

# **The Welfare Economics of Sharing Fixed Costs of Product Safety Regulation**

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# One-time Testing is Required to Assure Product Safety for Many Substances

## ➤ Alternative ways of ensuring product safety:

Legal liability (ex post)

Government licensing (ex ante)

Government inspection (on-going after standards are set)

## ➤ Standards must be developed for product inspection

## ➤ Licensing requires product testing before marketing

## ➤ Who should bear the costs of assuring product safety (testing and/or development of standards)?

## ➤ Assurance of product safety thus imposes a fixed cost (independent of product volume)

## Where One-time Testing is Required to Assure Product Safety

- If costs are not borne privately, the incentive to introduce risky products is excessive
- Other firms often cannot compete initially due to patents or trade secrets
- Later generic entry occurs (substantially similar)
- Duplication of tests is socially wasteful → sharing
- How much testing cost should later generic entrants bear?
- The typical argument is that *economics has nothing to say about how to share a fixed cost so per capita*

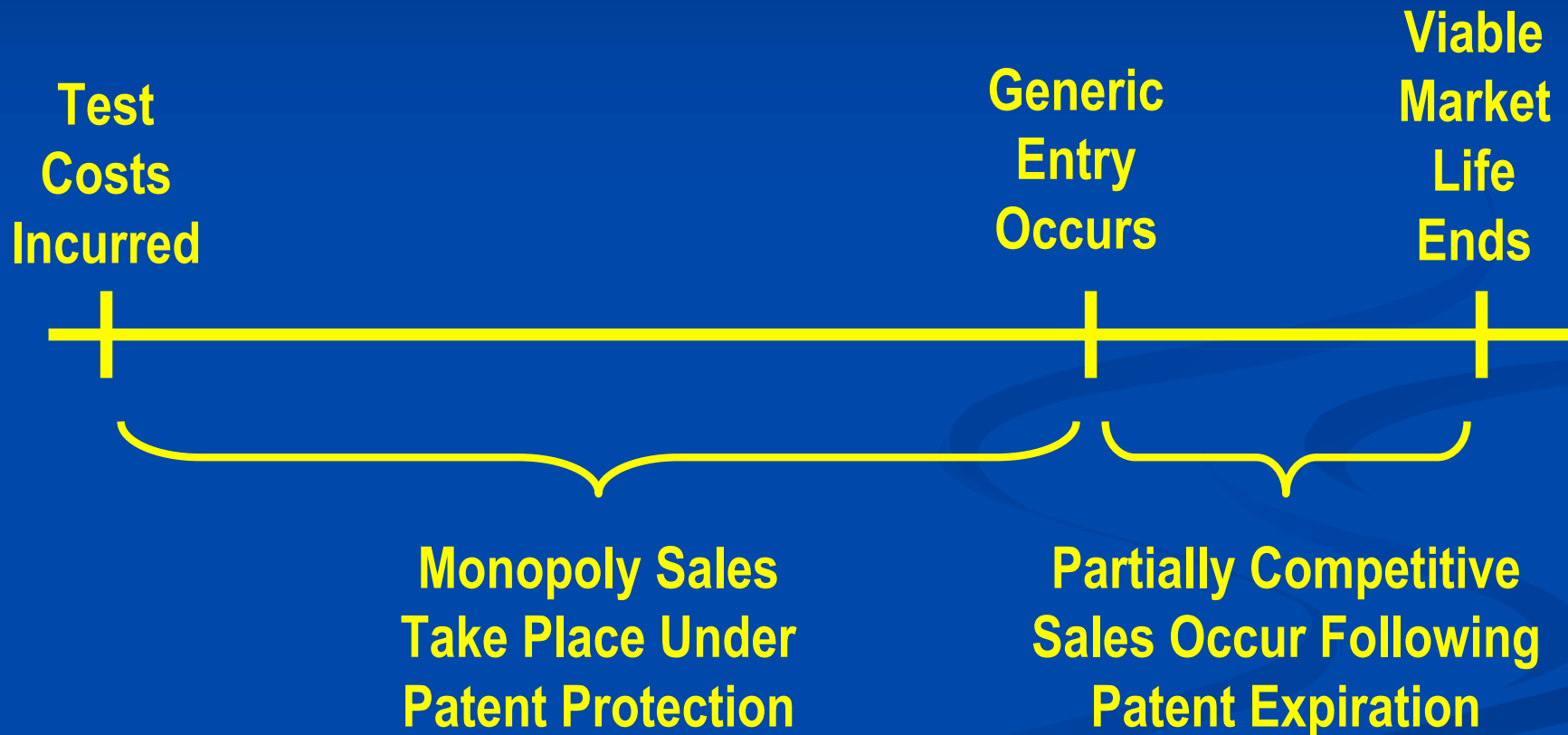
# Game Theory Possibilities

- Game theory has enabled studying optimal sharing of fixed costs of production
- Focuses on distributing the benefits
- Here the joint benefits to firms of generic entry is negative because monopoly profit is lost
- Most game theory solutions involve shadow values of constraints but safety info does not impose constraints
- Game theory has shown that a wide class of these problems has no equilibrium → gov't intervention

