

# The Disconnect Between Risk Assessment and Technology Deployment in the Pharmaceutical Industry

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Come Join Us In Michigan  
We Are Thawing Out Quickly and Will  
Be Open for Business Again Very  
Soon



# Abstract

The inability to quantify the effectiveness of product protection technology has slowed progress in the pharmaceutical industry.

David Howard, who initiated Johnson & Johnson's strategic approach to product production, will highlight the disconnect between the risk assessment process and technology selection and deployment.

He will also offer concepts and ideas to counter this trend.

# Wisdom of the Ages

Company A - We have been protecting our products for years now and we still have counterfeiting taking place.

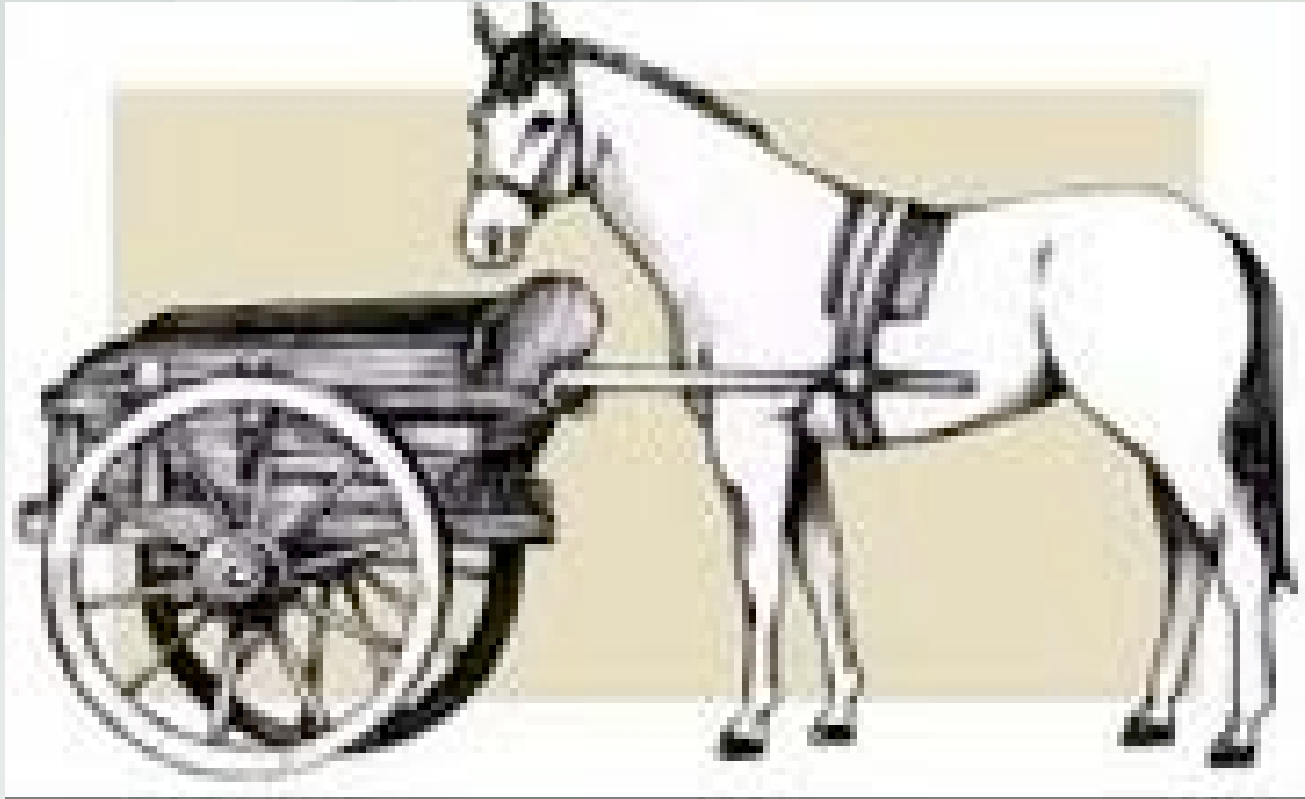
Company B - Maybe your program is addressing the wrong problem.

Company A - How can that be, my technology providers said they had exactly what we needed. They even called their products "Solutions".

