Regulatory Competitive Shelters (RCSs)

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What ARE Regulatory Competitive Shelters?

- Time-limited competitive advantages
- Resulting from statutory bars on regulatory action
- Where the regulatory action is otherwise mandated in legislation
- The bar was triggered by earlier regulatory action of the type that is being barred
- For example: the 5-year New Chemical Entity (NCE) exclusivity under the Hatch-Waxman Act

Other Examples of RCSs

RCS name and instituting statute	Year Instituted	Administering agency	RCS type	Length (years)
Pesticide Exclusivity under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)	1978	EPA	Data	10 + 3x1
Orphan drug exclusivity under the Orphan Drug Act	1983	FDA	Market	7
New chemical entity (NCE) exclusivity under the Hatch-Waxman Act	1984	FDA	Market and Data	5
New approved use under the Hatch-Waxman Act	1984	FDA	Market	3
Generic exclusivity under the Hatch-Waxman Act	1984	FDA	Market	0.5 (180 days)
New chemical compound exclusivity under the Generic Animal Drug and Patent Term Restoration Act (GADPTRA)	1988	FDA	Market and Data	5
New approved use under the Generic Animal Drug and Patent Term Restoration Act (GADPTRA)	1988	FDA	Market	3
Generic exclusivity under the Generic Animal Drug and Patent Term Restoration Act (GADPTRA)	1988	FDA	Market	0.5 (180 days)
Pediatric exclusivity under the FDA Revitalization Act of 1997	1997	FDA	Market	+ 1
Class III medical device exclusivity under the FDA Revitalization Act of 1997	1997	FDA	Data	6
New product exclusivity under the Biologics Price Competition and Innovation Act (BPCIA)	2010	FDA	Market	12
	2010	FDA	Data	4
Generic exclusivity under the Biologics Price Competition and Innovation Act (BPCIA)	2010	FDA	Market	1-3.5 (42 months)
Qualified infectious disease product designation under the Generating Antibiotic Incentives Now (GAIN) Act	2012	FDA	Market and Data	+ 5

Why "Regulatory Competitive Shelters"?

- Specifity
- Accurate characterization of effect
- "Regulatory exclusivities," and "statutory exclusivities" are overbroad; "data exclusivities" is a mischaracterization

Some common features of RCSs

- Primary purpose: technological innovation
- Predetermined term
- No formal "grant" by agency
- Automatic enforcement
- Difficult to challenge

When Should Congress Consider Instituting RCSs?

- Additional incentives for innovation are necessary (= where patents provide insufficient incentive for innovation)
- There are policy reasons to drive innovation in a certain direction (*e.g.*, in-vitro meat)
- The merits of a technology can be directly evaluated by an agency with appropriate expertise (*e.g.*, FDA, EPA, NIH)
- The practical application of the pertinent technology which is to be regulated requires regulatory approval or the removal of a regulatory bar

RCSs: Possible **Perils** (or: when we should oppose the institution of RCSs even though the industry might really-really want them)

- Potential societal waste: when there are sufficient incentives for innovation already in place (problem: difficult to determine and often controversial)
- Administrative costs might be substantial.
- Increased likelihood or evidence of patent abuse.

  (Possible fix: make RCS beneficiaries choose between RCSs and the ability to enforce their patents against follow-on applicants)
- Increased risk of agency capture of the administering agency

RCSs: Issues Requiring Further Study

- How to determine appropriate RCSs length?
- Why some RCSs work better than others?