## Examples: Regulation of Pesticides and Toxic Substances (FIFRA/TSCA)

- FIFRA/TSCA requires EPA to ensure safety for human health & the environment before commercialization
- Required regulatory tests cost as much as \$30-50 million before marketing & periodically later
- FIFRA gives no specific standard for cost sharing
- TSCA specifies market sharing of test costs
- New biotechnology products are being grandfathered into these regulatory schemes (EPA,FDA,APHIS)

# Typical Time Line



## FIFRA Experience \*

- **1972 Amendment shifted administration from USDA to EPA**
- **Increased magnitude of required test costs**
- **Anticompetitive sharing & market efficiency issues arose when patents began to expire**
- **1972, 1975 & 1978 Amendment intensifications:**
  - Promote post-patent competition**
  - Avoid duplication of tests**
  - Provide generic registration after offer to pay**

## Under the 1972 Amendment \*

### Original registrants claimed:

- Lost monopoly profits
- Early entry profits
- Compensation could exceed all future profits of a generic entrant

## Under the 1975 Amendment

- Congressional intended to limit compensation to “direct costs” rather than “value”
- Original registrants claimed regulatory test data contained trade secrets in order to block generic use of regulatory data

## Under the 1978 Amendment \*

**DOJ assessment—“needlessly anti-competitive”**

**Eliminated the “trade secret” loophole**

**Congressional debate recognized:**

- **Regulatory costs are minor to original registrants but not to generic entrants**
- **Congress was trying to avoid competitive advantages due to regulation**

**“... if a prospective competitor can be required to perform duplicate tests as a condition of market entry, in most cases the potential profits will not justify the expense of this duplicative testing & the developer will retain control over production and price levels.” (U.S. Senate Report No. 95-334)**

# Required “Offer to Pay” Like a Blank Check

**FIFRA/TSCA: Follow-on must make a binding offer to pay to cite others’ data for registration**

**Typically original registrants:**

- **Will not agree on compensation before generic entry**
- **Will not commit to a list of tests that are compensable**
- **Often do not keep records of all test costs**
- **Pad cost claims with royalties, mgmt fees, interest, risk premiums w/o quantification**
- **Claim compensation for questionable tests**

# Judicial Interpretation Run Amuck?

Litigation on generic sharing of regulatory cost continues with wide variations in claims/awards

Contention:

- FIFRA provides no standard for sharing
- FIFRA does not adequately define “costs”

*Thomas v. Union Carbide*—“The 1972 Act established data-sharing provisions intended to streamline pesticide registration procedures, increase competition, & avoid unnecessary duplication of data-generation costs ... Although FIFRA's language **does not impose an explicit standard**, the legislative history of the 1972 & 1978 amendments is far from silent ...”

**Table 1. Awards in FIFRA Compensation Cases with Public Information**

<b>Arbitration</b>	<b>Award Date</b>	<b>Claimed Data Cost</b>	<b>Claimed Compensation</b>	<b>Cost Share</b>		<b>Awarded Amount</b>	<b>Percent of Claim</b>
				<b>Claimed</b>	<b>Awarded</b>		
Ciba-Geigy v. Farmland	1980	\$2,636,024	\$8,110,000	100.0%	9.5%	\$240,682	3.0%
Union Carbide v. Thompson-Hayward	1982	\$689,000	\$1,317,500	50.0%	33.3%	\$51,760	3.9%
Stauffer v. PPG	1983	\$2,920,000	\$1,465,000 + Royalty	50.0%	50.0%	\$1,465,000 +25% of 10 yr profit	100.0%
American Cyanamid v. Aceto	1987	\$3,283,000	\$1,971,500	50.0%	35.0%	\$1,149,050	58.3%
Griffin & Drexel v. DuPont	1988						
Griffin		\$15,700,000	\$7,000,000	25.0%	18.3%	\$495,178*	7.1%
Drexel		\$15,700,000	\$5,000,000	25.0%	2.83/10.0%	\$125,986*	2.5%
Ciba-Geigy v. Drexel	1994	\$25,075,056	\$6,673,560			\$2,137,348	32.0%
Atrazine		\$14,688,486	\$3,672,122**	25.0%	5.5%	\$807,867	22.0%
Simazine		\$10,386,570	\$3,462,190**	33.3%	12.8%	\$1,329,481	38.4%
Enviro-Chem v. Lilly	1999	\$612,000	\$306,000 + Royalty	50.0%	33.3%	\$18,398	<6.0%

# Typical Claims

- **Equal per capita sharing of test costs regardless of time in market or potential market share**
- **Time value of money (inflation)**
- **Market return on investment as if no other return were already received**
- **A risk premium on investment as if taking the risk were not already rewarded**

# Competing Cost Sharing Standards

## Per capita versus market sharing

### Per capita claims ignore:

- Inability of generic entry to capture equal market share
- Exclusive use during the patent period
  - Inability of generic entrants to spread regulatory cost over both patent & post-patent periods
- Hard copy issues
  - Tests must be duplicated to compete some states
  - Tests can be used in other countries

