Decay, Shock and Renewal: Operational Routines and Process Entropy in the Pharmaceutical Industry

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Before Proceeding

Context - Pharmaceutical Industry

- Needs way to ensure quality of products
- Routines as quality control
- Therefore, routines as targets
- ... Imperfect compliance

Terms

- Intended Stability: Good for coordination, supervision, consistency
- Unintended Stability: Inertia, rigidity
- Intended Instability: Improvisation, flexibility
- Unintended Instability: Nonconforming output

Tends to Chaos

Theoretical framework: imperfect compliance as the result of process entropy - the system may steadily tend to more chaotic disorganized situations.

Hyp. 1 Absence of renewal $\Rightarrow$ organization's adherence to "routines as targets" tends to decay, leading to a state of higher entropy over time.

$$\frac{\partial Adherence_i}{\partial t} < 0$$

Hyp. 2 Organizational shocks cause an organization's adherence to "routines as targets" to decay and reach a state of higher entropy.

$$\frac{\partial Adherence_i}{\partial Shock} < 0$$

Hyp. 3 Degree to which an organization's adherence to "routines as targets" tends to decay over time varies by organization.

$$Adherence_i \neq Adherence_j \ (i \neq j)$$

Data & Empirics

FDA (Food and Drugs Administration)'s dataset on all manufacturing plants inspected by the FDA between (1994-2007)

- Consistent guidelines
- All plants that supply to the US
- Only data with more than 1 inspection: 20550 inspections of 5355 plants. 2048 inspections in 728 plants outside US
- Data from companies not identified or not pharmaceuticals classification removed: left: 8080 inspections (27% of original) of 1493 plants from 886 different companies
- Scrutinous inspections: 130 person-hours. Can lead to: product recalls, product seizure, injunctions or close a plant

Sample representative?

- Inspections follow Poisson process (random)

Outcomes of inspections: [Our entropy measure] [reflects compliance to good manufacturing practices (GMPs)] [malpractice punishment] [exogenous rewards]

- **Official Action**: public warning letter and consequences if not corrected
- **Voluntary Action**: observations but not formal that should be addressed until next inspection
- **No Action**: no major violations

$$
\begin{aligned}
Outcome_{i(p,t)} = \\
& a_1^p \ln(Time\ since\ last_{i(p,t)}) + a_2 \ln(Time\ since\ last_{i(p,t)}) POutcomeVA_{i(p,t)} \\
& + a_3 \ln(Time\ since\ last_{i(p,t)}) POutcomeOA_{i(p,t)} + a_4 Merger_{i(p,t)} \\
& + a_5 Acquired_{i(p,t)} + a_6 POutcomeVA_{i(p,t)} + a_7 POutcomeOA_{i(p,t)} \\
& + a_8 Compliance_{i(p,t)} + a_9 Complaint_{i(p,t)} + a_{10} Foreign_p \\
& + (IndustryDummies)_p + (YearDummies)_t + error_p + error_i
\end{aligned}
$$

Inspection

- Inspection as external rewards
- Presumably, internal rewards mechanism
- Literature show that more time between inspections, more chance of bad results

M & A as shocks.

- 148 Merges and 96 Acquisitions.
- Selection bias

Results

R.1 Entropy Increase in the Absence of Renewal

Plants on low or moderate entropy at the time at last renewal. (If official action, cannot be worse). But effect is not dramatic [write the numbers]

R.2 Entropy Increase as Shocks

Merger: plant's likelihood of obtaining a worse inspection outcome $b = 0.24, p \leq 0.05$.
Acquisition: $b = -0.19, p \leq 0.05$. Post hoc explanation: acquisition: big healthy company acquire small company. It's a renewal.
Negative shock after merger subsides after a year. Benefits of acquisition after a year. Not significant though

R.3 Significant Std. Dev of regression slope *ln*(*Time since last*)

$(\sigma_p = 0.0015, p \leq 0.01)$ and intercept's heterogeneity $(\sigma_p = 0.253, p \leq 0.01)$

Control Variables

- Consumer complaint inspections are less likely to bad results ($b = -0.23, p \leq 0.05$)
- Compliance inspections correlated with bad results ($b = 0.33, p \leq 0.01$)
- Overseas system: same ($b = 0.03, p = 0.52$)
- Official actions in 1994-2001 (21.2%) to 2002-2007 (12.6%)

Theoretical Implications

Legally required to be followed: so aware that external inspections can occur and can shut down the line, and failure of adherence to routines can give.
Insights: constant managerial attention to routines as targets
Plants that min decay: 1) tops: clear direction routines as targets. 2) Formal mechanism for renewal
Insights for Policy: FDA should target not random select plants: plants that went through merger and long-term have nots.

Limitations, Generalizability and Future Research

- Other events as renewals
- Dependent variable coarse representation of the continuous construct of state of process entropy
- Maybe more thorough check if inspected long time ago
- Small plants underrepresented (manufacturers with more than 3 inspections)
- Pharmacy is conservative: 1) legal requirements, 2) consequences harmful for human life.
- Operational routines, not search routines (R&D)

My Takes

- Adherence-aware algorithms. Perhaps, an optimal procedure with decay may be worse than without
- When a measure becomes a target, it ceases to be a good measure. - Goodhart's Law
- Putting off fire VS maximizing

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