

Thani Jambulingam, Ph.D.

Chair & Associate Professor of Pharmaceutical Marketing
Saint Joseph's University – Haub School of Business
5600 City Line Avenue, Philadelphia, PA 19131
Phone: 610-660-3382 Email: tjambuli@sju.edu



Dr. Thani Jambulingam, is Chair and Associate professor in the Department of Pharmaceutical Marketing at St. Joseph's University, Erivan K. Haub School of Business, Philadelphia, Pennsylvania. He received his Master's degree and Ph.D. from University of Wisconsin-Madison. Dr. Jambulingam is also a pharmacist. Currently he teaches both in online and traditional Executive Pharmaceutical MBA program and undergraduate program in Pharmaceutical Marketing. Dr. Jambulingam worked for Glaxo Inc. for several years in sales, marketing research and new product launches. He has also served as a consultant and provided training to several pharmaceutical firms such as Alkermes, Abbott, Astra Zeneca, Cardinal Health, Merck, Novo Nordisk, Pfizer, Solvay, Wyeth, and Procter & Gamble.

In 2002, Dr. Jambulingam served as the Elected Chair of the Economic, Marketing and Management Sciences division of American Association of Pharmaceutical Sciences, a division of the American Association of Pharmaceutical Scientists

Thani's research interests are in pharmaceutical strategy, supply chain and pricing. His work has been published in several journals, such as the *International Journal of Pharmaceutical and Health Care Marketing*, *Journal of International Marketing*, *Journal of Operations Management*, *Journal of Business Venturing*, *Journal of Pharmaceutical Marketing and Management*, *Journal of Research in Pharmaceutical Economics*, *Information & Management among others*.

The recipient of Saint Joseph's 2002 *Extraordinary Achievement in Research award* his primary research interest is in pharmaceutical strategy, supply chain and pricing. He is also the recipient of Saint Joseph's 2004 *Extraordinary Achievement in teaching award* for his teaching in the Executive Pharmaceutical MBA program and in the Undergraduate Program. Dr. Jambulingam has received best paper awards in several conferences such as Decision Science Institute, American Association of Pharmaceutical Scientists, among others. Dr. Jambulingam is a member of Beta Gamma Sigma – the honor society for business and Rho-Chi the honor society for pharmacy.

DOES REMS ENHANCE OR HINDER COMMERCIAL BRAND VALUE?

Strategies for Success

REMS and Patient Compliance Conference

Friday April 9th 2010

Thani Jambulingam Ph.D.

Chair, Department of Pharmaceutical Marketing

Saint Joseph's University

Philadelphia, PA 19131



SAINT JOSEPH'S UNIVERSITY

Erivan K. Haub School of Business

Executive Pharmaceutical Marketing MBA

Spirit | Intellect | Purpose

AGENDA

- Evolution of REMS
- Objectives of REMS
- REMS – Challenges
- REMS – Opportunities
- How can REMS enhance brand value?
- Future Issues



SAINT JOSEPH'S UNIVERSITY

Erivan K. Haub School of Business
Executive Pharmaceutical Marketing MBA

2010 Confidential and Proprietary to SJU

Spirit | Intellect | Purpose

EVOLUTION OF REMS

- Food and Drug Cosmetics Act 1938
- Kefauver-Harris Amendments 1962
- Late 1990s and early 2000s withdrawals of several high profile drugs
- Led to public scrutiny of FDA practices
- Prescription Drug User Fee Act (PDUFA) 2002
- Risk Minimization Action Plan (RiskMAP) 2005
- Food and Drug Administration Amendments Act (FDAAA) 2007 created REMS



SAINT JOSEPH'S UNIVERSITY

Erivan K. Haub School of Business
Executive Pharmaceutical Marketing MBA

2010 Confidential and Proprietary to SJU

Spirit | Intellect | Purpose

WHAT IS REMS?

- Title IX of the FDAAA 2007 authorizes the FDA secretary to require Risk Evaluation and Mitigation Strategies (REMS) program for any drug product pre- or post-marketing, to ensure that benefits of the drug outweigh its risks
- FDAAA went into effect March 2008



SAINT JOSEPH'S UNIVERSITY

Erivan K. Haub School of Business
Executive Pharmaceutical Marketing MBA

2010 Confidential and Proprietary to SJU

Spirit | Intellect | Purpose

OBJECTIVES OF REMS?