# Justification for Per Capita vs Market Sharing

- **Equal market opportunity**
  - Patent period and short remaining market life
  - Hard copy required for some jurisdictions
  - Mixes with patented products
- **Consistent with task force agreements**
  - Same time period in market
  - Access to hard copy for all parties
  - Terms named unilaterally by data owners
- **Equal citation rights**
  - Ignores jurisdiction & value of intellectual property
- **Inability to anticipate market share**
- **Potential gaming**
- **Unequal sharing subsidizes weak competitors**

# Per Capita Sharing Imposes Incentives for Generic Delay

- The first generic entrant is liable for  $1/2$  of test costs
- The second is liable for  $1/3$
- The third is liable for  $1/4$
- Promises or requirements to share future compensation cannot be enforced (supply agreements & quid pro quos)

Creates an artificial incentive to delay entry

The incentive is multiplied by the risk of not being able to quantify regulatory cost before entry

## Comparison with TSCA

TSCA was developed later—more experience (?)

TSCA includes a well-defined standard:

Market sharing of regulatory test cost

A clear EPA rule for computing the share

Federal Register (1990)—"EPA has extensive experience under TSCA section 4 with cost-sharing for testing. EPA has found that persons conducting testing under section 4 have chosen in each instance to date to work out their own arrangements for cost-sharing or reimbursement without any need for EPA involvement."

# Monopoly Pricing Under Patents

- Patents have been found highly effective for pesticides
- Profit margins for pesticides are high, often 60-80%
- Consistent with domestic versus off-shore price differentials
- Causes a large incentive to extend monopoly conditions (delay generic entry)
- Congress considered extending patents for pesticides due to regulatory delay and declined

**Table 2. Comparison of U.S. and Foreign Prices**

Product	U.S. Price	Foreign Price	Apparent U.S. Margin
Malathion	\$1.60 /lb.	\$0.89 /lb.	44.4%
Methyl Parathion	\$1.55 /lb.	\$0.99 /lb.	36.1%
Carbaryl	\$2.55 /lb.	\$1.85 /lb.	27.5%
Treflan	\$26.00 /gal.	\$16.00 /gal.	38.5%
Paraquat	\$34.00 /gal.	\$13.00 /gal.	61.8%
Roundup	\$68.00 /gal.	\$43.00 /gal.	36.8%

Note that midpoints of price ranges are given here to facilitate calculation of margins.

# Interaction of Patent Policy with FIFRA \*

## Typical lingering effects of patents:

- Generic firms must overcome brand name loyalty/recognition
- Generic firms must discount prices (5-10%)
- Generic firms often gain small market shares  
(initially 2-5%, ultimately 20-30%)
- Lower prices prevail with generic entry (20-50% lower)

## Generic success depends on low overhead

(attained by off-shore supply, toll manufacturing)

Per capita sharing of regulatory cost under FIFRA  
precludes this generic approach

# Should Regulatory Cost Sharing Provisions of FIFRA be Modified

- A cost-sharing standard is needed
- Congressional hearings have been held
- The status quo allows extending monopolies
- Large firms (original registrants) have an interest in the status quo
- Lobbying efforts (entrenched efforts) prevail

## **Two-Way Interaction between Regulation and Industry Structure**

- **Regulations can facilitate extending monopolies**
- **Entrenched interests in extending monopolies prevent improving statutes**
- **Illusion: Small market players really don't matter much**

**Table 3. Price Reductions Following Generic Entry**

Product	Pre-Generic Price	Post-Generic Price	Price Reduction
Atrazine	\$2.63 /lb.	\$2.00 /lb.	24.0%
Diuron	\$3.25 /lb.	\$2.40 /lb.	26.2%
Simazine	\$15.50 /gal.	\$9.50 /gal.	38.7%
Phostoxin	\$30.20 /kg.	\$24.28 /kg.	19.6%
Treflan	\$28.50 /gal.	\$21.43 /gal.	24.8%
Sutan	\$19.89 /gal.	\$17.90 /gal.	10.0%

Note that midpoints of price ranges are given here to facilitate calculation of price reductions.

# How 10-20% Generic Penetration Can Cause 20-50% Price Reductions

## Alternative theoretical models:

- Cooperative games and Nash bargaining
- Contestable markets
- Noncooperative games
- Dominant-firm price leadership (fit)

# A Simple Model

**Demand**  $p = a - q/\eta$       **Generic supply**  $q_2 = \alpha + \beta p$

**Excess demand to the original entrant**  $q_1 = q - q_2$

**Constant marginal cost**  $c_1 = \text{MR}$  implies  $p = \frac{a - \alpha/\eta}{2(1 + \beta/\eta)} + \frac{c_1}{2}$ .