# Wisdom of the Ages

- Putting product protection first is a common response
- Leaving product protection in place for an extended period of time is also common
- Trusting product protection to do the job without looking is flawed
- Not knowing what problem you're solving is a best guess effort which can waste time and money

# For The Visual Learners In The Audience



# First Step - Risk Assessment

- Do you have confirmed counterfeits/tampering?
  - PLEASE REFER TO ISO STANDARD 12931 for definitions.
- Do you have a risk assessment process?
  - Do you assess the risk of:
    - Your products being counterfeited?
      - What makes your products susceptible?
      - What processes/practices add to the susceptibility?
    - The impact if/when your product is counterfeited?
      - Health impact, image impact, financial impact
- Do you know what the risk root cause is for your products?
- Do you know where to begin to look?
- If the answer to any of these is “NO” let me

## A-CAPP Paper Series



### Assessing the Risks of Counterfeiting and Illicit Diversion for Health Care Products

Christopher Trent  
Senior Manager  
Product Protection  
Johnson & Johnson Global Brand Protection

Douglas C. Moyer, Ph.D., CPP  
Adjunct Instructor  
Program In Public Health  
Michigan State University

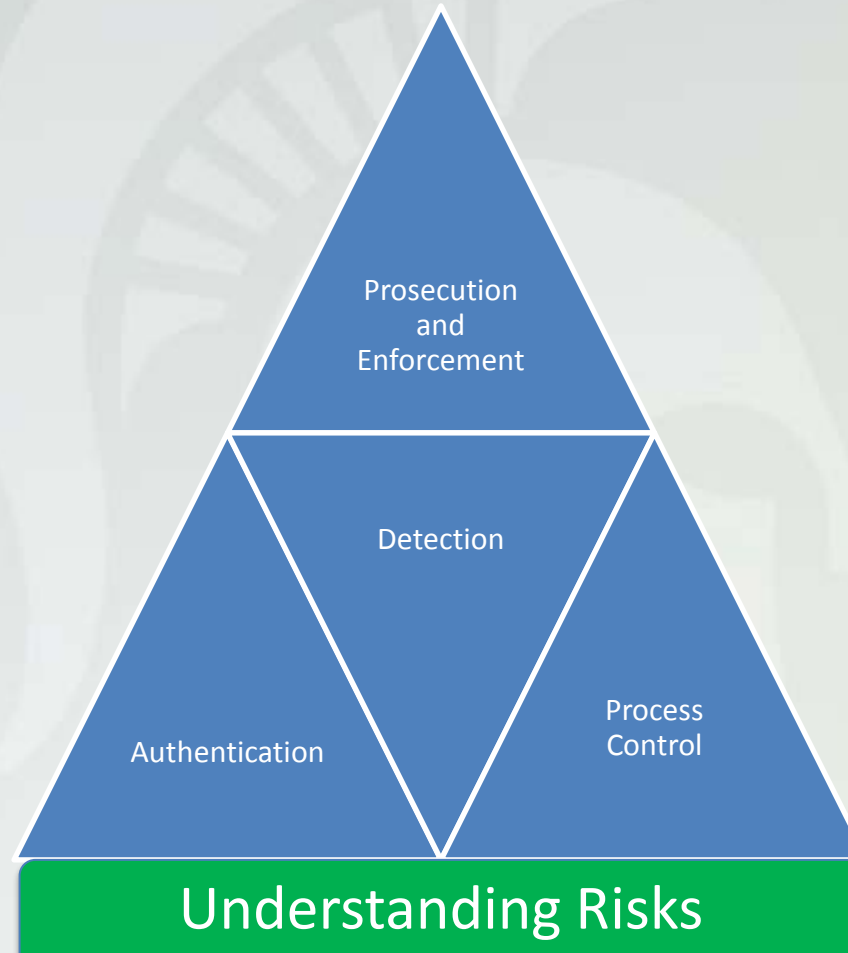
November 2013



# The Purpose of Risk Assessment is to Understand:

- What causes product risk
- Where risk exists and why
- The impact to your patients
- The impact to your business
- Source(s) and root cause(s)
- How your products are handled
- How your products are administered
- Who has your products and why
- Who needs your products and why

