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CBI'S 2ND ANNUAL LIFE SCIENCES SUMMIT ON

INTERNATIONAL TRADE COMPLIANCE

MANAGING COMPLIANCE IN A GLOBAL ENTERPRISE
GOOD IMPORTER PRACTICES • EXPORT CONTROLS AND SANCTIONS

OCTOBER 20-21, 2010 · TYSONS CORNER MARRIOTT · VIENNA, VA

— ATTEND ONE OR BOTH DAYS DEPENDING ON YOUR RESPONSIBILITIES —

— DAY ONE — IMPORT COMPLIANCE

- Learn best practices to comply with FDA, FTC, EPA, USDA and CBP import regulations
- Assess the Quality Trusted Importer Program (QTIP) initiative
- Hear FDA's update on PREDICT's national roll-out
- Comply with TSA's enhanced screening of pharmaceutical shipments
- Determine accurate country of origin and tariff classifications
- Assign value to imported, non-commercial R&D materials

PLUS! ATTEND AN EXTENDED SESSION ON:

"Best Practices to Gain Clearance through Customs"

— DAY TWO — EXPORT COMPLIANCE

- Analyze the impact of the National Export Initiative on the pharmaceutical industry
- Ensure compliance with international trade sanctions and find opportunity among the restrictions
- Tackle complex issues surrounding restricted/denied party screening
- Mitigate compliance risks when supplying clinical trial materials into Eastern Europe and emerging markets
- Develop best practices for export compliance program implementation and execution

PLUS! ATTEND AN IN-DEPTH WORKSHOP ON:

"Building a Tailored Export Compliance Program"

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MAIN CONFERENCE

Day One — Wednesday, October 20, 2010

IMPORT COMPLIANCE

7:30 *Day One Continental Breakfast and Conference Registration*

8:30 *Chairman's Welcome and Opening Remarks*

David Ulrich, Distribution and Logistics QA Director, Global Pharmaceutical Operations Division, **Abbott Laboratories**

Mr. Ulrich's responsibilities include standardization and optimization of quality systems (cGDPs), cold chain management, supply chain IT system optimization and import export compliance activities (FDA, USDA and EPA). He has been at Abbott for twenty-three years, with the majority of time spent in bulk (API) manufacturing operations, manufacturing QA and plant maintenance, validation and engineering.

8:45 **Comply with FDA, FTC, EPA, USDA and CBP Regulations**

There are many import regulations in place to protect national security, foreign policy and U.S. resources. These regulations are enforced by different agencies such as the FTC (Federal Trade Commission), U.S. Customs and Border Protection (CBP) and the FDA (Food and Drug Administration) and are often specific to certain goods or classifications of goods, but are not always clear to those in industry that need to comply to these regulations. It is critical as an importer, that there is an understanding of how to apply each regulation, how they interact and most importantly, how to reconcile compliance. This session discusses the requirements of each regulatory authority, highlights areas where there are synergies and conflicts as well as offers best practices for compliance.

- Overview of FDA, FTC, EPA, USDA and CBP import regulations
- Analyze where the regulations overlap and/or conflict
- Hear best practices to comply with each regulatory authority

David Ulrich, Distribution and Logistics QA Director, Global Pharmaceutical Operations Division,
Abbott Laboratories

9:30 **USDA Update on the Issuance of Import Permits and Vet Certificates**

This presentation gives an overview of recent activity of the USDA Animal and Plant Health Inspection Service, (APHIS) National Center for Import and Export (NCIE). APHIS serves to facilitate safe international trade, regulate the import and export of animals, animal products and biologicals and issuance of Import permits.

Pamela Simpson-Diedrick, DVM, MPH, Senior Veterinary Medical Officer,
National Center for Import and Export (NCIE)

10:00 **Assess the Potential for Integrated Border Management between FDA, Customs and USDA**

Currently the FDA, Customs and USDA operate independently of each other with regards to approving goods into the U.S. This process is very complex and is subjected to each import transaction which can cause undue delays at the border. An integrated border management framework, where the various agencies work in concert with each other, can allow a drug to be pre-approved for distribution and help to streamline the process of crossing the border. A promising initiative, the Qualified Trusted Importer Program (QTIP), would assess a company's internal processes and controls with respect to product quality, supply chain security and trade compliance. Upon review, companies that qualify as "trusted importers" would be afforded interagency green lane status. Not only would this allow a company to receive a pre-admission decision from the FDA, Customs and USDA, but it would also prevent a company from having to go through a lengthy process for each transaction. For a company that imports on a large scale, it would be a significant savings of time and resources. This session discusses the potential benefits of an integrated border management program.