**Without generic entry**  $c_1 = \text{MR} = \partial(pq)/\partial q = a - 2q/\eta$

**Let  $p = 1$  and  $q = 1$  at equilibrium with generic competition**

**Then monopoly price is**  $p = 1 + \frac{1}{2\eta} - \frac{1 - \alpha - \beta}{2(\eta + \beta)}$ .



**Table 5. Approximate Incentives for the Original Entrant to Extend Monopoly Pricing**

Compound	Monopoly Price	Competitive Price	Unit	Price Effect	Market Volume	Monopoly Revenue	Competitive Revenue	Monopoly Incentive
	(\$/unit)	(\$/unit)		(%)	(mil. lbs.)	(mil. \$)	(mil. \$)	(mil. \$)
Linuron	\$12.25	\$7.75	lbs. a.i.	36.7	4.0	\$44.9	\$31.0	\$16.5
Gibberellic Acid	\$1.64	\$0.85	grams	47.8	14.0	\$20.5	\$12.0	\$9.8
Atrazine	\$2.63	\$2.00	lbs. a.i.	24.0	70.5	\$174.9	\$141.0	\$41.9
Simazine	\$3.88	\$2.38	lbs. a.i.	38.7	4.5	\$15.9	\$10.7	\$6.2
Glyphosate	\$77.50	\$44.52	gallons	42.6	27.5	\$481.6	\$306.1	\$204.9
Trifluralin	\$28.50	\$21.43	gallons	24.8	25.5	\$171.1	\$136.6	\$42.4

Source: The sources of prices and market volumes are explained in the text. Regarding market volume as a partial-competition volume, the monopoly volume is estimated using a demand elasticity of -.25.

**Table 7. Welfare Impacts of Delaying Generic Entry for One Year**

Compound	Generic Market Share	Generic Profit Loss		Farmer & Consumer Loss	Original Registrant Gain		Net Social Loss	
		Competitive Margin 10%	Competitive Margin 20%		Competitive Margin 10%	Competitive Margin 20%	Competitive Margin 10%	Competitive Margin 20%
	%	----- million \$ -----						
Linuron	21.1	\$0.7	\$1.3	\$17.2	\$16.9	\$17.3	\$1.0	\$1.3
Gibberellic Acid	50.1	\$0.6	\$1.2	\$10.4	\$10.3	\$10.7	\$0.7	\$0.8
Atrazine	5.5	\$0.8	\$1.6	\$43.2	\$41.9	\$41.9	\$2.1	\$2.8
Simazine	12.8	\$0.1	\$0.3	\$6.5	\$6.2	\$6.2	\$0.4	\$0.5
Glyphosate	10.0	\$3.1	\$6.1	\$215.8	\$205.1	\$205.2	\$13.8	\$16.8
Trifluralin	10.8	\$1.5	\$3.0	\$43.8	\$43.1	\$43.8	\$2.1	\$2.9

Prices and market volumes with and without competition are as given in Table 9. The basis for market shares is given in the text except that the share for glyphosate is merely given as an example.

# Observations

- Generic firms usually gain less than \$1M per year (10% profit margin)
- Claims of \$12M (linuron) or \$6.7M (atrazine/simazine) can be more than all discounted future profit
- Effects on farmers/consumers are
  - 31-87% of total competitive revenue
  - 310%-870% of competitive profit if 10% profit margin
- Farmer/consumer losses are larger than original entrants gain from extending a monopoly
- Social loss is 5-8%

# **A 5-Stage Model of a Product Life Cycle**

- 1. Original entrant decides whether to incur development expenses**
- 2. Original entrant decides investment in plant capacity & incurs regulatory test costs**
- 3. Original entrant produces & sells as a monopolist**
- 4. Patent expires—generic entrants decide whether to enter/invest & incur uncertain test cost obligation**
- 5. Production & sales occur with limited competition until market termination**

# The Model

Quasilinear consumer utility  $u = h(q) + z$  s.t.  $m = pq + z$

Demand  $p = a - bq$  where  $h(q) = aq - bq^2 / 2$

Patent period: Fixed cost  $f_0 + k_0 \bar{q}_0$  (testing + plant capacity)

and constant variable cost  $v_0$

$$\max_{\bar{q}_0 \geq 0} \left\{ n_0 \left[ \max_{q_0} E[q_0(p_0 - v_0)] \Big| 0 \leq q_0 \leq \bar{q}_0 \right] - f_0 - E(k_0) \bar{q}_0 \right\}$$

Backward dynamic programming leads to

$$\max_{\bar{q}_0 \geq 0} \left\{ n_0 \bar{q}_0 E(p_0 - v_0) - E(f_0 + k_0 \bar{q}_0) \right\}$$

and implies  $\bar{q}_0 = (\bar{a} - \bar{c}_0) / 2b$ ,  $\bar{c}_0 \equiv \bar{v}_0 + \bar{k}_0 / n_0$

## Post-patent period:

$$\max_{\bar{q}_1} \left\{ n_1 \left[ \max_{q_1 \geq 0} E[q_1(p_1 - v_1)] \mid 0 \leq q_1 \leq \bar{q}_1 \right] - E[f_1 + k_1(\bar{q}_1 - \bar{q}_0)] \right\}$$

implies  $\bar{q}_1 = (\bar{a} - \bar{c}_1) / 2b$ ,  $\bar{c}_1 \equiv \bar{v}_1 + \bar{k}_1 / n_1$

