REMS Challenges

and

Real World Solutions

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Providing Strategic Planning and Tactical Execution in the Commercialization of Pharmaceuticals, Medical Devices and Diagnostics
# Table of Contents

Introduction..................................................................................................................3

Executive Summary.......................................................................................................4

Business Challenge......................................................................................................7

Solutions.......................................................................................................................10

Case Studies.................................................................................................................15

Additional Information..............................................................................................16

Conclusion...................................................................................................................18

About the Authors.......................................................................................................19

About D2 and Contact Information.............................................................................21
INTRODUCTION

This document will provide insight into effective solutions to meet the expansion of controls around pharmaceuticals through FDA mandated Risk Evaluation & Mitigation Strategies. The reader will be able to identify the crucial steps in designing and executing a REMS solution that meets regulatory requirements while allowing ongoing patient access to critical drug therapies.

The paper will outline the current regulatory environmental challenges, a protocol for assessment and resulting strategies. The conclusions will provide a way forward for drug manufacturers to implement a realistic REMS solution that is operationally sound and executable and meets FDA regulatory mandates.

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EXECUTIVE SUMMARY

Overview

The passage of FDAAA Title IX in September of 2007 has expanded FDA’s authority and reach regarding safety standards around many drug approvals. A key provision, Risk Evaluation and Mitigation Strategies (REMS), is fast becoming part of the regulatory approval landscape. A significant impact of this expanded authority is that a REMS requirement may have meaning to significant numbers of pharmaceutical and biotech manufacturers. The FDA Guidance is very clear that literally every NDA under review has the possibility of a REMS requirement. Further, with an FDA pipeline rich in niche products for narrow therapeutic areas D2 believes manufacturers will need to be “market knowledgeable”. Market knowledgeable not only about the FDA requirements, but equally, the distribution partners who will be providing the market based solutions.

In addition, FDA has the authority to require a REMS post approval. Manufacturers are faced with a myriad of challenges as they attempt to predict the potentially far reaching requirements that FDA could impose impacting approval of their product(s). The requirements may range from a simple medication guide to a communication plan to Elements to Assure Safe Use (ETASU). These more comprehensive REMS programs with ETASU may include such components as a patient registry, physician and pharmacy certification, to name a few.

In reviewing REMS requirements, we find that potentially the old is new again. Many products particularly in the specialty pharmacy sector contain distribution and patient management requirements that entail all or parts of what is quickly becoming a REMS requirement. That said, many infusion suites and retail outlets are also providing distribution and data collection for products with unique requirements. As REMS requirements become reality, many of the distribution channel participants have developed (or are developing) the enhanced systems necessary to support current and future REMS.

D2 has been monitoring REMS requirements and working with a variety of clients to support REMS in the distribution channels. This white paper endeavours to assist industry in understanding REMS requirements while providing a roadmap to develop FDA compliant solutions.

Current Trends

While the majority of currently approved REMS are comprised of a medication guide, an increasing number of approvals are being saddled with far more stringent safety measures (ETASU).

In addition, many of the pharmaceutical products subject to REMS to date have been considered in the category of “specialty” products and thus are often distributed through a limited or restricted distribution model. This type of model has inherent, built-in
characteristics that increase a manufacturer’s ability to control the distribution of their product while also limiting potential access to the product.

However, the tide is changing as FDA sets its sights on products that have been distributed through a traditional retail pharmacy model. On February 6, 2009, the Food and Drug Administration (FDA) sent letters to manufacturers of certain opioid drug products, indicating that these drugs will be required to have a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of the drugs continue to outweigh the risks.

What makes this requirement most significant (for both current and future products) is that these products are indicated to treat pain, which is an acute medical condition. Regardless of the “product profile”, patients in need of drug therapies should not be faced with delays and/or access restrictions due to a burdensome and onerous REMS program. A REMS program must be designed to ensure a seamless and timely delivery of optimal drug therapy to patients in need and not negatively impact those very patients whom the program is designed to protect.

Is Your Organization Prepared?

It is critically important that a drug manufacturer identify early in the REMS process an optimal channel distribution strategy to ensure maximum marketplace uptake, as well as a structure that can support a leadership position for their product(s).