- Apply risk management techniques to ensure compliance
- Advocate for Qualified Trusted Import Program (QTIP)
  * account management rather than transaction
  * "green lane" status
- Achieve pre-admission decisions prior to reaching border

Anthony Barone, Director, Global Logistics Policy, **Pfizer Inc**

10:45 *Networking and Refreshment Break*

— FDA ADDRESS —

11:15 **FDA Update on PREDICT Import System Deployment**

FDA's new PREDICT risk-based screening system for imports will augment FDA's admissibility screening functions. It will assist entry reviewers in targeting higher-risk shipments for examination and also expedite the clearance of lower-risk cargo, but only if accurate and complete data are provided by importers and entry filers. The expected national rollout of FDA's PREDICT had been delayed due to infrastructure problems that resulted in server crashes and overloads. This address provides an update on the deployment of the PREDICT import system.

Steve Kendall, PREDICT Project Director,
U.S. Food and Drug Administration

12:00 **Prepare for and Comply with Enhanced TSA Cargo Screening on Pharmaceutical Shipments**

In 2007, Congress passed the 9/11 Commission Act, which requires the Transportation Security Administration (TSA) to create a system capable of screening all air cargo transported on passenger aircraft. A key component of this initiative is the Certified Cargo Screening Program (CCSP). Under CCSP TSA will certify cargo screening facilities located throughout the United States that screen cargo prior to providing it to airlines for shipment on passenger

flights. Participation in the program is voluntary and designed to enable vetted, validated and certified supply chain facilities to meet the 100 percent screening requirement. TSA has put in place procedures to meet the Congressionally-mandated requirement to screen fifty percent of all cargo on passenger planes by February 3, 2009. This session discusses the impact of the enhanced cargo screening on pharmaceutical shipments and offers best practices for preparation and compliance.

- Automatic triggers of enhanced screening
  - * sponsors of terror
    - – Cuba, Sudan, Syria and Iran
  - * countries of interest
    - – Afghanistan, Algeria, Iraq, Lebanon, Libya, Nigeria, Pakistan, Saudi Arabia, Somalia and Yemen
- Screening of cargo on passenger planes

Thomas J. Carter, Assistant General Manager, Air Cargo Compliance and Oversight, Department of Homeland Security, **Transportation Security Administration (TSA)**

12:45 *Luncheon*

1:45 **Applying Valuation and Record Keeping Regulations for Clinical Trial Shipments**

In the ever changing environments of trade regulations and clinical trials, it is critical not only to establish smooth distribution pathways, but also to ensure the process is in compliance with trade regulations. Often valuation of products during the R&D development stage is not straight forward and can be difficult. In addition, documents which are required for customs often reference terms such as "buyer" and "seller" which leads to confusion when the regulations are being applied to R&D. This session discusses:

- Documentation and record keeping related to the import/export of the shipment
  - * blinding of commercial/Proforma invoices
  - * what records need to be maintained and who is responsible for it
- Determination of the value on R&D materials when you are not selling them
  - * valuation methodologies
  - * determine what regulations apply and how to apply them

Roopal Patel, MS, MBA, Senior Import/Export Specialist, **Takeda Global Research and Development Center, Inc.**

2:30 **Discuss Growing Trends and Vulnerabilities to U.S. Import System Created by Counterfeiters**

The National IPR Center is a multi agency task force responsible for coordinating a unified U.S. Government response to IP enforcement issues. Particular emphasis is given to protecting the public health and safety of U.S. consumers, investigating major criminal organizations involved in transnational IPR crime and pursuing the illegal proceeds derived from the sales of counterfeit merchandise. The U.S. Department of Homeland Security initiated Operation Guardian to target, interdict and investigate substandard, tainted and counterfeit products being imported into the U.S. that pose a health and safety risk to consumers. Counterfeit pharmaceuticals are very profitable and on the rise. This session covers the growing trend of counterfeiting and offers insight into what industry can do to protect against them.

- The current situation and future threat
- Initiatives the National IPR Center is employing to fight counterfeits
- Employ practical solutions to protect against counterfeiters

Craig Thurber, Section Chief, U.S. Immigration & Customs Enforcement, IPR Center, **U.S. Department of Homeland Security**

3:15 *Networking and Refreshment Break*

3:45 **Country of Origin Determinations**

Country of origin determinations for imported goods grow increasingly complex as the long-standing substantial transformation rule now applies only to certain goods from certain countries. More detailed "tariff shift" rules often apply for merchandise from free trade partner countries or for certain goods. This discussion covers the intricacies of determining country of origin and offers insights into best practices within the industry.

- Determine correct country of origin rules and appropriate tariff classifications
- Design required country of origin labels
- Comply with U.S. Customs and FTC

Ted E. Murphy, Partner, **Baker & McKenzie LLP**
Susie Hoeger, Director, Global Trade Compliance & Policy, **Abbott**

Extended Interactive Session

4:30 **Best Practices to Gain Clearance through Customs**

Delays at customs can be very costly. It is beneficial for importers to put processes in place to ensure quick and seamless clearance through customs. In order to do so, an understanding of the most common causes of "holds" is useful in developing and implementing processes to avoid these pitfalls. This extended session provides in-depth coverage of FDA, USDA, CBP and manifest holds. Common triggers leading to "holds" are explored and solutions are presented.