# Building Upon Risk Understanding Fundamental Principals in Brand Protection



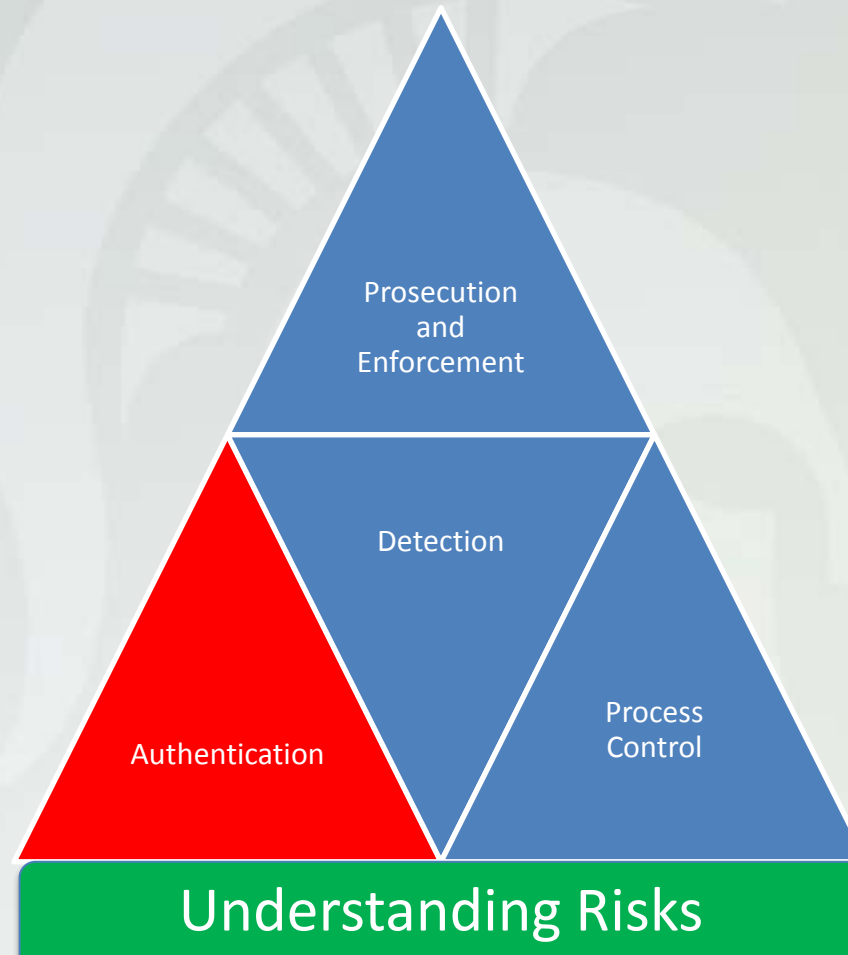
## Second Step - Risk Mitigation

The key disconnect in the Pharmaceutical Industry is attempting to do this without knowing

root cause issues and without fixing issues that may be causing you unnecessary risks.

So lets take a few minutes to break down what you need to do.

