

Approval Regulation: Theory, Empirics and Possible Applications to Consumer Finance

Dan Carpenter

Department of Government
Center for American Political Studies
Institute for Quantitative Social Science
Harvard University

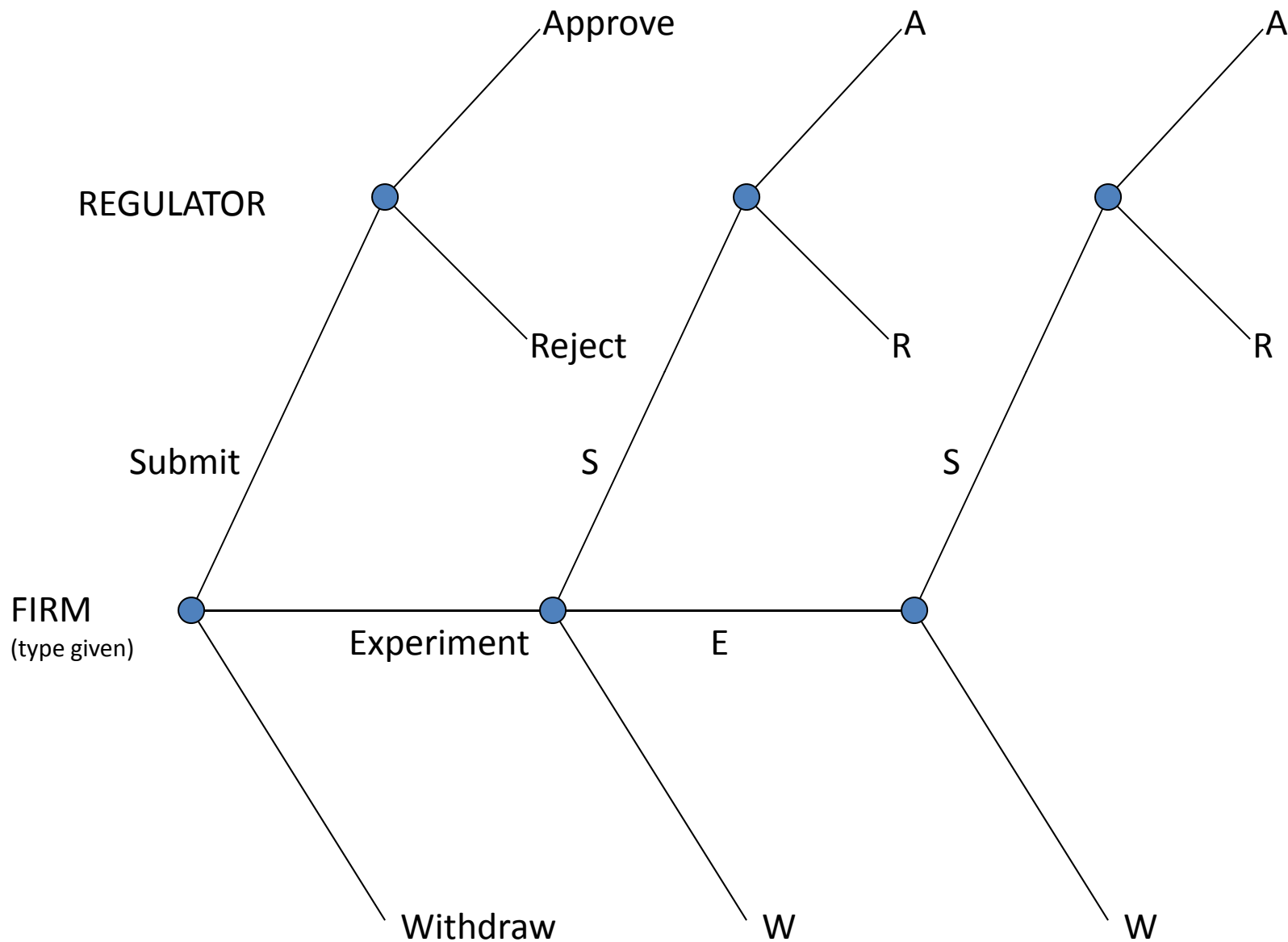
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What is Approval Regulation?