The fact is that, when it comes to the current distribution landscape, many manufacturers are not aware of the current product delivery options that will ensure compliance, safety and ease of access to their portfolio of products. A REMS strategy must be vetted early in the process to ensure that the drug sponsor can meet the REMS program criteria. According to the FDA Guidance to Industry (September 2009), a subset of the ETASU considerations should include “Verification that the proposed elements are not unduly burdensome of patient access to the drug considering the risk being mitigated. Include particular consideration of patients with serious or life-threatening diseases or conditions and patient who have difficulty accessing healthcare”.

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If you are faced with REMS challenges you must first ask yourself the following questions:

**Table 1**

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>YES / NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are you aware of the multiple options for creative REMS compliant distribution strategies in today’s healthcare environment?</td>
<td>Yes / No</td>
</tr>
<tr>
<td>Does your product profile best fit a retail, specialty pharmacy, hospital, home infusion or some combination thereof for an optimum distribution model?</td>
<td>Yes / No</td>
</tr>
<tr>
<td>Can your REMS strategy deliver an end to end solution ensuring alignment of all of the REMS components?</td>
<td>Yes / No</td>
</tr>
<tr>
<td>Will your selected solution be executable in the “real world” based on the products optimal channel strategy?</td>
<td>Yes / No</td>
</tr>
<tr>
<td>Will your REMS solution meet the goals of risk mitigation and patient access?</td>
<td>Yes / No</td>
</tr>
<tr>
<td>Have you contemplated any and all possible FDA scenarios and are you prepared to act?</td>
<td>Yes / No</td>
</tr>
<tr>
<td>Is your solution scalable in the optimum distribution model?</td>
<td>Yes / No</td>
</tr>
</tbody>
</table>

**REMS Rules of Engagement**

- Identify early on the necessary alignment of the end-to-end healthcare delivery model.
- Review capabilities of all possible participants using a standardized format that enables an “apples-to-apples” comparison.
- Identify optimal distribution strategy based on product profile, patient requirements, physician requirements, market size and data requirements.
- Design a REMS solution to fit the optimal distribution model based on providing appropriate access to the physician and patient communities.
- Implement a “Real World” REMS solution that is operational today and scalable in the future.

**Heed Stakeholder Comments**

- Solutions must be balanced, preserving patient access while ensuring that the benefits of a drug outweigh the risks of the drug.
- Solutions must leverage current technologies and systems and take advantage of sophisticated and emerging market providers.
- Understand FDA goals of program including key metrics to measure success.
- Avoid unintended consequences including barriers to patient access.
BUSINESS CHALLENGE

To date, many of the FDA approved REMS programs are comprised of a simple medication guide and/or communication plans. Compliance and implementation with these requirements is relatively straightforward. However, as the complexity and scope of REMS programs continue to evolve, the challenges facing drug sponsors grow exponentially, particularly for products where delivery to patients is time sensitive.

Figure 1

Approved REMS as of October 2009

FDA REMS Guidance Document

On September 30, 2009, the FDA published the long awaited REMS guidance. The document is entitled “Format and Content of Proposed Risk Evaluation and Mitigation Strategies (REMS), REMS Assessments and Proposed REMS Modifications”.

While much of the information in the guidance is not new, it is one of the first times that FDA has shared its thinking to this extent with the public. This guidance does not establish legally enforceable responsibilities but rather provides recommendations to industry that will have a direct impact to distribution channel participants. FDA can require REMS as part of the drug approval process, and can additionally require holders of covered applications approved without REMS to submit proposed REMS should FDA become aware of certain safety issues. An applicant may also voluntarily submit proposed REMS without having been required to do so.

The document also discusses the relationship between RiskMAPs and REMS. As many of the principals that comprised the RiskMAPs are included in REMS, look for similarities.

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2 http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111350.htm
3 This Guidance document includes an example of a REMS document for a fictitious drug. A template for proposed REMS is available on FDA’s “Postmarket Drug Safety Information for Patients and Providers” is available on the Internet at http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/default.htm
to cross over from RiskMAPs to REMS. In fact, all current products that would have previously been approved with a RiskMAP will, instead, are approved with REMS if statutory requirement for a REMS are met.

The FDA guidance indicates that an “ANDA for which the reference drug listed has a REMS will be approved with the elements of that REMS applicable to the ANDA”.