- Ensure that the benefits of drug outweigh the risks
- Improve drug safety by
 - Providing adequate information to stakeholders
 - Requiring stakeholders to be fully aware of the drug and its risks
 - Improve the appropriateness of drug use
 - Monitor and measure drug safety outcomes



SAINT JOSEPH'S UNIVERSITY

Erivan K. Haub School of Business
Executive Pharmaceutical Marketing MBA

2010 Confidential and Proprietary to SJU

Spirit | Intellect | Purpose

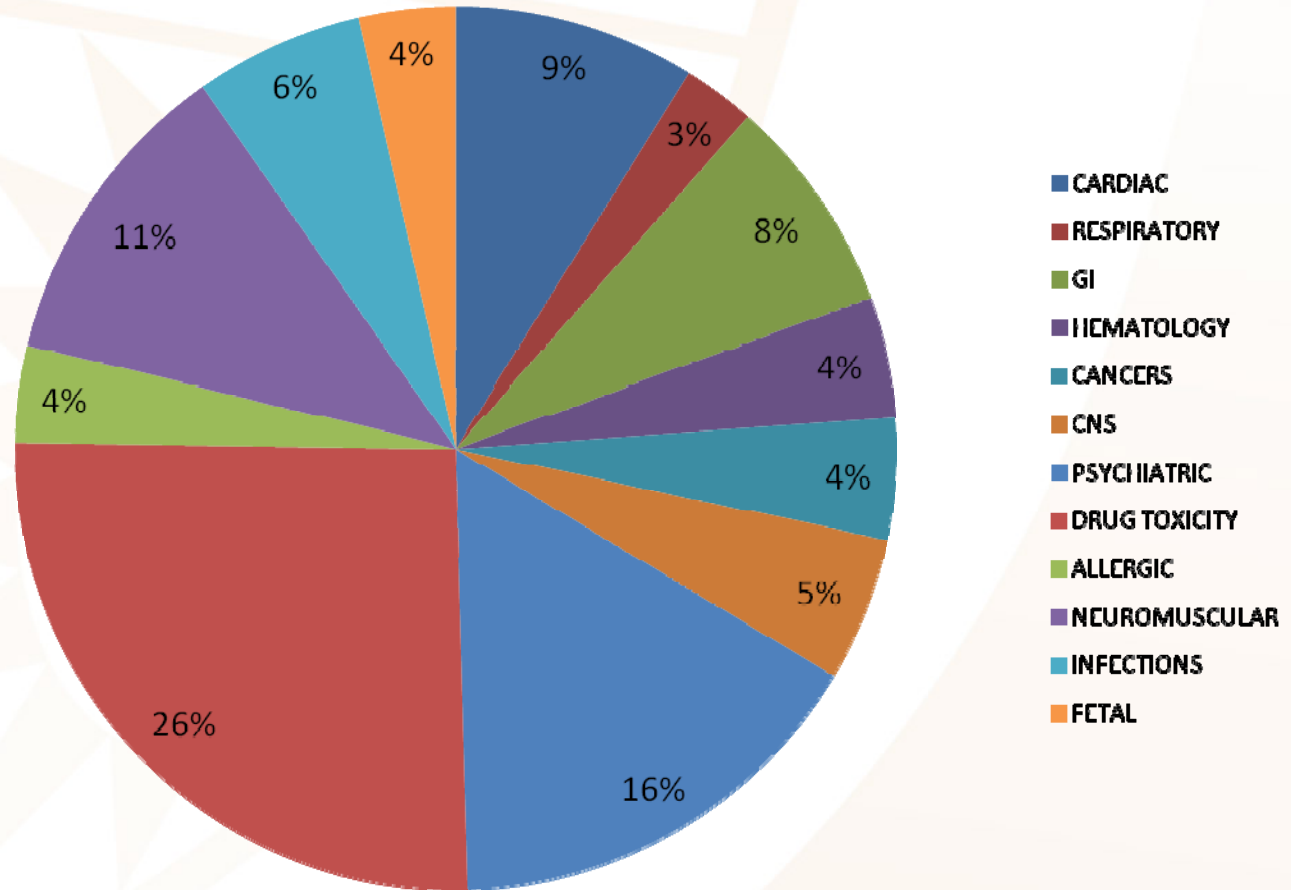
REMS STATISTICS*

- Total of 108 products have approved REMS programs
- Almost all products have medication guides
- 30 products have communication plans
- 11 products have Elements to Assure Safe Use (EASU) and Implementation plan

* Note: N = 108. Data obtained from FDA Website March 29th, 2010.