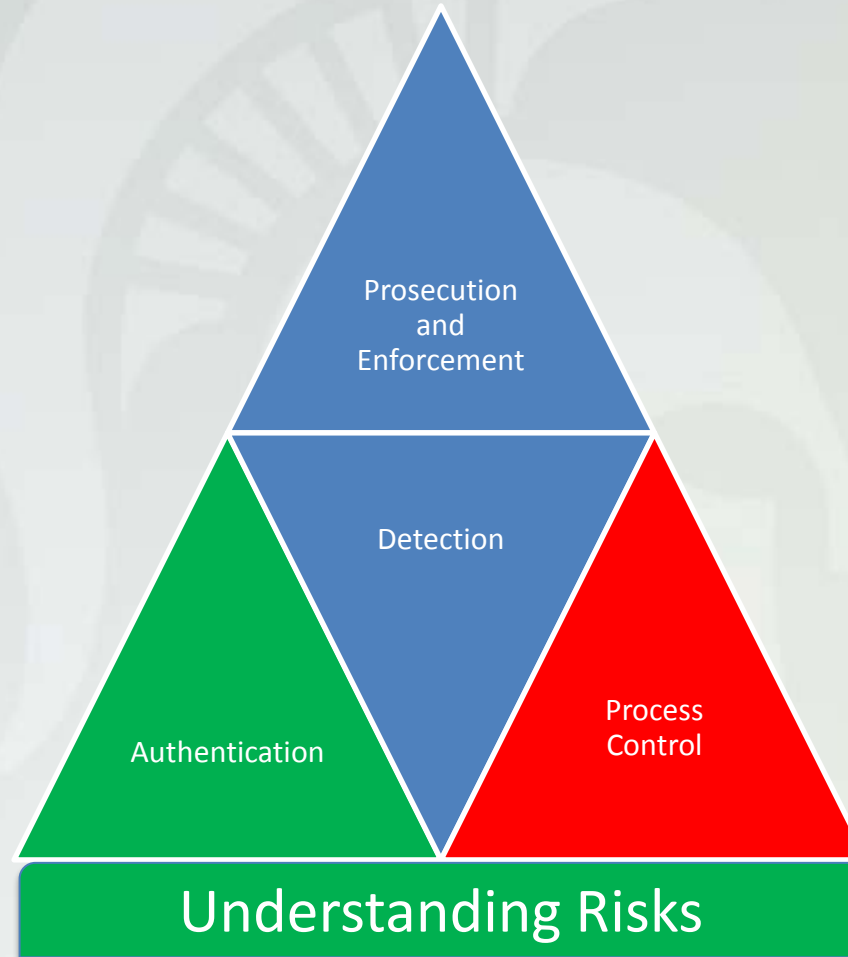
# Authentication – What Makes Any Product True and Originally Ours



# Authenticating Your Products

- How much do you know about your products really?
- Product, Packaging, Graphics attributes are known by whom, where is data kept, how secure is that data?
- Who can change these products? Who Is Informed of Changes When They are Made?
- Promotional changes in packaging and printing can disrupt field authentication.
- Lot code, exp dates, bar codes, 2D codes, product shape, size, color...
- What makes this product unique?
- Who knows how to authenticate product and

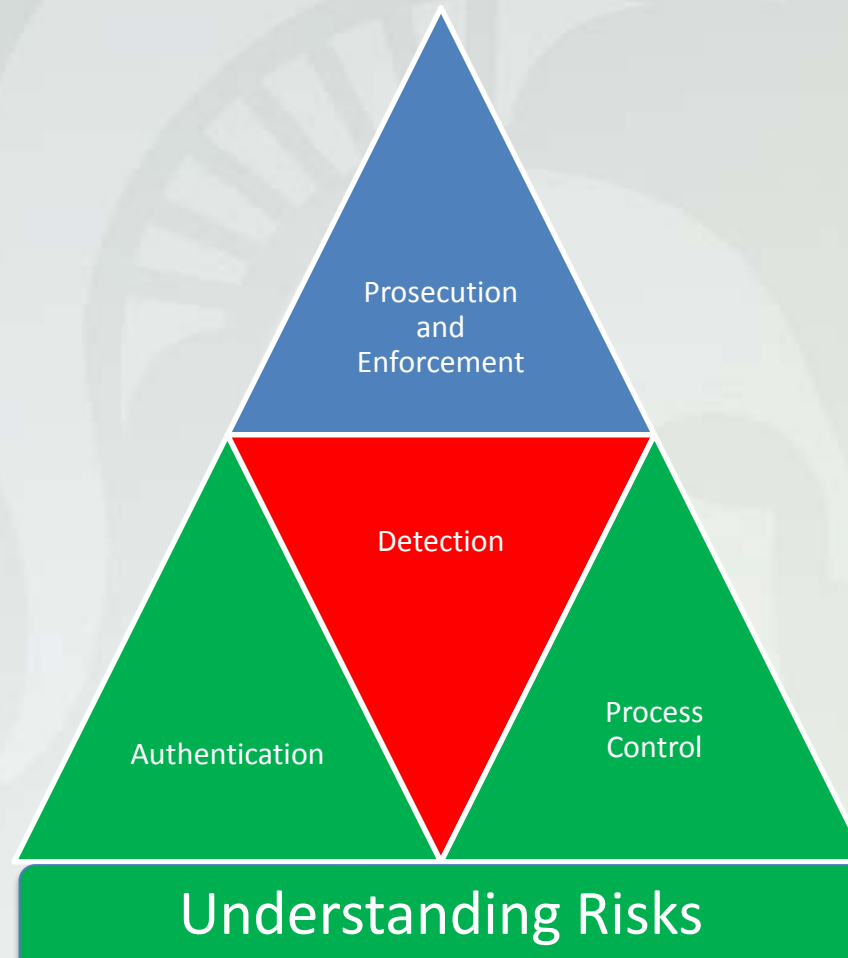
# Internal and External Understanding of Processes and Their Controls