The guidance addresses three main areas, including:

- **Content of a REMS submission**
  a. Timetable for submission of assessments that are 18 months, 3 years and 7 years after the strategy is approved
  b. Additional Potential Elements of REMS that may include
    i. A medication guide, patient package insert and communication plan to health care providers and implementation plan
  c. Elements to Assure Safe Use
    i. May be required if drug is effective but associated with serious adverse events
    ii. ETASU must include one or more goals to mitigate the risks
    iii. May include particular training/certification for patients, prescribers and dispensers, patient registries, implementation systems, and restricted distribution

- **REMS assessment and modification of a REMS**
  a. Assessment may be
    i. Voluntary assessment and proposed modifications or
    ii. Required assessments
  b. Assessment should describe the rationale and supporting information for the proposed plan to assess the REMS
  c. Assessment should include an evaluation of the extent to which each of the REMS elements is meeting the goals and objectives and any proposed modifications
  d. Assessment should include the proposed metrics/goals and timelines for achievement

- **Communication with FDA regarding REMS**
  a. Proposed REMS may be included in the initial submission of an original or supplemental application

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b. Assessment of approved REMS may be submitted voluntarily at any time and must meet the required timetable

c. All REMS documents submitted to FDA should include identifying information for tracking and routing purposes

- **Enforceability**
  a. REMS required under section 505-1 are subject to inspection and are enforceable
  b. Violations are subject to specific civil monetary penalties
  c. Penalties increase if the violation continues more than 30 days after FDA notification
     i. Penalties double for second and subsequent 30-day periods up to $1M per period and $10M per proceeding.

**CHALLENGES FACING DRUG SPONSORS**

**REMS Solutions Must:**

- Be balanced preserving patient access while mitigating risk thereby ensuring that the benefits of a drug outweigh the risks of the drug
- Not be overly burdensome to the health care system including physicians, patients, pharmacists, distributors and other stakeholders
- Leverage current technologies and systems, including knowledge of channel participants who are developing specific compliance solutions
- Not negatively impact those that REMS were designed to protect by limiting and/or creating onerous drug access requirements
- Be flexible, scalable and measurable with timely, reportable data

**Figure 2**

*Balancing Market Objectives with Risk Mitigation*
SOLUTIONS

Begin with the End Goal in Mind

There is no doubt that REMS of any sort provides significant challenges to manufacturers. This challenge is magnified when the REMS includes Elements to Assure Safe Use (ETASU). The complexity then rises exponentially, impacting not only the manufacturer, but all of the parties that touch the prescribing, dispensing and distribution of the product subject to the REMS. The manufacturer must first know where they need to end up before embarking on their journey. By understanding the desired distribution model, the manufacturer can be prepared to:

a) Understand based on the product requirements (i.e. oral, infused, injected), the channel participants (Retail, Specialty Pharmacy, Specialty Distribution, Hospital, Infusion Suites etc.) that might have the capability to meet the FDA's REMS requirements.

b) Develop an RFP process that matches REMS requirements, with the right channel providers, from an operational, reporting and Fee for Service perspective.

c) Design an FDA compliant solution that meets the needs of the physician and patient community.

d) Conduct a systematic review of potential channel partners, which include data collection and reporting.

e) Create contracts which align incentives for the channel providers with the manufacturer to mutually meet the REMS requirements.

Figure 3
Back Into Your Solution
Initial Steps to Building and Managing a REMS Solution Aligned with Manufacturer Goals

- **Planning**
  - Build cross function internal team
  - Assess the need for REMS/Risk Analysis
  - Understand channel capabilities
  - Monitor and consider FDA mandates for similar products
  - Identify multiple REMS strategies for all potential scenarios
    - Assess success drivers for all potential models
    - Be prepared to react to FDA responses

- **Build**
  - Identify end-to-end REMS model leveraging optimal channel strategy
  - Assess REMS solution providers for comprehensive end-to-end capabilities and efficiencies
  - Create systematic comparison for all potential participants (i.e. distributors, HUB providers, specialty pharmacies, etc.)
  - Identify key providers’ strengths and weakness, including data management and scalability
  - Leverage efficiencies for maximizing performance and to mitigate costs

- **Implementation**
  - Build REMS implementation project plan
  - Define achievable timelines