**Generic entrant has constant variable cost  $v_2$**

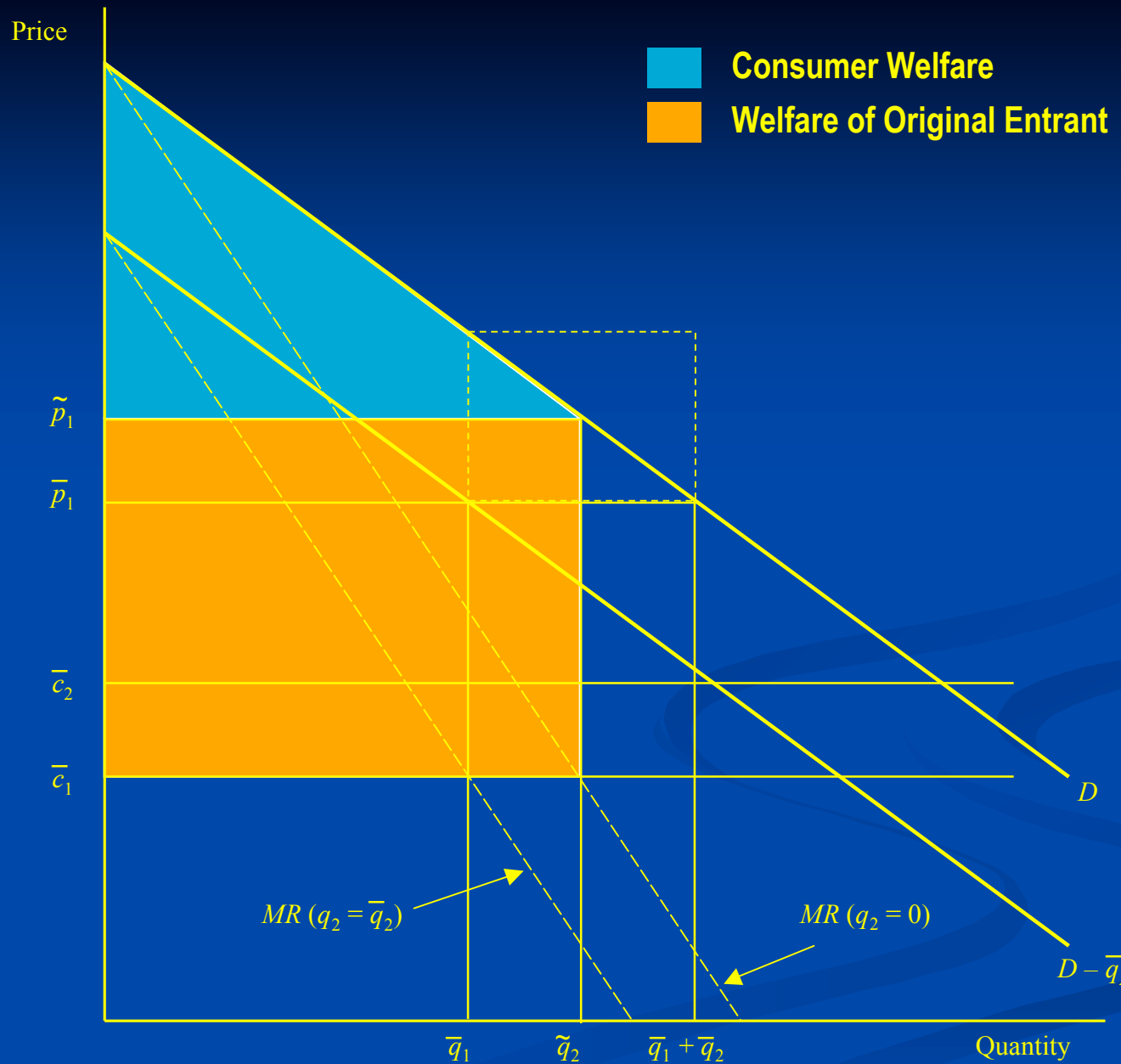
**Fixed cost  $f_2 + k_2 \bar{q}_2$  (generic test cost + plant capacity)**

$$\max_{\bar{q}_2} \left\{ n_2 \left[ \max_{q_2 \geq 0} E[q_2(p_1 - v_2)] \mid 0 \leq q_2 \leq \bar{q}_2 \right] - E[f_2 + k_2 \bar{q}_2] \right\}$$

