



The Impact of Quality Ratings Systems: Lessons from other Industries

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Study Overview & Objectives



- Quality ratings are used in many industries
- Use cases were selected based on a set of key criteria critical to the success of QMM ratings:
 - Ability for ratings to reduce manufacturing quality information asymmetry problem
 - Ability for ratings to affect product pricing and quantity
 - Ability to expand pool of rating participants
 - Ability for federal regulator to effectively use ratings to oversee industry



Use Case 1: Information Asymmetry



- For decades, used car market characterized by information asymmetry between buyers and dealers
 - So-called "lemons problem" created
 - Market imperfections include mispricing of good and bad quality used cars
 - Adverse selection leaving only bad quality cars in the market



Use Case 1: Information Asymmetry



- CARFAX® revolutionized used car buying
 - Aggregated data from variety of sources on vehicle history; repairs and damages
- CARFAX® is not a rating per se, but does use information that generates a riskbased value for a used car
- The market for used car information has since flourished among buyers and sellers
- Implications for QMM:
 - Widespread adoption of used car reports and quality-based estimators demonstrates that product assessment processes can reduce information asymmetries, promoting better quality product



Use Case 2: Ratings Impacts on Pricing



- Centers for Medicare and Medicaid Services (CMS) established a 5-star quality rating for nursing homes
- Basis for ratings:
 - Health inspections and complaints
 - Facility staffing levels
 - Facility quality



Use Case 2: Ratings Impacts on Pricing



 An empirical study of this program sought to understand the effect of ratings on nursing home prices

Study findings:

- Prices for highest rated nursing homes rose 5-6% over lowest rated facilities
- Higher prices mostly observed where markets were more competitive
- This suggests that with scarcity, high quality facilities might be able to raise prices more than lower-rated competitors

Implications for QMM:

 Potential that capacity constraints in competitive drug product markets where a QMM rating exists could raise pricing somewhat more for higher-quality manufacturers over lower-rated ones



Use Case 3: Adoption of Quality Ratings



- French manufacturer adoption of ISO 14001 environmental management standards (EMS)
- More than 360,000 firms worldwide have adopted ISO 14001 since versions appeared in the early 1990s
- What factors differentiate early- from late- or nonadopters?
 - International presence
 - Operate in moderate to high-tech manufacturing
 - More innovative
 - Larger
 - Experience with adopting other standards (e.g., ISO 9001, TQM)



Use Case 3: Adoption of Quality Ratings



 Investigators found companies adopting ISO 14001 realized productivity gains

Implications for QMM:

- FDA could "grow" participation in QMM by developing an outreach plan targeting firms most likely to adopt
- Once early-adopter experiences have been communicated, a bandwagon effect could take hold



Use Case 4:Federal Regulatory Use of Ratings



- Federal agencies regulating the safety and soundness of depository institutions (banks, thrifts and credit unions) develop and apply CAMELS ratings
 - C Capital adequacy
 - A Asset quality
 - M Management
 - E Earnings
 - L Liquidity
 - S Sensitivity to market risk



Use Case 4:Federal Regulatory Use of Ratings



CAMELS ratings features:

- 1-5 scale (1 = best, 5 = worst)
- Mandatory ratings developed by regulator from examinations
- Disclosed only to the bank
- Ratings can affect depository activities and pricing of deposit insurance

Implications for QMM:

- Ratings have been highly successful for federal regulators managing safety and soundness of banking sector
- FDA could consider developing risk-based policies (e.g., regulatory flexibility for drug applications) to further incent manufacturer investment in QMM



Summary



- A variety of use cases highlight key success criteria for QMM:
 - Ratings can reduce information asymmetry problems and create incentives for investment in QMM
 - Differentiating price based on quality is possible under a ratings system
 - Targeting companies most likely to adopt QMM will help build momentum in industry adoption over time
 - Tying ratings to risk-based regulatory policies has been successful for federal banking regulators to incent company focus on managing risk





Questions?

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Closing Thought



Based on my research, FDA should not only embrace the implementation of QMM ratings but provide sufficient resources to build it out for maximum industry impact



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