# Mapping Your Process Controls

- Who buys the active ingredients?
- Who procures the packaging?
- Who makes the product?
- Who Packages and labels the product?
- You, others? Contract or pure buy?
- Do you even have the legitimate flow of your goods documented and mapped?
- Can you verify where your products are at any point in time along the supply chain through tracking of tracing technology use?

# You Cannot Prosecute What You Cannot Find So You Must Detect

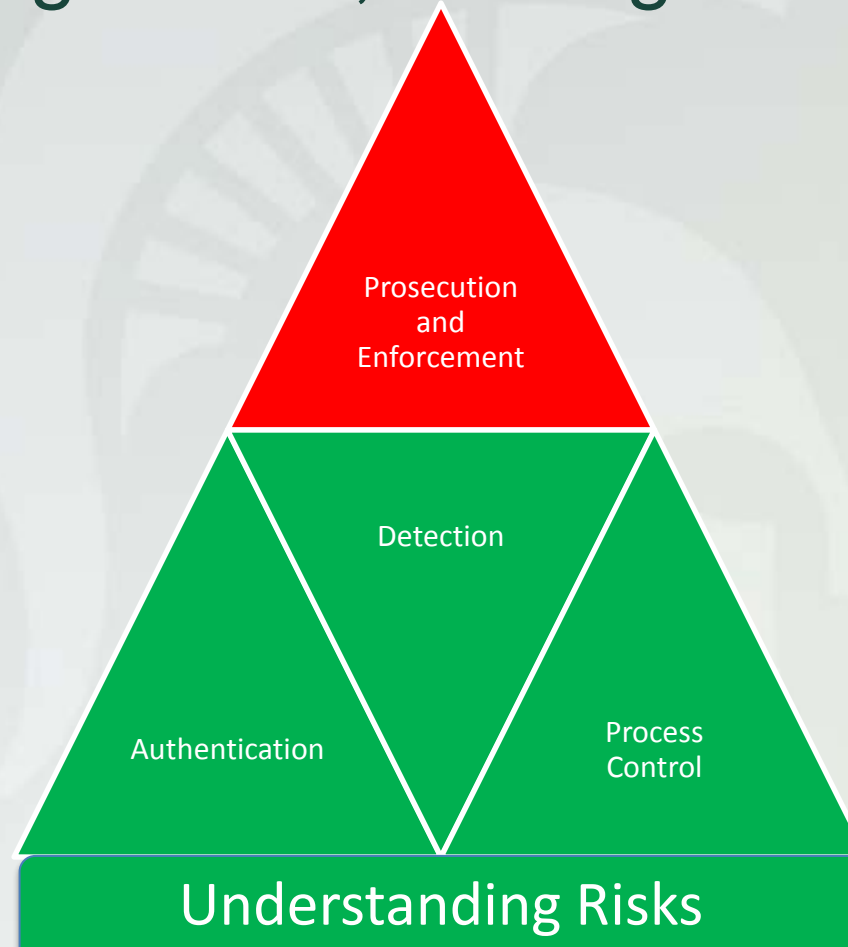




# Monitoring Effectiveness Through Detection

- You know your processes and you know your products, great. Do you have a plan to detect when a good product leaves the legitimate supply chain or a falsified product enters the legitimate supply chain?
- Who know where to look? Can you get access to all nodes along the supply chain easily?
- Who knows how to look? What are they seeking to detect? What do they do with suspicious products? Do you have an incident management program that stores