REMS – RISK STATISTICS

Percent of side effects



Note: Author's Analysis, Data obtained from FDA Website March 29th, 2010.



SAINT JOSEPH'S UNIVERSITY

Erivan K. Haub School of Business
Executive Pharmaceutical Marketing MBA

2010 Confidential and Proprietary to SJU

Spirit | Intellect | Purpose

REMS - CHALLENGES

- Regulatory uncertainty
 - Slowed down reviews
- Burden of compliance
 - Cost of programs
 - Maintaining registries
 - Data tracking and analysis
- Burden on stakeholders (example: providers)
 - Complicated REMS (Nplate, Promacta)

REMS - CHALLENGES

- REMS Audits
 - Legal and practical issues
- Blockbuster to Niche product
 - GSK/Adolor's Entereg
- Delay launch
 - Cephalon's Fentora
- Distribution control
 - Retail channels

Challenges present Opportunities!!!

REMS - OPPORTUNITIES

- Improve Drug Safety
 - Assurance of safety
- Improve Probability of Approval
- Improve Access and Interactivity with Stakeholders
 - Example: Providers, Patients
 - Improve Compliance

REMS - OPPORTUNITIES

- Improve Value Proposition
 - Cellegene's STEPs program for Thalomid and Revlimid
 - Biogen Idec/Elan's MS drug Tysabri
- Improve Pharmacovigilance
 - Enhance signal management solutions
 - Data mining

REMS - OPPORTUNITIES

- Improve Data Collection
 - Registries (ex: Sabril)
 - Distribution tracking of product and Rx data
 - Survey insight on market dynamics (ex. Entereg)
- Improve Market Analytics
 - Prescriber segmentation (ex: Forteo)
 - Preferred prescriber programs (ex: Sabril)