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6 Other Hybrid options might include Infusion Suites and Long Term Care facilities
- Ensure "Plan B" if additional requirements may be added later
- Execute REMS program meeting milestones, timelines and business goals

- Maintenance
  - Timely reporting of information from vendor(s) to manufacturer
  - Ongoing management of vendors including business/operational review
  - Retrospective effectiveness analysis and ongoing program improvement
  - Auditing
    - Reporting (with flexibility to meet future requirements)

The evolution of the “Specialty Pharmacy Model” began with the advent of complex and expensive drug therapies to treat serious conditions needing high touch patient services. Specialty pharmacies today provide a host of specialized services that are not traditionally offered in the retail setting. These include services, such as reimbursement support, patient assistance programs, nursing services, clinical programs, call-center services to name a few. Due to the added requirements for managing specialty products and patients requiring these products, retail pharmacy and other delivery options have not been the optimal environment for these products.

However, as FDA has expanded regulatory requirements beyond specialty to retail based products, retail pharmacy is reacting and developing creative solutions to meet regulatory demands that have been traditionally served by the specialty pharmacy sector.

One should expect to see systems based alternatives in multiple pharmacy practice settings, which in theory could offer many of the same types of controls previously only thought to be available in a closed setting.

There are many examples of specialty open, limited and exclusive distribution arrangements. The advantage of the specialty pharmacy model is that specialty pharmacy providers can design customized programs to meet the therapeutic and business needs of a particular product. In today’s environment, the argument could be made that the specialty pharmacy sector already provides current products with REMS compliant distribution and patient monitoring models.
Technology changes and an evolving delivery market, however, are changing the viability for additional market providers to participate in a REMS compliant delivery model. Many of the retail chains have added enhanced patient services, including walk-in healthcare clinics within their retail stores that are staffed with healthcare professionals. These clinics create a near term opportunity to open the door for additional services to be provided at the retail level that were not an option in the recent past, such as injection training and administering of injections. While retail has not traditionally focused on products with unique distribution requirements, the retail environment certainly has exceptions with products like Clozaril. In the near term, we can expect retailers across both the chain and independent spectrum prepared to participate in distribution models which require a REMS solution.

Further market expansion of REMS compliant distributors will include Hospitals, Outpatient Clinics, Infusion Suites and other channel providers. Many of these outlets currently support the distribution of unique pharmaceutical and biotech products with some very complex programs, the Tysabri distribution model being a prime example. An FDA pipeline full of specialty products for closely defined patient groups, including products that cross provider channels (i.e. Hospital and Infusion Suites), will continue to demand channel providers that support the types of complex delivery models that encompass REMS requirements.
### Table 1

**An Effective REMS Solution Must Haves**

<table>
<thead>
<tr>
<th>Must Haves</th>
<th>Business Benefit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compliant and effective strategic program design</td>
<td>Regulatory compliance</td>
</tr>
<tr>
<td>Solution options for all possible scenarios</td>
<td>Timely response to FDA-avoid approval delays</td>
</tr>
<tr>
<td>Integration alignment with distribution partners</td>
<td>Seamless delivery of therapies to patients</td>
</tr>
<tr>
<td>Solution providers with comprehensive capabilities</td>
<td>Operational and cost efficiencies</td>
</tr>
<tr>
<td>Creative vision leveraging best practices, historical lessons and current and future technologies</td>
<td>Compliance, market leadership, positive view of healthcare providers and patients</td>
</tr>
</tbody>
</table>