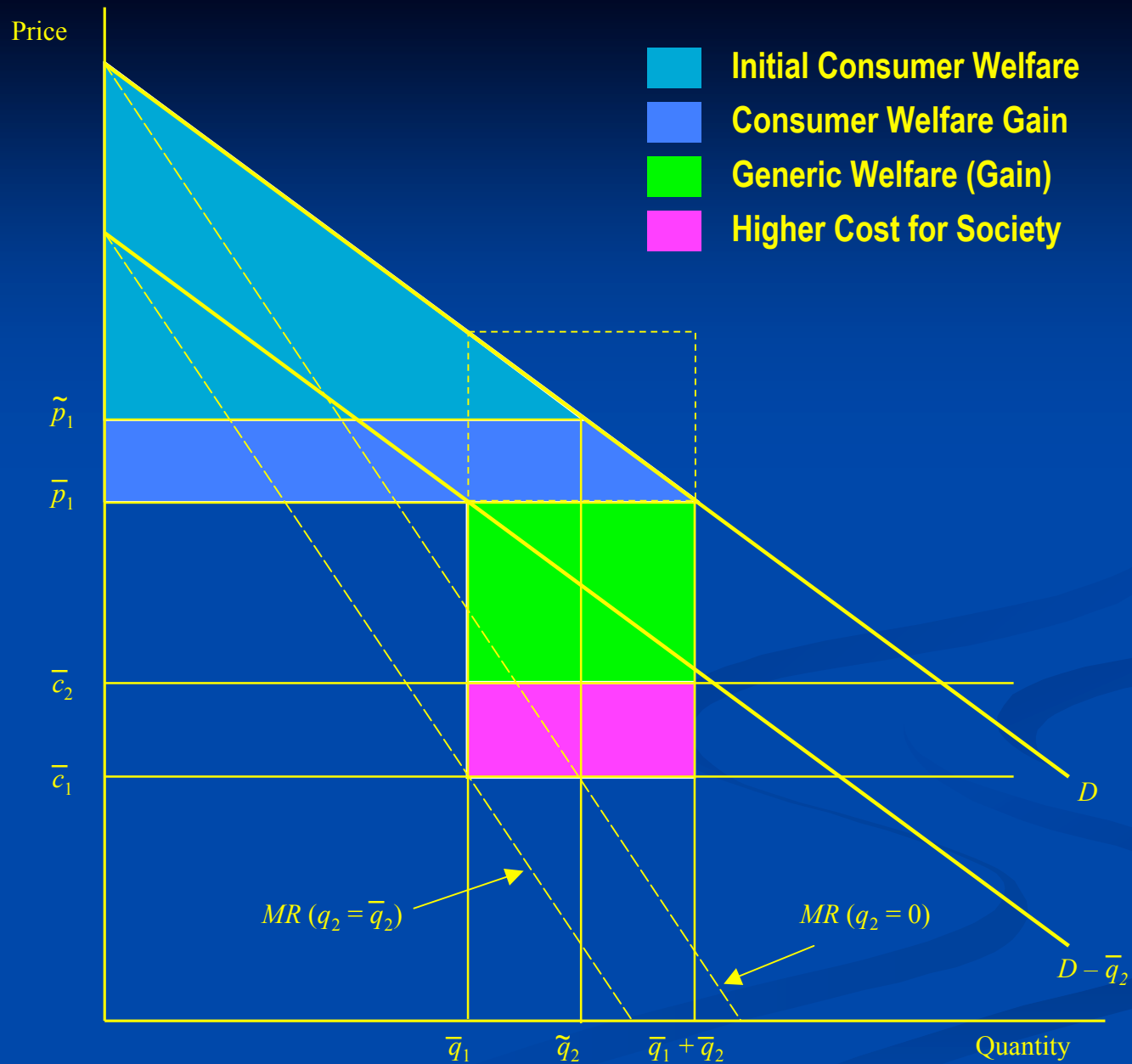
implies  $\pi_2 = \bar{q}_2(\bar{p}_1 - \bar{c}_2) - \bar{f}_2 / n_1$ ,  $\bar{c}_2 \equiv \bar{v}_2 + \bar{k}_2 / n_1$ .

