Economics and Risks Associated with FDA's QMM Rating Program

Clifford Rossi, PhD
Professor-of-the-Practice and Executive-in-Residence
Robert H. Smith School of Business
UNIVERSITY OF MARYLAND, COLLEGE PARK, MD

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

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

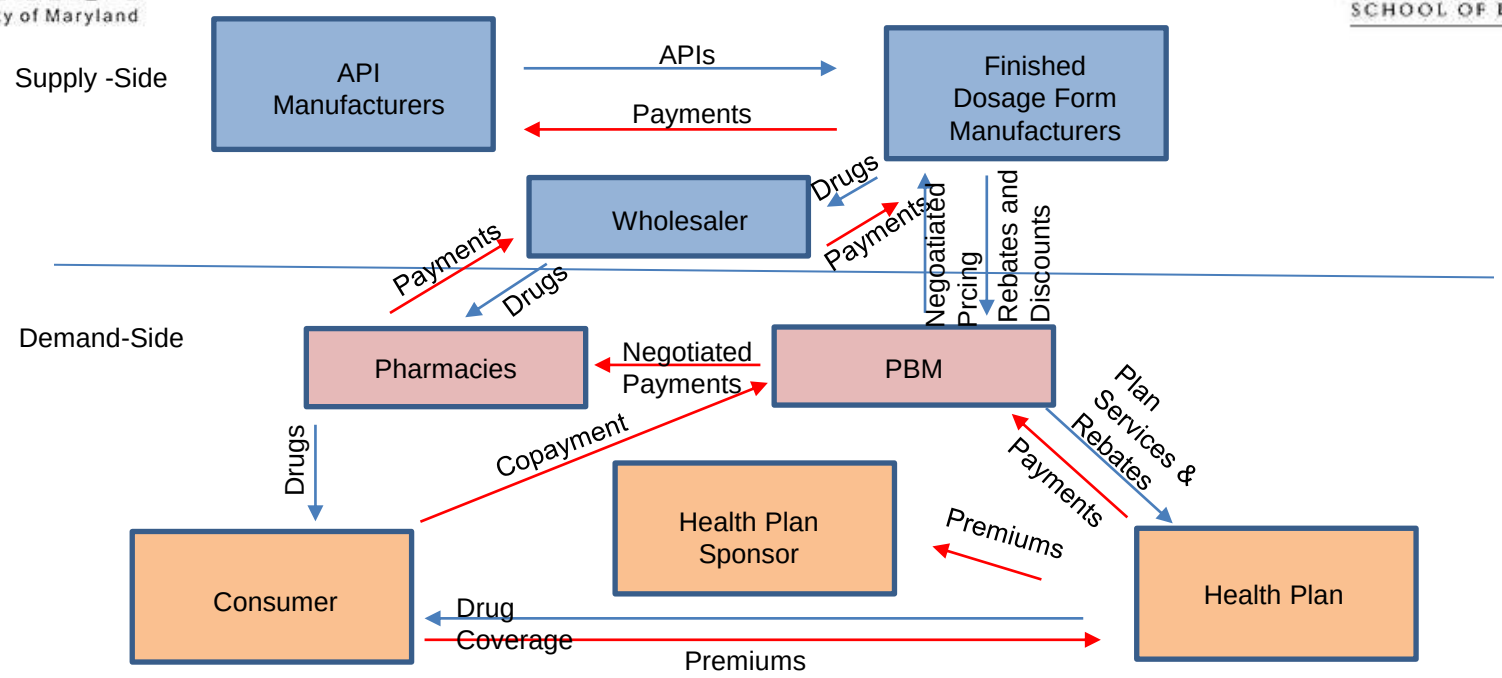
Pharmaceutical Market Structure Factors Affecting Investment in QMM

- 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

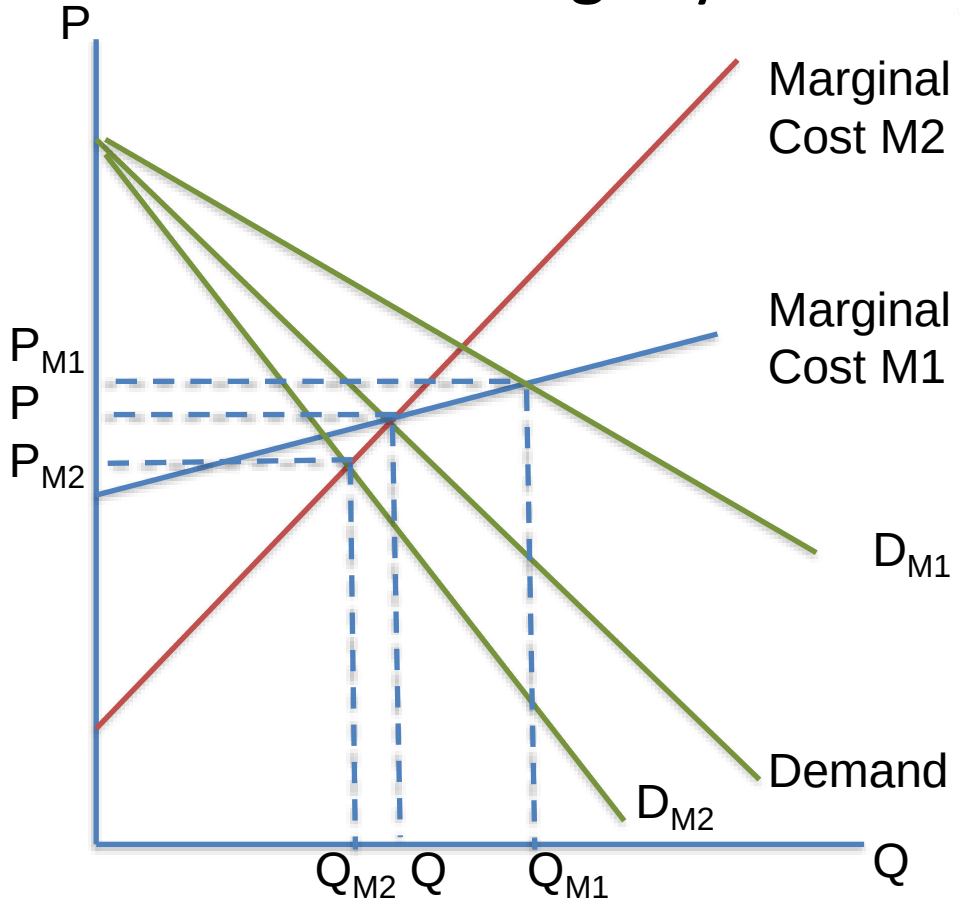
- Consider a market with 2 sellers (oligopoly) where no manufacturing quality rating exists
- Buyers are unable to distinguish a high-quality manufacturer (M1) from low quality (M2)
- As a result, both sellers face the same demand curve

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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University of Maryland

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ROBERT H. SMITH SCHOOL OF BUSINESS

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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