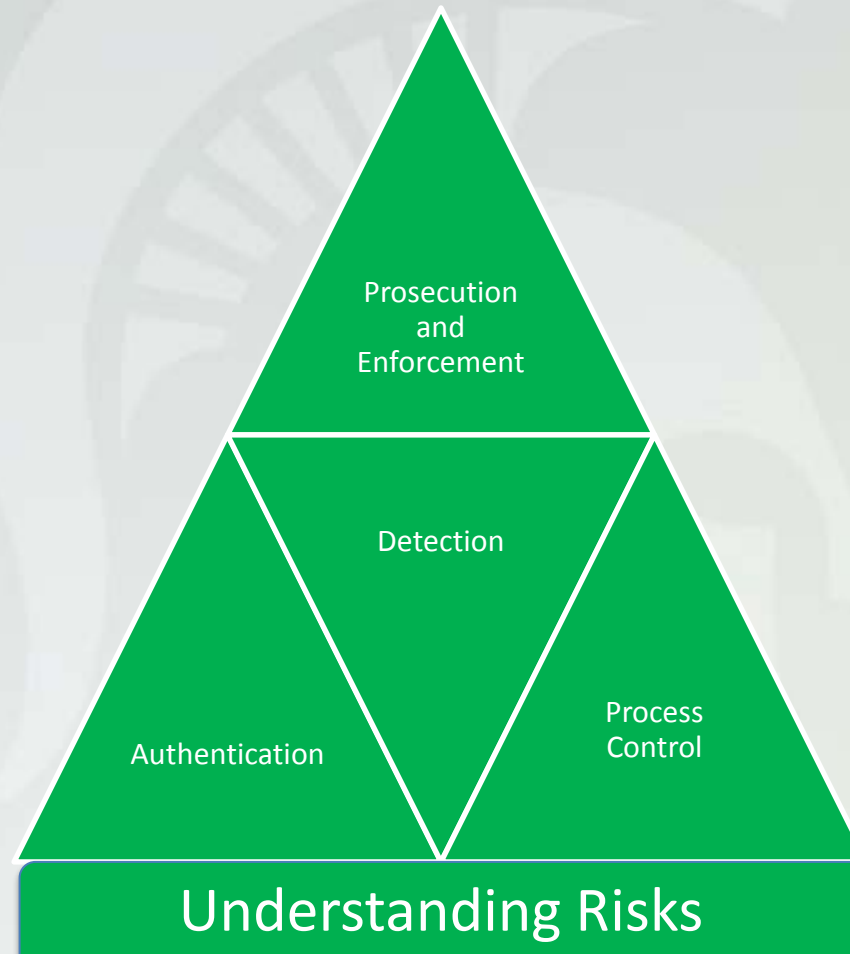
# Making Use of Your Findings, Making it Hurt, Making it Stick, Making it Public...