**Change in social welfare depending on generic entry:**

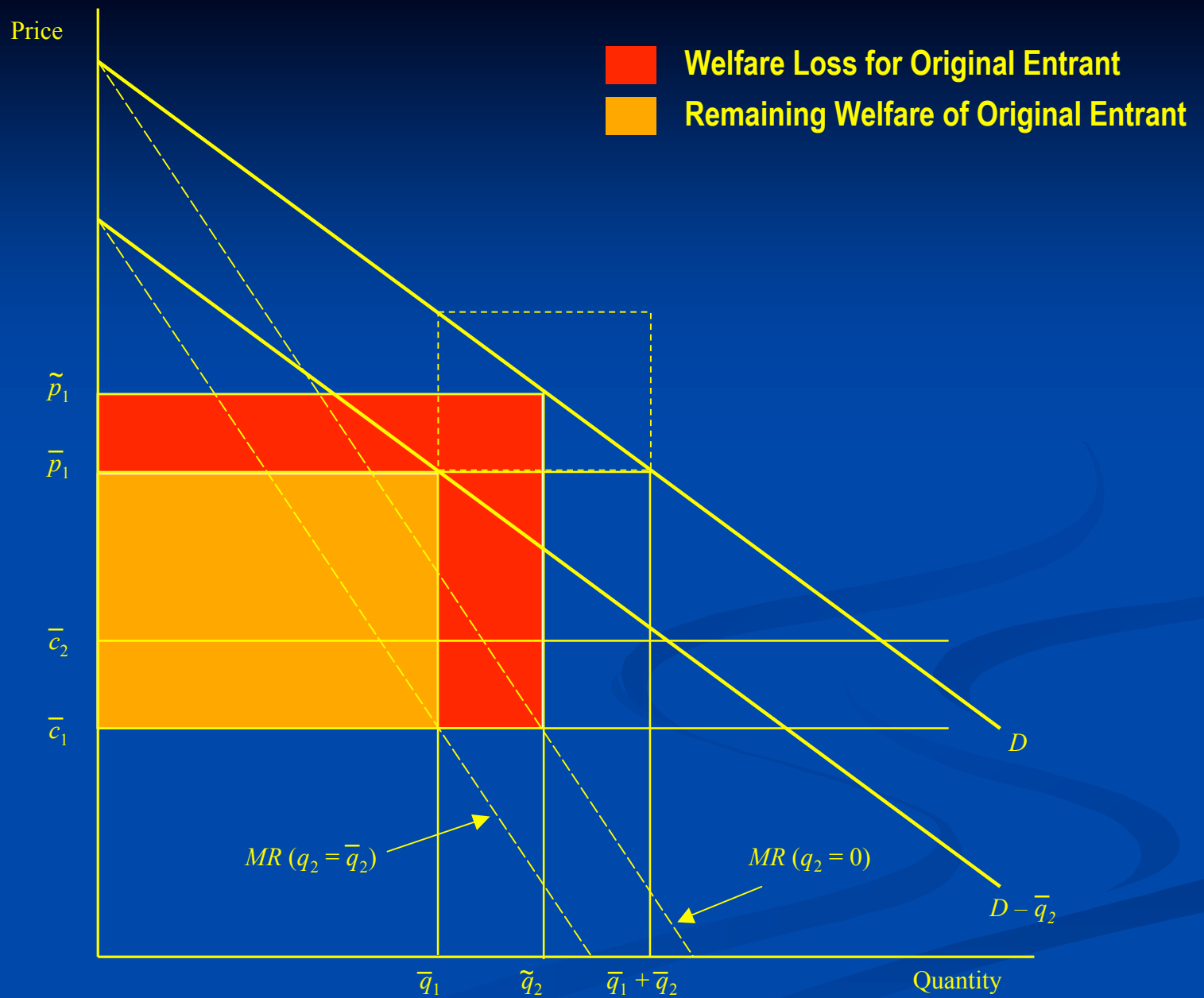
$$\Delta w = \frac{b\bar{q}_2^2}{8} + \frac{\bar{q}_2}{4} (\bar{a} - b\bar{q}_2 + \bar{c}_1 - 2\bar{c}_2) - \frac{\bar{q}_2}{2} (\bar{c}_2 - \bar{c}_1) - \frac{\bar{f}_2}{n_1}.$$



