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Director of Strategic Programs and Accounts
Covectra (formerly PharmoRx)

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Dan has over 15 years experience building teams and leading projects to develop enterprise and web-based software applications for the pharmaceutical and life sciences industries. Experienced in all phases of product management and software development, Dan has commercialized solutions focusing on anti-counterfeiting, brand protection, track-and-trace and cold chain management. Dan received his MBA from the McCallum School of Business at Bentley University and a Bachelors of Electrical Engineering from Rensselaer Polytechnic Institute.

John A. Cervione

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John Cervione is a Managing Partner and Principal Consultant with the Blue Fin Group and has spent the last 22 years in the pharmaceutical, pharmacy benefit management, health information management and health care consulting industries. He has produced award winning results for Fortune 500 and entrepreneurial health care companies including Hoechst Marion Roussel and sanofi-aventis.

John's experience in the pharmaceutical industry spans across commercial operations including sales, sales management, sales training, sales operations, trade and managed markets. His experience in pharmacy benefit management and health information management includes sales, marketing, employer group and public/private payer account management.

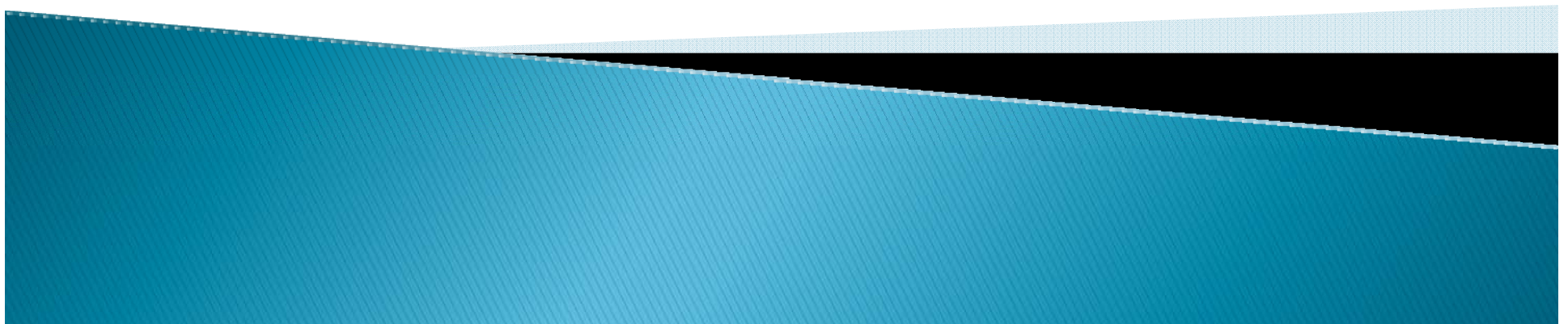
John speaks frequently at industry events on subjects related to trade channel management and has been published in industry journals such as Pharmaceutical Commerce.

John has an undergraduate degree in Finance from Providence College, Providence, RI and a MBA from the Stern School of Business at New York University. He is an elected member of the Providence College Board of Governors.

John resides in New York City.

Serialization-enabled Patient Services for Brand Security and Competitive Advantage

Using serialization to support ETASU components
of REMS



Overview

- ▶ REMS is an opportunity
- ▶ Ensure you have the right people around the table
- ▶ REMS improves cross-functional communication and business processes, increases focus on the patient and serves as a lever for competitive advantage and optimizing revenues