Optimally, Making a Market

1. Regulation of entry by a submission process requiring pre-market approval of products based upon an experimental record.
2. Partial or full veto over product entry; can be approximated by rapid product removal capacity.
 - Prime example: FDA regulation of new drugs, biologics, devices, food additives.
3. Sum point: regulation doesn't just intervene into existing markets; it also makes a market.

Stages of Approval Regulation Game



Source: Carpenter and Ting (2007); Carpenter, Grimmer and Lomazoff (2009)

Confidence Effects I

Key: what incentives does regulation create for the provision of high-quality information about products?

Theory: (1) Distribution of regulated products has less uncertainty than unregulated distribution.

- Required provision of near-experimental information
- Truncation of quality distribution – lower likelihood of ‘lemon’ entry

(2) Carpenter et al (2009 working paper): first effect is sufficient to increase utilization/consumption **for risk-neutral consumers** given strictly positive cost of product switching. Similar result would hold for investment products with costly reversibilities.

“Confidence Effects” II

If model is right, dominant effects are not supply contraction, but demand expansion.

Eqm Price may rise, but this is endogenous to ‘confidence’.

Critical test: does consumption expand or contract after introduction of entry/quality regulation?

Marc Law (*Journal of Economic History*) [2006]: expansion in food consumption in Progressive Era

Sukkoo Kim (*JEH*, others): occupational licensing, also expansion, esp. for minorities

Pharmaceuticals: does Rx utilization increase after FDA regulation? [Some positive evidence from formulary decisionmaking by insurance plans, but observational and too early to say.]

Tale of Success: The Quasi-Experiment in Pharmaceuticals (DESI)

Drug Efficacy Study Initiative (1960s, 1970s),
removed hundreds of drug products from market
(predominantly, fixed-combo antibiotics,
tranquilizers).