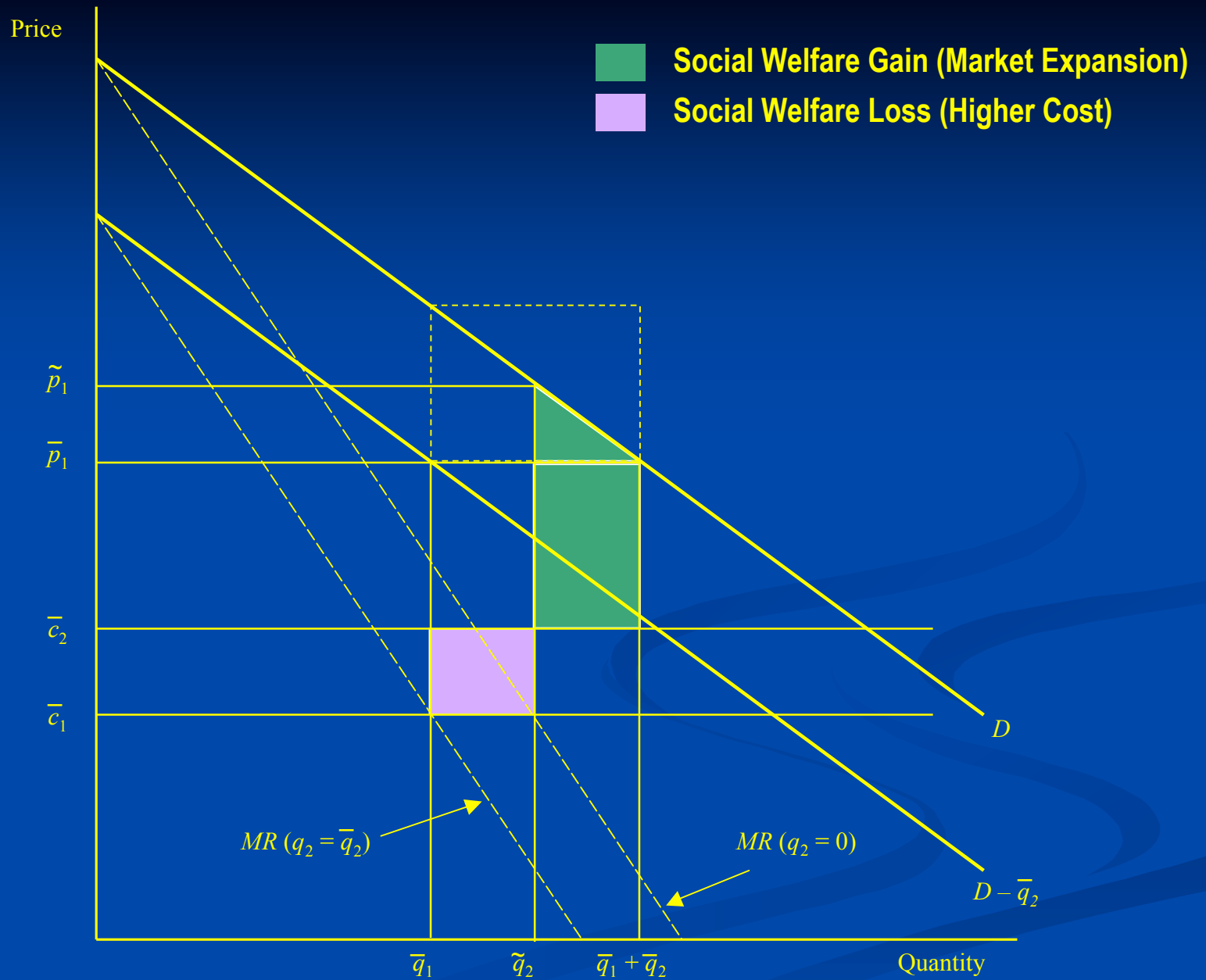
**Without Generic Entry**



## Consumers and Generic Welfare With Entry



## Impact of Generic Entry on Original Entrant



## Net Social Welfare Effects of Generic Entry

# Optimal Sharing of Regulatory Test Cost

Trade-off: Incentives for innovation vs later competition

$K$  = aggregate regulatory cost,  $\alpha$  = generic share of cost

$F(\Pi_2)$  = distribution function of generic profit

$G(\Pi_1)$  = distribution function of original entrant profit  
(both exclusive of regulatory cost)

$$\Pi_2 = n_1\pi_2, \quad \Pi_1 = n_0\pi_0 + n_1\pi_1, \quad \Pi_1^* = n_0\pi_0 + n_1\pi_1^*$$

$$C = F(\alpha K)K + [1 - F(\alpha K)](1 - \alpha)K$$

$$W = G(C)(n_0 + n_1)m$$

$$+ [1 - G(C)] \{ n_0 w_0 + n_1 w_1 + [1 - F(\alpha K)] n_1 \Delta w - K \}.$$

$$W_\alpha = -[1 - G(C)]F'(\alpha K)Kn_1\Delta w < 0$$

$$- G'(C)C_\alpha \{n_0(w_0 - m) + n_1(w_1 - m) \text{ sign}(-C_\alpha)$$

$$+ [1 - F(\alpha K)]n_1\Delta w - K\}$$

$$C_\alpha = \{\alpha KF'(\alpha K) - [1 - F(\alpha K)]\}K.$$

$$C_\alpha \geq 0 \text{ implies } W_\alpha < 0$$

**Which implies minimizing the generic share if:**

- **Regulatory cost is high**
- **Marginal effect of  $\alpha$  on probability of generic entry is high, or**
- **Probability of generic entry is low**

# Sharing Post-Patent Regulatory Cost

Suppose  $K$  applies only to the post-patent period (call-in data)

$$W = n_1 w_1 + [1 - F(\alpha K)] n_1 \Delta w - K.$$

- Social welfare (increased competition) follows from decreasing  $\alpha$ .
- If the original entrant behaves competitively, social optimality implies market sharing
- A similar result applies for sharing between the patent and post-patent periods

## Implications for FIFRA versus TSCA

- **Cost sharing provisions of TSCA are consistent with economic efficiency if competitive pricing is enforced**
- **Cost sharing provisions of FIFRA depend on implementation in arbitrations**
- **Most awards are not consistent**
- **15-year compensability considerations**

# Conclusions

1. Novel products tend to have unknown risks
2. Risky products require government regulation
3. Costs of testing must be borne privately to avoid excessive incentives for risky products
4. Novel products tend to involve high development costs
5. High development cost implies large post-patent benefits of competition (> average total cost pricing)
6. Duplication of tests with later generic entry is wasteful
7. Private sharing fails; original entrant prefers monopoly
8. Regulated sharing should impose standards to avoid litigation and manipulation for anticompetitive purposes

## Conclusions for Sharing Test Costs

1. Per capita sharing is not socially optimal
2. Sharing based on time in market is socially optimal
3. Market sharing is socially optimal if the original entrant prices competitively and costs of production are uniform among firms
4. Generic share is less under dominant-firm price leadership
5. Without cost information, market sharing likely works well under contestable market theory (tends to low cost production)
6. Gaming is not likely if profits are high relative to test costs
7. Gaming can be avoided by step functions (Dearden and Einolf)
8. With risk preferences, little of the original entrant's risk premium is likely due to test costs whereas most of generic firm's is

