} \right] - m.$$

$$\text{Var}^p[\hat{\xi}_k] = \left[ 1 + \left\{ \sum_{i=0, k=K}^{N_k - M_k} \frac{r(t_{\text{sub}(ik)})}{s} + M_k \right\} \right]^{-1}, \quad (7)$$

**Proposition 5. The Advantage of Familiarity.** For any set of firms  $k = 1, 2 \dots K$  such that  $\xi_1 = \xi_2 = \dots = \xi_K$ , the following two statements hold:

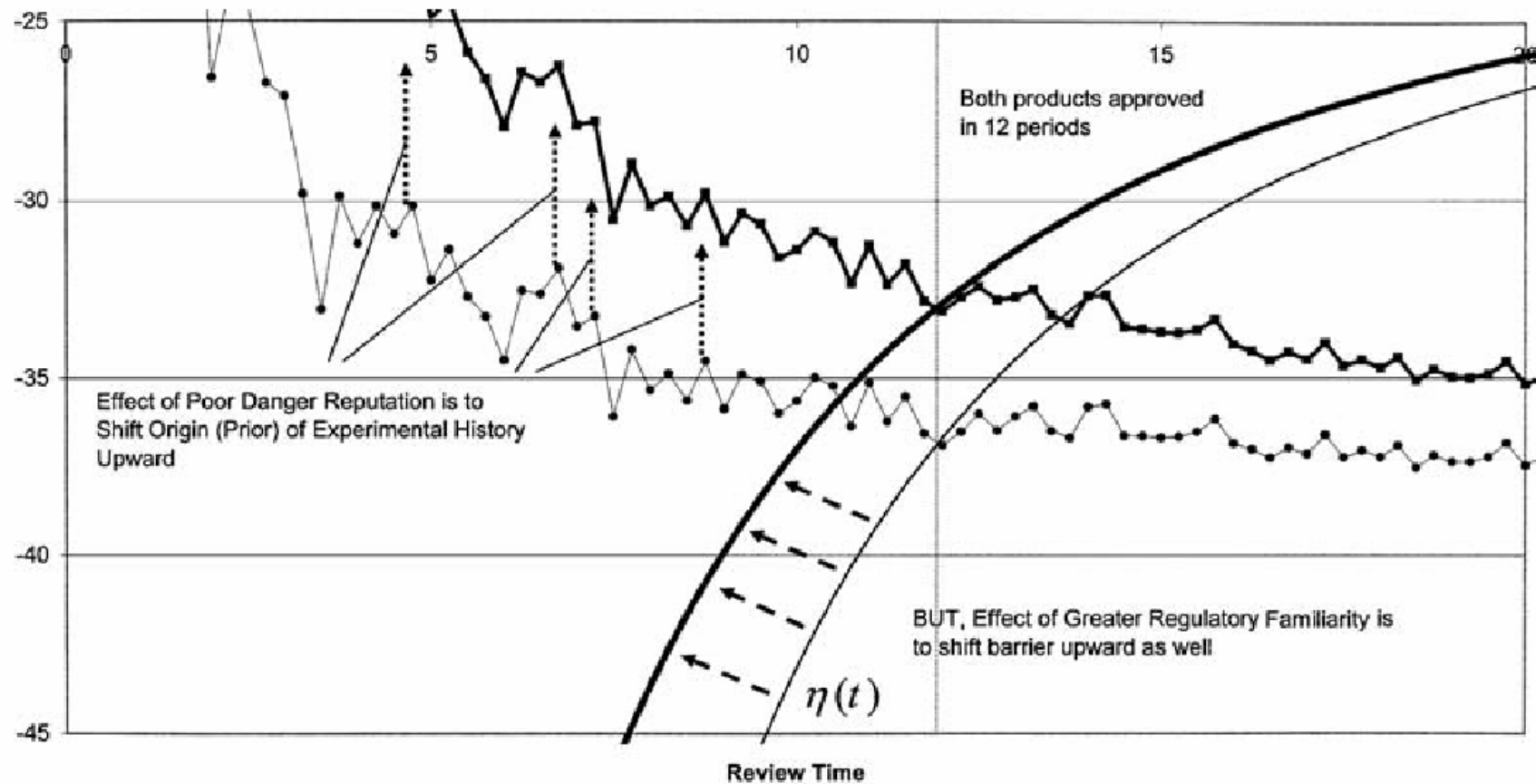
- (a) the expected review time  $E[t_{app}(ik) | \xi_k]$  conditioned on the posterior variance  $Var^P[\hat{\xi}_k]$  is a strictly decreasing function of  $N_k$ ,
- (b) the expected review time  $E[t_{app}(ik) | \xi_k]$  conditioned upon the sample variance of the danger estimate ( $\hat{\xi}_k$ ) is decreasing in  $N_k$  unless  $(\mu_{N_k+1} - \bar{\mu}_{N_k})^2 - \hat{\sigma}_{\bar{\mu}, N_k}^2 / N_k > \Phi(\delta A - m, s)1/N_k^2$ , where  $\hat{\sigma}_{\bar{\mu}, N_k}^2$  is the mean square error of  $\bar{\mu}_{N_k}$ .

**Corollary 5.1.** Consider two products with identical experimental histories and identical approval payoffs but submitted by different firms: one ( $k = k^0$ ) with no previous submissions, the other ( $k = k^B$ ) with a “bad reputation” ( $\hat{\xi}_{k^B} > 0$ ) but positive familiarity ( $N_{k^B} > 0$ ). Let  $t_{\text{stop}}$  be the approval time for the drug submitted by the unknown firm ( $k^0$ ). Then when

$$\hat{\xi}_{k^B} \leq \frac{\sigma_i^2 + st_{\text{stop}}}{\sigma_i^2} [S_{k^0}(t_{\text{stop}})^2 - S_{k^B}(t_{\text{stop}})^2]$$

or (conceptually) when drugs receive sufficiently “early approval” or the bad firm has a sufficiently low firm danger estimate low ( $\hat{\xi}_{k^B}$ ), the product submitted by the bad but familiar firm receives quicker approval than the product submitted by the unknown firm.

**FIGURE 2. Trade Off between Firm Danger Reputation and Regulatory Familiarity**



- — Danger Estimate
- Danger Estimate adjusting for "Bad" Firm Reputation
- Optimal Stopping Barrier adjusting for Regulator's Familiarity with Firm
- Optimal Stopping Barrier

# Problems...

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- Among many problems, exogenous submissions. R never induces F behavior. (See Carpenter and Ting 2004, 2005 for model that does this.)
- Not clear that EEP holds for non-satiating markets.
- Does this model assume too much rationality?