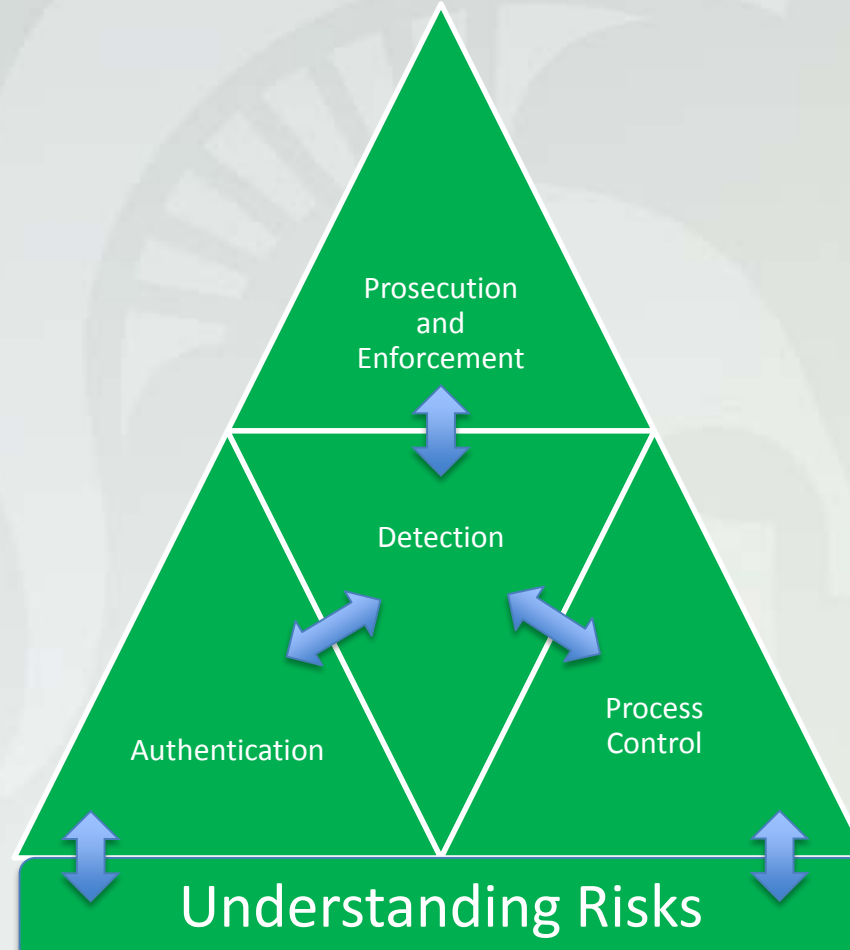
# Prosecute When Verified

- All lower elements are up and running well, you are looking and finding, authenticating and learning who is not playing nice with your products. Great.
- Have you gained the insight necessary to allow your security team to take a case?
- Have you handle the data properly to allow your legal team to prosecute?
- Do you know what both of those teams need from you?

# Holistic Approach to Brand Protection



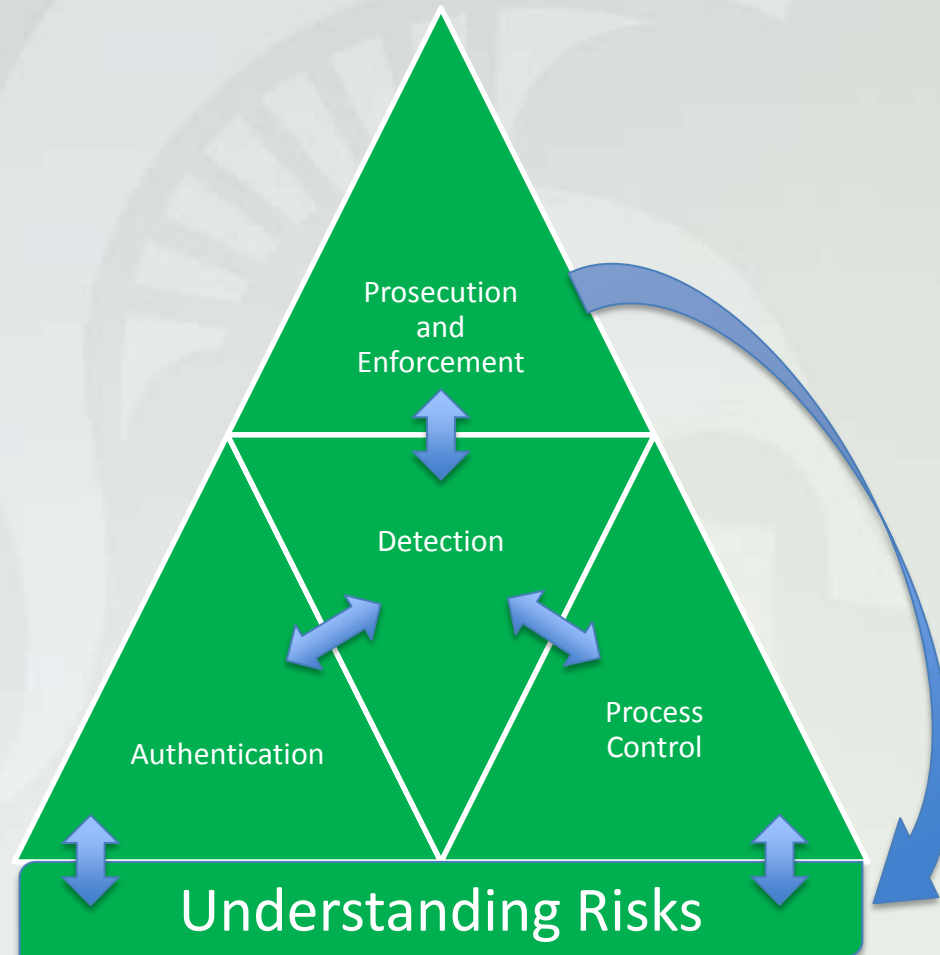
# Data Sharing Among Departments and Stakeholders