### Table 2

**Strategy, Tactics, Measurement**

<table>
<thead>
<tr>
<th>Objectives</th>
<th>Solution &amp; Execution</th>
<th>Analytics &amp; Metrics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety</td>
<td>Distribution Efficiencies</td>
<td>Auditing</td>
</tr>
<tr>
<td>Compliance</td>
<td>Leverage Technology</td>
<td>Channel Performance</td>
</tr>
<tr>
<td>Product Access</td>
<td>Operational Excellence</td>
<td>Key Performance Metrics</td>
</tr>
<tr>
<td>Product Security</td>
<td>Services &amp; Systems</td>
<td>Service Levels</td>
</tr>
<tr>
<td>Data &amp; Business Intel</td>
<td>Data &amp; Transparency</td>
<td>Inventory Levels</td>
</tr>
<tr>
<td>Demand Control</td>
<td>Policies &amp; Process</td>
<td>Sourcing</td>
</tr>
<tr>
<td>Channel Strategy</td>
<td>Workflows</td>
<td>Diversion</td>
</tr>
<tr>
<td>Channel Influence</td>
<td>People</td>
<td>Data &amp; Reporting</td>
</tr>
<tr>
<td>Forecasting</td>
<td>Score Carding</td>
<td>Standards</td>
</tr>
<tr>
<td>Cost Control</td>
<td>Business Review</td>
<td>Program Improvement</td>
</tr>
</tbody>
</table>
CASE STUDIES - Limited Distribution Program Market Learning

Case Study 1
Product Class: Growth Hormone
Program Goal: Mitigate diversion, counterfeiting, product traceability and maintain patient access
Program Description: Limited trace & track program-product available only through contracting/drop shipment-managed through pharmacy claims processing technologies
Result: Significant decrease in diversion, no counterfeiting events, continued patient access

Case Study 2
Product Class: Respiratory
Program Goal: Mitigate diversion, counterfeiting, and provide product to offices on a timely basis
Program Description: Four distributors selected to manage prescription intake, adjudication, patient reimbursement services, robust persistency and compliance program.
Result: No counterfeiting, diversion, ease of patient access, key performance metrics achieved, increased inventory control

Case Study 3
Product Class: Oncology
Program Goal: Mitigate diversion, counterfeiting, and provide product to offices on a timely basis
Program Description: Select wholesalers/distributors performed tasks to ensure timely delivery of product to physicians' offices. All customers were pre-screened for approval.
Result: Eliminated counterfeiting, diversion, key performance metrics achieved, product inventory reconciliation

Case Study 4
Product Class: Respiratory
Program Goal: Provide premium service levels for product
Program Description: Initial model was very limited, then opened up to a broad network of providers
Result: Price competition amongst providers resulted in deep discounts and a decline in premium service levels, data integrity, and inventory control. Result was high cost program providing a negative return. Network opened to any provider meeting service requirements.

These case studies reflect marketed products that have specialized support programs to support unique product requirements. These products may or may not be currently required by FDA for REMS programs.
## ADDITIONAL INFORMATION

### Table 3

Select Industry Comments to FDA Docket No FDA-2009-N-0143 on class wide Opioid REMS

<table>
<thead>
<tr>
<th>Industry</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Pharmacist Association</td>
<td>While we recognize that each new drug product requiring a REMS will have different risks to address, REMS must be designed to ensure that workable and long-range goals are met. We believe that FDA must require a common framework and set of requirements that make each program more alike than different.</td>
</tr>
<tr>
<td>American Pain Foundation</td>
<td>It is critical that prescribers have a variety of opioid analgesics at their disposal to address the individual needs of pain patients. As outlined by the World Health Organization (WHO), an essential principle in using medications to manage pain is to individualize the regimen to address patient needs based on thorough assessment, which requires flexibility in opioid choice, formulation and dosage. Any class REMS acknowledges the importance of opioids in the management of pain and should not introduce new barriers to their appropriate and legitimate use.</td>
</tr>
<tr>
<td>Industry Working Group (IWG)</td>
<td>The unprecedented scope of class-wide REMS for opioid analgesics requires a carefully crafted design and implementation that would place the least burden on all stakeholders. The IWG believes that minimizing the burden on healthcare prescribers, dispensers, and patients is critical for enhancing their compliance with programmatic risk management requirements and ultimately improving program efficacy.</td>
</tr>
<tr>
<td>National Council on Prescription Drug Programs (NCPDP)</td>
<td>The pharmacy segment of healthcare recognizes the important role that NCPDP plays in the development of pharmacy data communications, specifically with the universal adoption of the prescription “billing” transactions. NCPDP recommends that the FDA leverage the industry-wide technology infrastructure and business processes that are currently in place, using the NCPDP standard as the real-time REMS solution.</td>
</tr>
<tr>
<td>National Community Pharmacist Association (NCPA)</td>
<td>Community pharmacies are highly regulated in each state by Boards of Pharmacy and other administrative bodies in addition to being regulated by the DEA. It is therefore NCPA’s position that any state- and DEA-licensed pharmacy should be eligible to dispense opioid products. Not only do restricted distribution programs interfere with patient access to prescribed therapies, they may limit legitimate access to long acting opioid products and shift illegitimate use to other products.</td>
</tr>
<tr>
<td>Health Care Delivery Management Association (HDMA)</td>
<td>However, before applying sweeping distribution industry-wide controls as part of the REMS for certain opioids, HDMA believes it is critically important that FDA (1) consider carefully how it defines the problem it seeks to address with the proposed REMS, and (2) consider what reasonably can be accomplished through a REMS that would not duplicate the already substantial regulatory structure for wholesale distribution that exists for opioid products vis-à-vis the Drug Enforcement Administration (DEA) and other federal and state statutory and regulatory authorities.</td>
</tr>
</tbody>
</table>