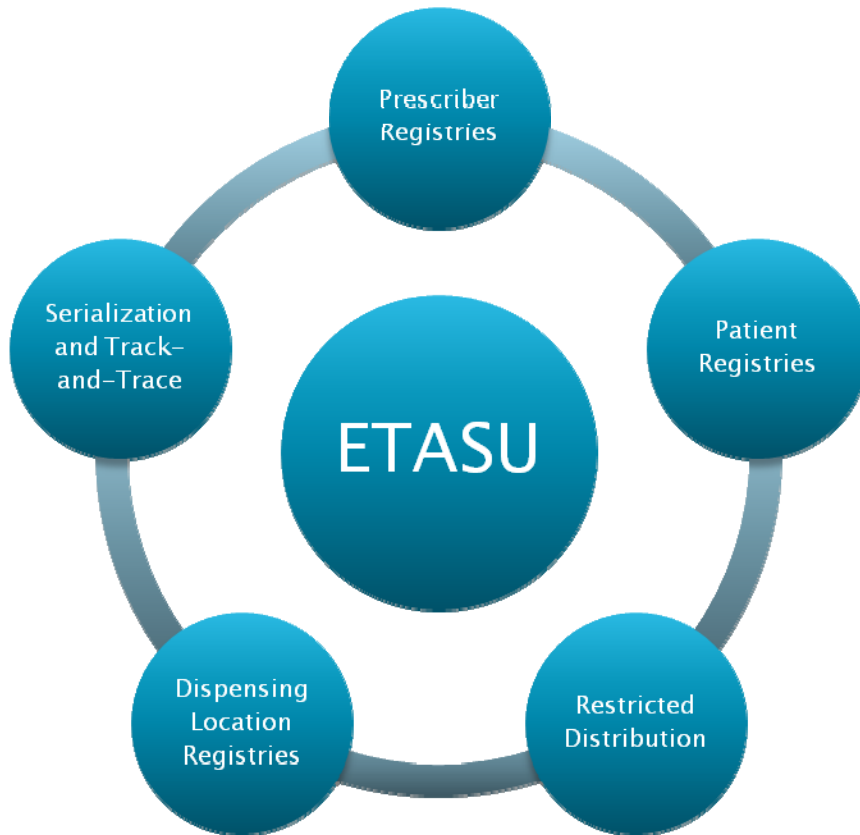
Elements to Assure Safe Use

- ▶ Elements to Assure Safe Use (ETASU)
 - Health Care Provider Training and Certification
 - Dispensing Pharmacies, Practitioners and Healthcare setting Certification
 - Dispensing Location restrictions (i.e., only dispense in hospitals)
 - Documented evidence of safe use (i.e., review of laboratory results)
 - Patient Monitoring
 - Patient Registry
- ▶ Implementation System
 - Monitor and evaluate implementation of ETASU components by stakeholders
 - Identify implementation areas of improvement

ETASU: Burden or Opportunity?

- ▶ Number of approved REMS programs that include complex elements such as ETASU is growing
- ▶ What approach should my organization take when designing a REMS program?
 - Meet the minimum regulatory requirements
 - Leverage REMS to differentiate from competitor branded products and generics
- ▶ How can a complex REMS program provide a competitive edge?
 - Additional opportunities to educate prescribers on drug benefits
 - Closer relationship to patient to improve adherence
 - Prevent diversion and protect against counterfeiting
 - Physicians more likely to prescribe the drug given the above benefits
 - Channel transparency and pristine data collection

Technology Implementations of ETASU



- ▶ **Prescriber Registries**
 - Prescriber Enrollment, Training and Certification
- ▶ **Patient Registries**
 - Patient Enrollment, Education and Treatment Monitoring
- ▶ **Restricted Distribution**
 - Pharmacy Enrollment
 - Controlled Product Access
- ▶ **Serialization and Track-and-Trace**
 - Supply Chain Monitoring
 - Complete Visibility
 - Pristine Data Collection

Serialization and Track-and-Trace

▶ Serialization

- Uniquely identify each unit-of-sale or unit-dose
- Authenticate patients by ensuring they have valid product
- Deliver drug information, medication reminders, safety information and incentives directly to patient

▶ Track-and-Trace

- Monitor product movement through distribution to patient
- Ensure only certified or registered organizations can procure the product
- Identify if product is being diverted from legitimate channels

