The Impact of Quality Ratings Systems: Lessons from other Industries

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CDER's Quality Management Maturity (QMM) Program – May 25, 2022

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 risk-based 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

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Questions?

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Economics and Risks Associated with FDA's QMM Rating Program

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Study Objectives and Overview

- Identify market barriers to manufacturing investment with and without a quality rating
- Understand the economic consequences and effectiveness of manufacturing quality ratings

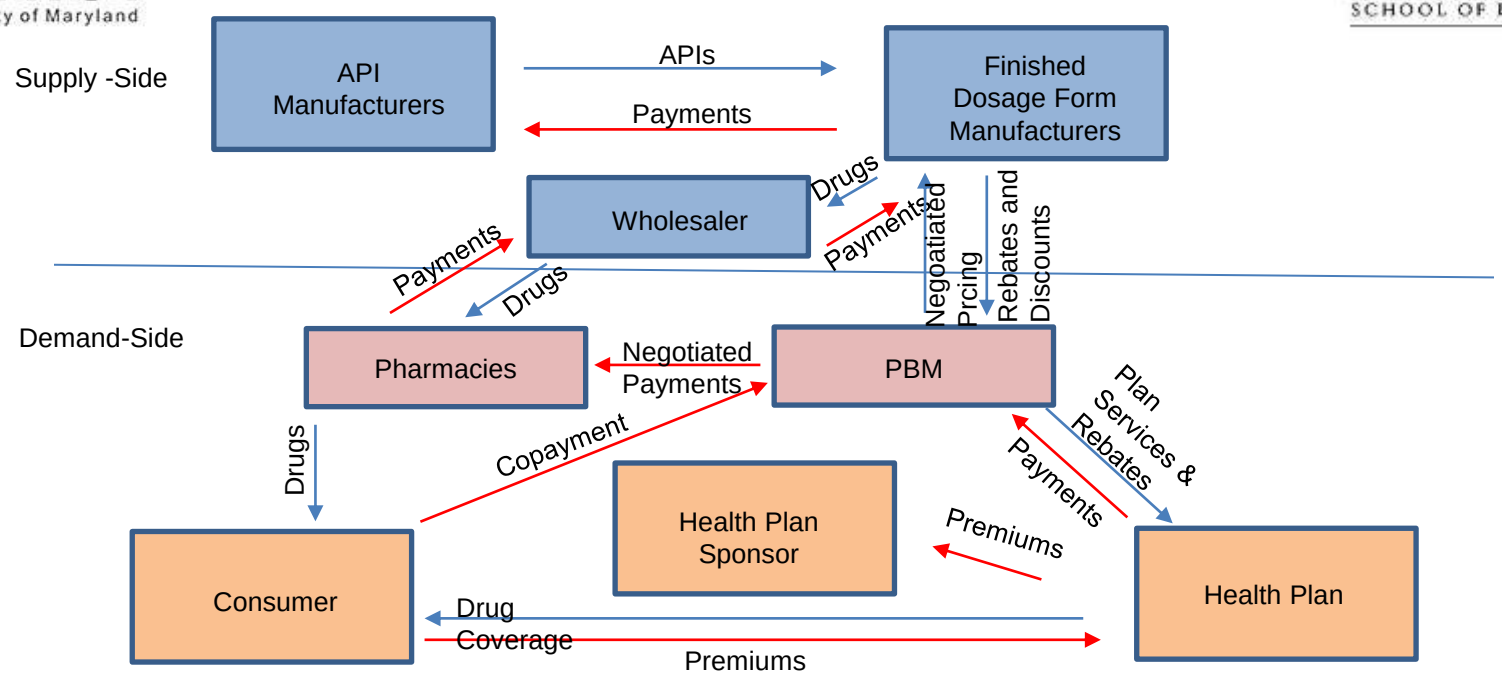
Pharmaceutical Market Structure Factors Affecting Investment in QMM

- Information asymmetry precludes manufacturing quality from entering product negotiations
- FDA “Safe & Effective” doctrine contributes to lack of product differentiation by quality
- Price inelasticity of drug products as necessities, limits effectiveness of quality-based pricing

Pharmaceutical Market Structure Factors Affecting Investment in QMM

- Wide variation in degree of market competition for drug products
- Generally tight manufacturing capacity
- Complexity among buyer, sellers and intermediaries for pharmaceutical products