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Table 4

Approved REMS with Elements to Ensure Safe Use

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Required Elements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Entereg (avimopan) Capsules</td>
<td>Com Plan, ETASU, Imp System</td>
</tr>
<tr>
<td>N Plate (romiplositim) Injection</td>
<td>Med Guide, Com Plan, ETASU, Imp System</td>
</tr>
<tr>
<td>Onsolis (fentanyl) Buccal Filmtab</td>
<td>Med Guide, Com Plan, ETASU, Imp System</td>
</tr>
<tr>
<td>Promacta (eltromboapag) Tablets</td>
<td>Med Guide, ETASU, Imp System</td>
</tr>
<tr>
<td>Sucraid (sacrosidase) Oral Solution</td>
<td>Comm Plan, ETASU</td>
</tr>
</tbody>
</table>

Table 5

Target Opioids Potentially Subject to REMS

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Dosage Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fentanyl</td>
<td>Extended Release Transdermal</td>
</tr>
<tr>
<td>Hydromorphone</td>
<td>Extended Release Capsules</td>
</tr>
<tr>
<td>Methadone</td>
<td>Tablets</td>
</tr>
<tr>
<td>Morphine</td>
<td>Tablets and Extended Release Capsules</td>
</tr>
<tr>
<td>Oxycodone</td>
<td>Extended Release Tablets</td>
</tr>
<tr>
<td>Oxymorphone</td>
<td>Extended Release Tablets</td>
</tr>
</tbody>
</table>

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CONCLUSION

The key to success for any drug manufacturer whose product may be subject to REMS is to design a REMS program that accommodates the manufacturer's identified optimal distribution strategy. Anything less would be akin to trying to fit a round peg into a square hole. There are many creative distribution options in today’s market that will allow a drug sponsor to meet the goals of patient safety and product access, while developing a leading market position.

In summary, a drug manufacturer must be educated on all of the options available to build a REMS program. These programs should be robust, efficient and cost effective, while enabling maximum product access for patients and physicians, given the products unique characteristics. Many of the current and future pharmacy services, across multiple distribution channels, fit the operational and reporting requirements of a properly designed REMS program. Custom design of a distribution model that truly balances product risk and product access will result in the intended goals of the FDA's REMS guidance to preserve patient access, while ensuring that the benefits of a drug outweigh the risks of the drug.
ABOUT THE AUTHORS

Dean P. Erhardt, MBA
Principal
Strategic Distribution and Product Support Initiatives

Dean Erhardt offers over 20 years of strategic marketing and management experience across both the consumer product and pharmaceutical arenas. His areas of expertise include analysis and development of pharmaceutical support programs, pharmaceutical and consumer product distribution, and specialty pharmaceutical product management. Prior to his current role Mr. Erhardt’s experience spanned several Fortune 500 organizations including Express Scripts, Cardinal Health and U.S. Healthcare.

While at Express Scripts Mr. Erhardt served as Vice President of Sales and Marketing for the Specialty Pharmacy Benefits Management group. In this role Mr. Erhardt worked with multiple Managed Care and Payer organizations developing formularies, reimbursement models and product support programs for specialty and biotech therapeutic categories. Prior to that position Mr. Erhardt headed Sales and Marketing for Express Scripts Specialty Distribution working with pharmaceutical manufacturers in the areas of limited distribution programs, Patient Assistance Programs, Sampling, Reimbursement Support and other product specific support programs.