# Ongoing Feedback and Updates

- Every new incident is measured against the Product Risk Assessment Questionnaire
- Questions can be updated if they are found to be inadequate or incapable of detecting counterfeit, diversion, or tampering risks
- Annual review of questions

# Ongoing Feedback and Updates



# Want To Know More?

Michigan State Can Help You through Education.

Through the power of an industry/academic partnership, the MSU Center for Anti-Counterfeiting and Product Protection is offering to help educate staff members, leadership, educators, and employees in the fundamentals of brand protection.

We have course work from introduction to advanced learning.

We have executive education programs for targeting specific learning needs and practices.

And we are building a Brand Protection Certification program launching in 2015.



# Executive Education Offerings

June 10, 2014 - *Building An Effective Risk Assessment Program*

Part 1 of 3 - Full Day Course (Includes Follow-Up Assistance)

August 12, 2014 - *Building An Effective Risk Mitigation Program*

Part 2 of 3 - Full Day Course (Includes Follow-Up Assistance)

October 14, 2014 - *Using Technologies to Combat Counterfeits*

Part 3 of 3 - Full Day Course (Includes Follow-Up Assistance)

Courses to be held at Michigan State University, East Lansing,  
Michigan Campus

Course Instructor - David Howard

# Online Course Offering 20 14

## May 12 – June 26 Registration Open

### CJ491 - Topics In Criminal Justice; Section 732-Introduction to Product Counterfeiting.

#### About the Instructor

Rod Kinghorn - Mr. Kinghorn is a graduate of Michigan State University and a seasoned brand protection professional. Throughout his 38 year career at General Motors, he served in a variety of brand protection roles, including responsibility for the Global Security Operations.

Since his retirement from General Motors, Mr. Kinghorn offers his expertise to the A-CAPP as an Outreach Specialist. As a member of the A-CAPP team, he works closely with government agencies, professional associations, and brand owners, assisting with their anti-counterfeit strategies.

**Course Description:** Students will explore the elements of product counterfeiting and begin to understand how this illicit trade functions, its multidimensional effects, and formal responses to it. Discussions will include defining product counterfeiting, managing trademarks, and understanding how global cultures and markets impact the manufacturing, distribution and sales of counterfeit products. Particular attention will be given to the evolution of methods to combat product counterfeits and what options brand owners and law enforcement have to protect trademarks in the global marketplace. Students that successfully complete the coursework will begin to understand why the FBI has called product counterfeiting the crime of the 21st century.

# Online Course Offering 20 14

## May 12 – June 26 Registration Open

### CJ809 - Issues in Criminal Justice; Section 731- Understanding Product Counterfeiting.

#### About the Instructor

Meghan Hollis - Dr. Hollis is an Assistant Professor with the A-CAPP and the School of Criminal Justice. She received her Ph.D. in criminology and justice policy from Northeastern University. Before joining MSU, Dr. Hollis was a research associate with Northeastern University and the Netherlands Institute for the Study of Crime and Law Enforcement.

**Course Description:** Product counterfeiting is a relatively new area of criminology inquiry, and research is steadily growing. In this course, students will explore the product counterfeiting phenomenon. First, students will be introduced to product counterfeiting, focusing on definitions, legal frameworks and extent. Next, the focus will shift to theory with an examination of how criminology and sociological theory can be applied to understand product counterfeiting. The final segment of the course will examine legal and other responses to product counterfeiting with a focus on application of crime prevention techniques and research to the prevention of product counterfeiting.

Course can be completed as part of a certificate, Master's or Ph.D. program.

# Course Registration Contact

- Non-MSU students please contact Sara Heeg for assistance with registration: 517.432.2204, [heegsar1@msu.edu](mailto:heegsar1@msu.edu)

# The Disconnect Between Risk Assessment and Technology Deployment In The Pharmaceutical Industry

## We Are Interested In Partnering With You

### Thank You

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