Providing Patient Safety and Enhancing your Brand: A Case Study

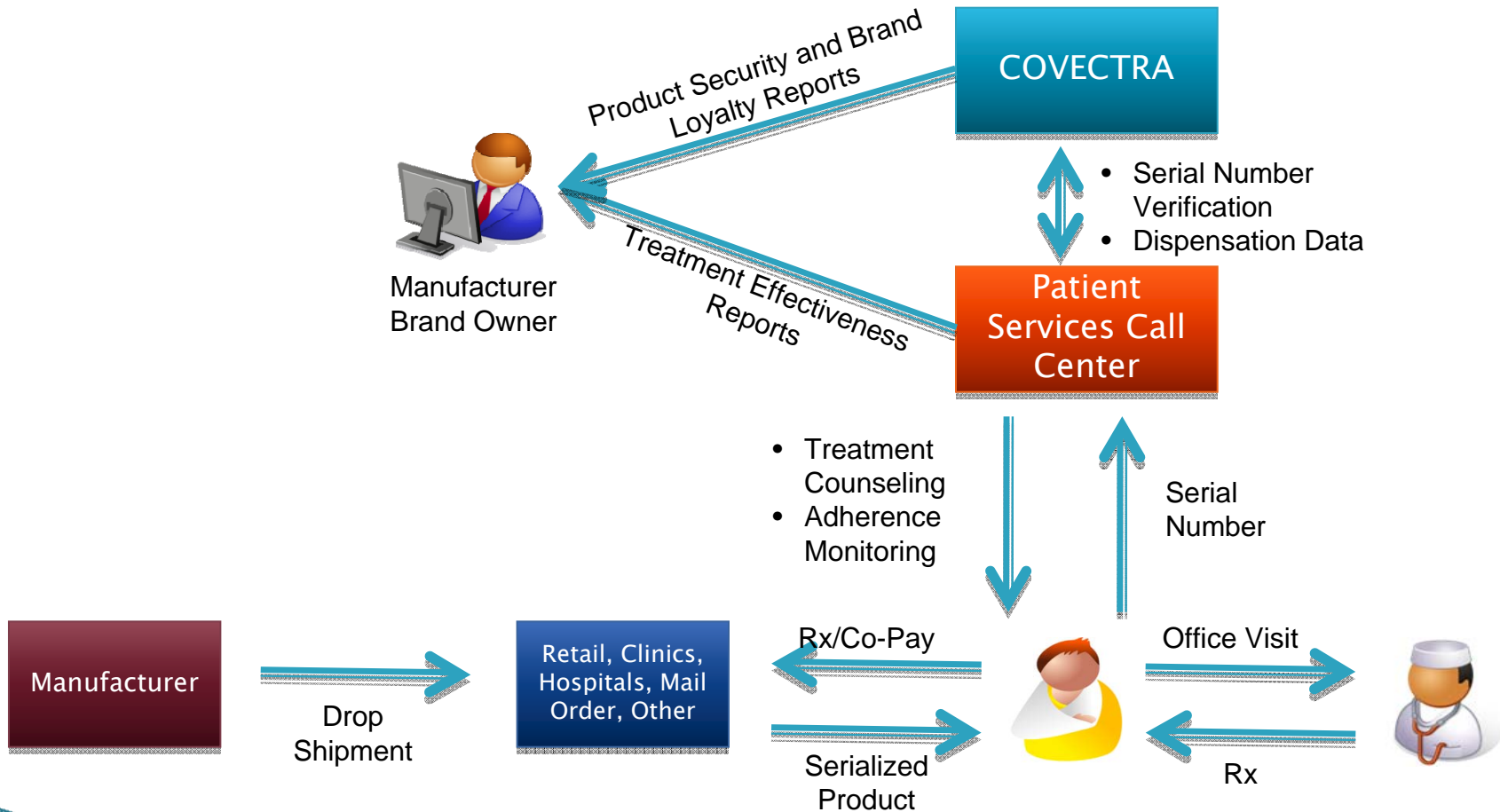
▶ Company:

- Pharmaceutical company commercializing potentially abused and diverted branded pharmaceutical

▶ Challenges:

- Identify and deter patient abuse and diversion
- Provide compassionate patient care to facilitate enrollment and available physician identification
- Increase patient compliance and ensure patient continues recommended treatment through on-going counseling
- Ensure only valid patients are obtaining company sponsored patient counseling services
- Defend against threat of generic entry into market
- Convince prescribing physicians that this program will enhance therapy and limit physician liability

Providing Patient Safety and Enhancing your Brand: A Case Study



Providing Patient Safety and Enhancing your Brand: A Case Study

▶ Solution Summary:

- Serialized unit dose packaging supported by track and trace platform for abuse and diversion detection
- Patient and Physician registry to monitor treatment and identify available physicians
- Call center staffed by healthcare professionals including trained nurses and pharmacists
- Patient verification through serialized carton and/or unit dose

▶ Results:

- Order of magnitude increase in patient enrollment over initial estimates
- Abuse and diversion deterred through more vigilant product tracking
- Delay of competitive entry into the market
- REMS Impact
 - Manufacturer able to leverage unit-dose serialization and track-and-trace platform as part of upcoming REMS requirement
 - Patients provided with treatment tools and options to ensure that the benefits of treatment out-weigh the risks