Currently Mr. Erhardt assists organizations with product launch/re-launch strategies, channel optimization strategies and the structuring of marketing and channel support programs including REMS. He supports D2 clients in the launching of pharmaceutical, biotech and device products across the Specialty Pharmacy, Specialty Distribution, Retail, Long-Term Care and Hospital Markets.

Mr. Erhardt has a BA in Marketing from the University of Oklahoma and an MBA from the Keller Graduate School of Management.

Dan Steiber, R.Ph.
Principal
Commercial Operations and Trade Development

With over 30 years experience, Mr. Steiber has served as a practicing pharmacist, store manager, pharmaceutical buyer, clinical services director, pharmacy marketing leader for one of America’s leading chain drug stores. Serving as Vice President of Marketing, he oversaw all retail programs and was Vice President of Branded Rx for AmerisourceBergen (ABC) and General Manager of their third-party logistics, focusing specifically on specialty products. Mr. Steiber’s expertise stems in part from his tenure with Eli Lilly and Longs Drug Stores.

Currently, Mr. Steiber focuses on new product launch strategies, formulary and contracting initiatives, compliance and persistency programs, return goods programs,
packaging strategies, e-commerce design, supply chain optimization, and other business development efforts.

Mr. Steiber earned his pharmacy degree from Washington State University and has attended several executive programs at Northwestern and Harvard Universities. He is a registered pharmacist in California, Washington, Pennsylvania and Texas.

David M. Suchanek, R.Ph.
Senior Vice President
Biotech & Specialty Services

David Suchanek, in his current role with D2, assists pharmaceutical and biotech organizations in the areas of commercialization and program development in the support of biotech and bio-equivalent products.

Prior to joining D2, Mr. Suchanek was the Vice-President of Pharma Programs at CuraScript (the specialty pharmacy division of Express Scripts Inc.) and had responsibility for the complete management and oversight of the organizations largest and most profitable business product/disease segments. Other positions with CuraScript included serving as the VP of Pharma Account Management and Implementation overseeing teams with responsibility of over $1B in annual sales. David had originally joined CuraScript as the VP of Operations: Biotech Solutions. In this role, he had responsibility for the organization’s trade relations department, wholesale operations/distribution department, and implementation operations of new biotech products, programs, and services.

Mr. Suchanek has also served as the Vice President of Pharmaceutical Services for Cardinal Health Inc. (CAH) focusing on services that enhanced the corporate offerings of their Specialty Distribution and Third Party Logistics divisions. David has also worked as the Director of Clinical Program & Product Development for Caremark’s Therapeutic Services Division, National Clinical Director at MIM Health Plan/BioScrip, Director of Specialty Pharmacy Operations at Scrip Solutions/Bioscrip mail-order and specialty pharmacy, and Clinical Manager for CVS Procure and Allscripts Pharmaceuticals.

Additionally, Mr. Suchanek currently acts as independent consultant for SRI Inc. (Stanford Research International), University of California: San Francisco, and Yale University: peer-reviewing studies, grants, and proposals. He has also provided consultative services to many of the industry’s top biotech and traditional pharmaceutical manufacturers. David has participated in numerous advisory boards for new and emerging technologies and has been a featured Keynote Speaker and National Panel participant on the subjects of Specialty Pharmacy, Specialty Distribution and Supply Chain Channel Management.

David attended the University of Texas for undergraduate pre-pharmacy work, continuing his educational training with the attainment of a degree in Pharmacy from the Ohio Northern University College of Pharmacy. During this time he implemented and coordinated research projects on several biotechnology pipeline products at the University of Texas, M.D. Anderson Cancer Center in Houston, Texas.

Mr. Suchanek is a Registered Pharmacist in Ohio, a Licensed Designated Representative in Florida, and currently resides in Orlando, Florida.
**About D2 Pharma Consulting LLC**

D2 Pharma Consulting LLC (D2) is a Life Sciences consulting firm comprised of accomplished industry personnel who provide “hands on” expertise in all aspects of channel management including commercialization, distribution and compliance activities from launch to life cycle management for pharmaceutical products and devices.

D2 provides strategic and tactical expertise to emerging and existing pharmaceuticals, biotech, and specialty organizations focusing on the individual clients business objectives.

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