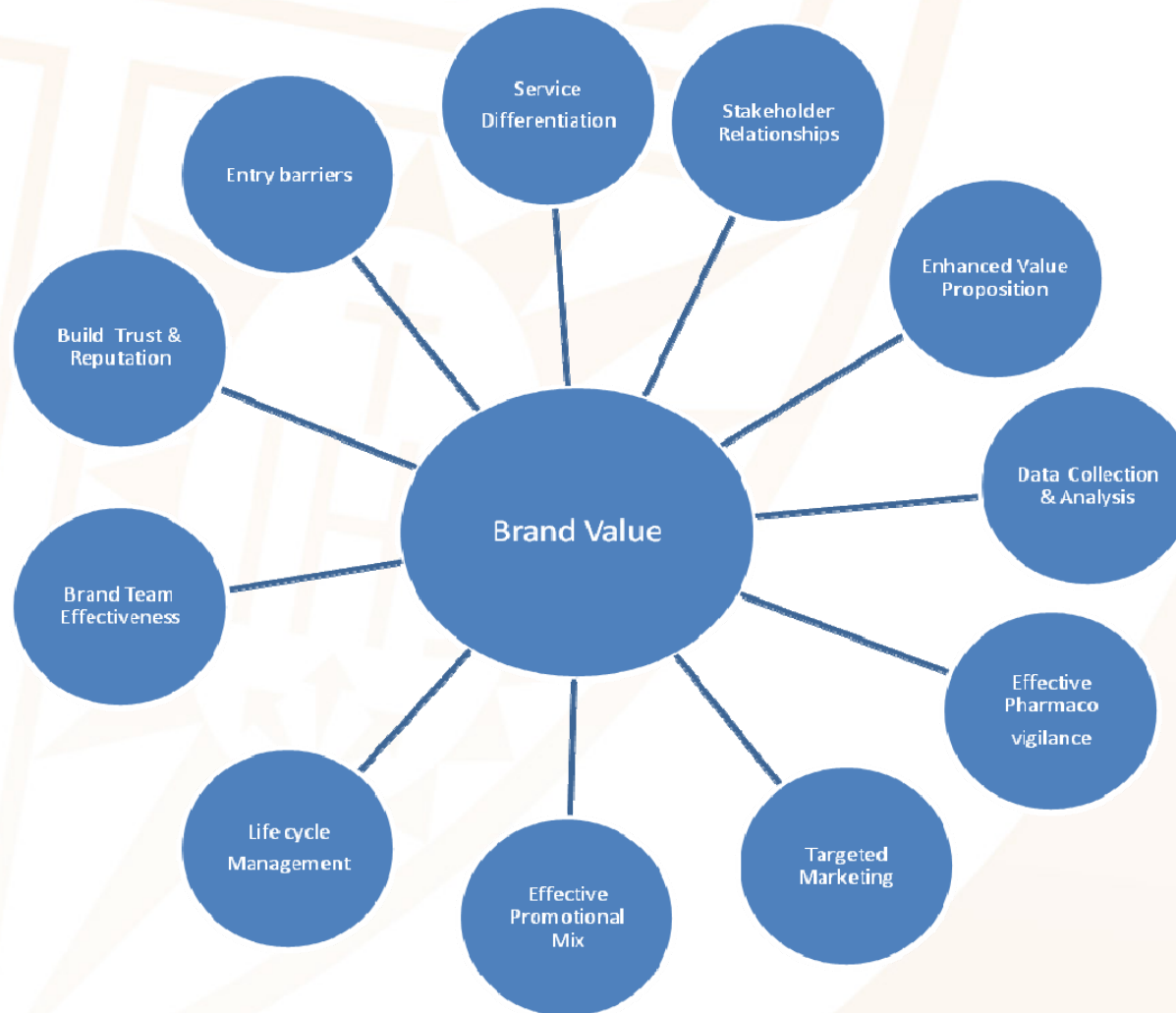
REMS - OPPORTUNITIES

- Improve Promotional Mix
 - Role of sales reps (ex. Effient)
 - Role of MSLs (ex. Cimzia)
 - Speaker Bureaus (ex. Xenazine)
 - Journal Advertising (ex. Multaq)
- Improve Lifecycle Management
 - Non interchangeability (ex. Botox)
 - Entry barrier (Ex. Generics)
 - Program patent

REMS - OPPORTUNITIES

- Improve Reputation of Pharma
 - Reputation of FDA and Pharma are related
 - Safety of products = trust on pharma
 - Reduction of product liability
- Improve Brand Team Effectiveness
 - Can build strong cross functional teams (clinical, safety, regulatory and marketing)
 - Build close relationship with service providers

HOW CAN REMS ENHANCE BRAND VALUE?



SAINT JOSEPH'S UNIVERSITY

Erivan K. Haub School of Business
Executive Pharmaceutical Marketing MBA

2010 Confidential and Proprietary to SJU

Spirit | Intellect | Purpose

FUTURE ISSUES

- Implications of the first set of reviews
- FDA's interest in periodic REMS audits
- Implications of Kaiser's citizen's plan
- Future role of providers and payers in REMS development
- Implications of class wide REMS for Opioids
- Health care reform

CONCLUDING REMARKS

- Challenges present opportunities
- REMS creates new market dynamics
- Understand the challenges and opportunities presented by REMS
- Know what trigger a REMS for a new/existing drug?
- You should appropriately prepare, plan and execute a REMS program
- Partner if you are not equipped to deal with REMS
- REMS adds value to a brand

Thank You!!!

Dr. Thani Jambulingam
Chair and Associate Professor
Department of Pharmaceutical Marketing
Saint Joseph's University
Philadelphia, PA 19131
610-660-3382
tjambuli@sju.edu

FACULTY



Dr. Thani Jambulingam, PhD

- Chair and Associate Professor of Pharmaceutical Marketing Department.
- Teaches in both the Executive MBA program and undergraduate programs in Pharmaceutical Marketing.
- Teaching Focus: Pharmaceutical Strategy, Pricing, Competitive Analysis and emerging topics.
- Career in sales and marketing, both domestically and globally, primarily in the pharmaceutical industry. Served as a consultant to several major pharmaceutical firms – Abbott, Astra Zeneca, Merck, Novo Nordisk, Pfizer, Wyeth, and Procter & Gamble.
- Received his Master's Degree and PhD (Pharmacy and Marketing) from the University of Wisconsin-Madison.
- Inducted into Rho Chi – the honor society for pharmacy and Beta Gamma Sigma – the honor society for business