Eliminate Diversion and Rebuild a Brand Image

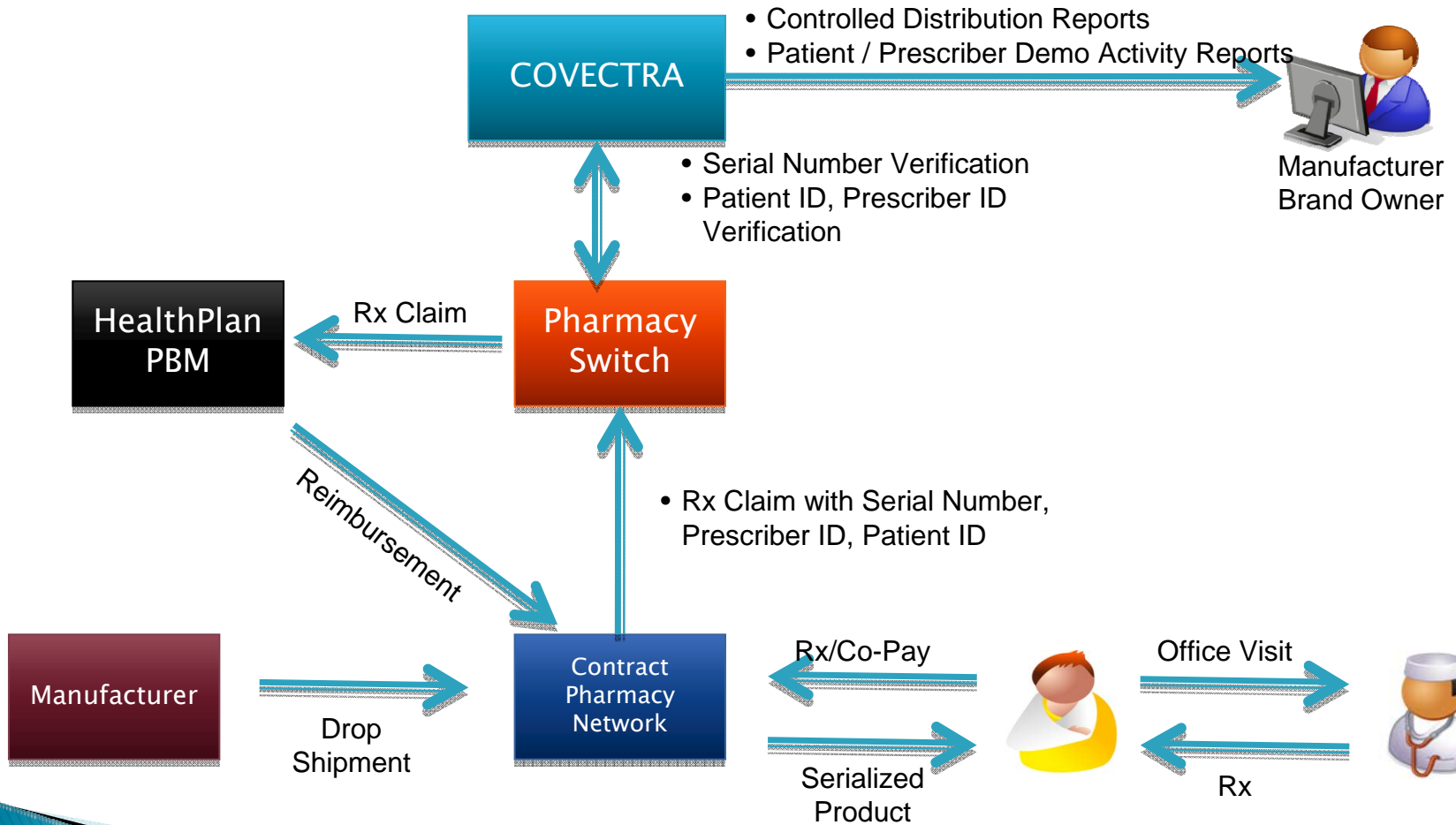
▶ Company:

- Pharmaceutical company facing regulatory pressure and eroding brand because product is heavily diverted and abused

▶ Challenges:

- Detect and prevent product from being diverted from the legitimate supply chain
- Ensure only registered pharmacies can order product
- Enforce tighter control over supply chain to eliminate diversion and detect counterfeit product
- Rebuild brand image by building a secure supply chain

Controlled Distribution Model: Drop Ship to Contracted Pharmacy Network



Eliminate Diversion and Rebuild a Brand Image

▶ Solution Summary:

- Implement controlled distribution program where product is drop-shipped from manufacturer to network of contracted pharmacies.
- Incorporate Prescriber ID, Pharmacy ID and Product Serial ID as part of Rx Claim processing for Pharmacy reimbursement.
- Develop reporting and data analysis to monitor supply chain activity.

▶ Results:

- Dispensing through contracted pharmacies limits number of dispensing sites and provides tighter control and reduction in diversion and no reports of counterfeiting.
- Addition of Prescriber ID, Pharmacy ID and Product Serial ID in the Rx Claim verification process provides complete transparency and ensures on authorized personnel handle the product.
- REMS Impact
 - Each patient is receiving the psychosocial support necessary for safe and effective use of product
 - Interactive website, Patient/Physician Agreement
 - Each patient adheres to the conditions of safe use explained to him/her
 - Medication Guide, Interactive website, Patient/Physician Agreement, Appropriate Use Checklist, Rx Limits, Pharmacist Interaction
 - Each patient is using product appropriately and making adequate progress towards treatment goals
 - Medication Guide, Communication Plan, Safe Use Conditions, Voluntary Patient Monitoring

Summary

- ▶ Forward thinking organizations view REMS as an opportunity to differentiate themselves from generic alternatives
- ▶ REMS enables Manufacturers to become more active in patient treatments and better position their product for success
- ▶ Serialization, Track-and-Trace and Registries can provide the technical foundation for
 - Increased supply chain visibility and control
 - One-to-One Manufacturer & Patient communication to support treatment goals and monitor patient progress