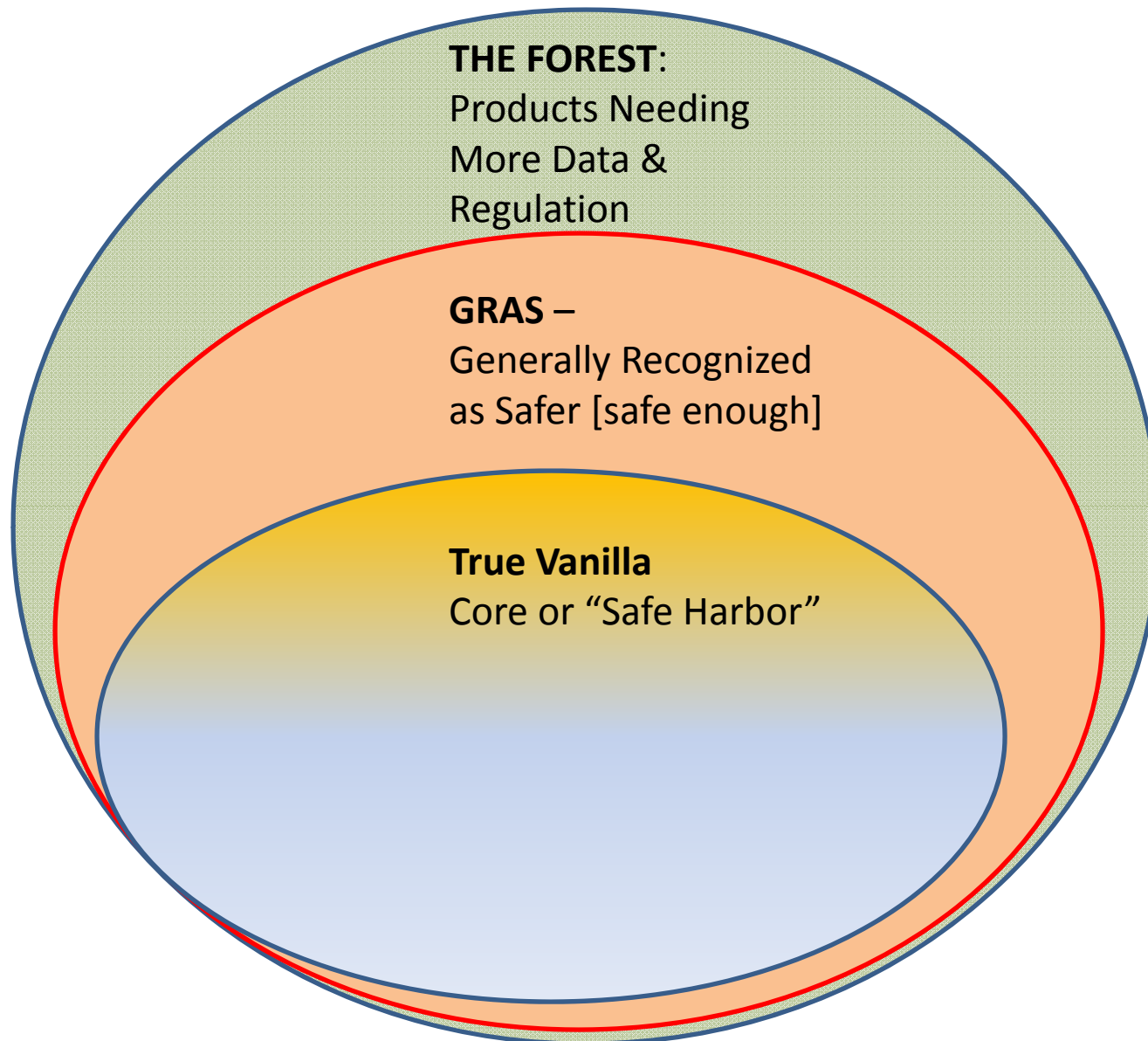
Ten years later, we get the rise of much more
effective psychopharmaceuticals (tricyclic
antidepressants, then SSRIs, ...); the market has
been largely cleared of 'lemons.'

Ongoing research: Carpenter et al (2009), "Health
and Economic Effects of Regulatory Product
Removal: The Case of DESI."

Can it Map to Consumer Finance?

I Don't Know

1. NEED TO BE CAREFUL. No need for a 3-phase, 10-year trial process – could have roll-out .
2. Could combine with “file-and-use” process – regulator & public know the population of products, allowing for better “post-market surveillance” and superior quasi-experiments.
3. From theory, KEY strategy is (a) warning labels, (b) required data collection and experimentation on products about which we know less. →



4. Larger information requirements for newer, riskier products. But, who pays for the information?

Can it Map to Consumer Finance?

5. PROBLEM: What if disclosure, “nudging,” etc., doesn’t solve problem of fraud or repeated mistakes? What happens then?

6. PROBLEM: FINANCIAL INNOVATION

- (a) depends on marginal regulatory costs attached to being outside of pure vanilla category
- (b) theoretically, not true that approval regulation will lead to less innovation. Truncation of lemons from distribution creates space for ‘good’ product entry. This is extension of Akerlof, lemons argument.
- (c) Need more rigorous discussion of what financial innovation is and what its utility is.
- (d) ARGUMENT: Rx innovation actually saves lives, yet we (& everyone else) regulate it stringently.

SUM

1. Approval regulation has informational effects; customary CBA will miss benefits as well as costs of approval regulation.
2. Regulation does not always limit innovation; properly designed, it can enhance innovation.
3. **Institutions**, not markets alone, needed for provision of high-quality information.

Q: What incentives/structures does regulation provide for revealing and aggregating information? Does it allow anyone to take a view that is [a] bird's eye and [b] near-experimental?

Q: Re heterogeneity, will regulation preserve subpopulation analysis?