Multiple Touchpoints in Pharmaceutical Market Reduces Potential Demand for Quality



Economics of Pharmaceutical Market

- Multiple markets exist with varying degrees of competition
- Market competition defined by the number of sellers and buyers and their market power
- Markets considered for this study:
  - Competitive (baseline)
  - Oligopolistic (few sellers)
  - Monopolistic (1 seller)
  - Oligopsonistic (few buyers)

Economics of Quality Ratings

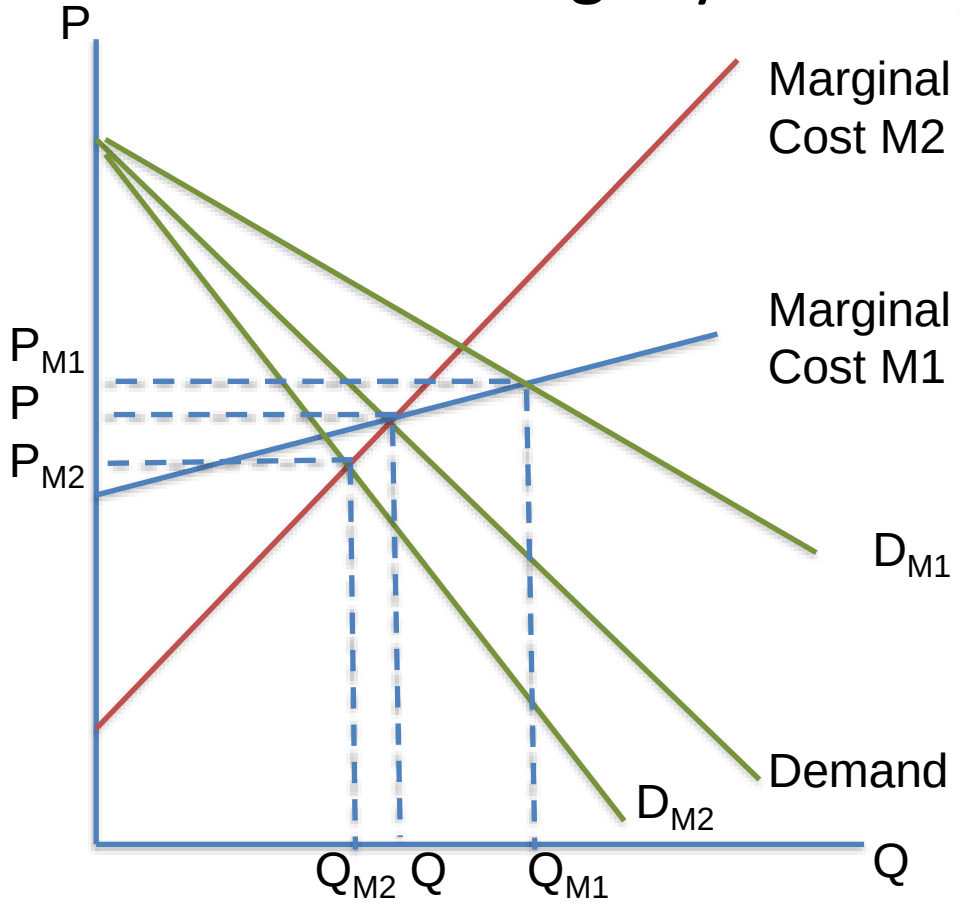
- Consider a market with 2 sellers (oligopoly) where no manufacturing quality rating exists
- Buyers are unable to distinguish a high-quality manufacturer (M1) from low quality (M2)
- As a result, both sellers face the same demand curve

Economics of Quality Ratings

- Introduction of a quality rating changes the market dynamics from before
- If M1 (M2) receives a higher (lower) rating, each face a different demand curve
- Subsequently, this could affect price and quantity in the market for a drug product

Price Differentiation Under a Ratings System

- In a market without a rating, equilibrium is found at price P and quantity Q
- With a rating, prices and quantities differ between M1 and M2



Implications for QMM

- Product differentiation based on quality ratings provides market signals that could incent manufacturers to invest in QMM practices
- Market limitations include:
  - Product price inelasticity
  - Level of market adoption of a voluntary rating
  - FDA resources to support a ratings assessment process
  - Existing market complexities reducing end user demand for quality
- Quality ratings may have greater utility in promoting investment in QMM via negotiations for drug formulary placement

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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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