- Overview of FDA, USDA, CBP and Manifest holds
- Explore common triggers leading to holds
- Generate solutions and implement procedures to avoid holds

Matt Guarrera, Director of Global Trade Compliance, **Covidien**

6:00 *Close of Day One*

6:00-7:00 ***Networking, Wine & Cheese Reception***

Join colleagues and friends in a relaxed setting.

Photo by: Photolink / Getty Images

Day Two — Thursday, October 21, 2010

Export Compliance

7:30 *Day Two Continental Breakfast and Conference Registration*

8:30 *Chairman's Welcome and Opening Remarks*

8:45AM-12:30PM • In-Conference Workshop

Building a Tailored Export Compliance Program

Workshop Objective:

Any company involved in international trade should have an export compliance program. This program does not have to be complicated; in fact, the best ones are simple to follow. This interactive in-conference workshop provides a step-by-step process to build a tailored export compliance program that develops internal procedures and provides evidence of your company's commitment to following U.S. export control and anti-boycott laws.

Key Questions to Be Addressed:

- What are the proper steps in writing a compliance program?
- How do you keep the program up-to-date with current law?

Workshop Outline:

I. Understand the Cost/Benefit of Developing a Program
- Overview of penalties of non-compliance
- Provide evidence of company's commitment to compliance

II. Learn the Minimum Requirements of a Solid Program
- Appropriate, consistent documentation
- Identify individuals dealing with exports
- Implement procedures to determine license requirements and license exceptions
  * controlled equipment * controlled technology
  * controlled pathogens and toxins
- Screening parties to a transaction
- Documentation and record-keeping
- Training and monitoring

III. Best Practices in Program Implementation and Execution
- Incorporate continuous improvements

There will be a 30-minute networking and refreshment break at 10:00 a.m.

Workshop Leader:

Nancy Grygiel is Director, Global Trade and Export Compliance with **Mylan Pharmaceuticals.** Ms. Grygiel has a broad range of experience in international business transactions, legal and over seven years in compliance. She is also accountable to the Senior Vice President Chief Compliance Officer for leading on the implementation of the Global Compliance Program (with presence in over 140 countries) and FCPA related policies, procedures and operational challenges. Ms. Grygiel is familiar with GAAP internal controls and wide knowledge of export control laws. She is responsible for operation and continuous improvement of the elements of the program and for ensuring that appropriate processes are in place to meet various requirements, including the preparation of regular reports to other members of the U.S. and global leadership teams and the BOD.

Tom Scott is Of Counsel to the Houston firm **Ladner & Associates PC** and is resident in the firm's Washington, D.C. office. He received his Bachelor of Arts degree from Davidson College in 1980, and a Juris Doctor from the University of Georgia School of Law in 1983. After graduation from law school, Mr. Scott worked in-house in Amsterdam prior to entering private practice in Washington. Mr. Scott's practice has focused on U.S. trade law and regulation for the past twenty-five years, with a particular emphasis on export controls and embargoes. He advises clients on export control matters under the Export Administration Regulations, the International Traffic in Arms Regulations and the various sanctions programs administered by the Office of Foreign Assets Control. Mr. Scott handles internal investigations of export control violations and assists in designing and implementing comprehensive trade compliance programs.

Plenary Sessions Resume

12:30 *Luncheon*

1:15 **National Export Initiative — Impact on the Pharmaceutical Industry**

In January 2010, President Obama announced that the U.S. was going to double exports over the next five years. In doing this, the current export control systems would be overhauled and there would be an increased focus on security and enforcement of the new controls. Pharmaceuticals are one of the key areas outlined for increased exportation. What is the impact on the industry? What will the new export controls look like and what can be expected in terms of enforcement actions? This session gives an overview into the new initiative and its impact on the pharmaceutical industry.
- Overhaul of outdated export control system
- Eliminate obstacles exporting to countries that employ dual nationals
- Closer trade ties with Panama, Columbia and South Korea
- Enhanced national security — Focus on enforcement

Judy Kornfeld, International Trade Specialist, **U.S. Department of Commerce**

2:00 **Restricted Parties Screening**

The U.S. government maintains a number of lists designating certain individuals and entities as denied, debarred or otherwise restricted parties with whom U.S. entities and individuals may not do business, or who may be prohibited from receiving U.S. goods or technology irrespective of whether a U.S. entity or individual is involved. In addition, other countries, including Canada and Japan, as well as the European Union and international organizations maintain restricted parties lists. While U.S. laws generally do not mandate screening against restricted parties list, engaging in a transaction with a restricted party can result in civil and criminal penalties, as well as reputational harm. This session addresses the following areas:
- Key lists of concern to global U.S.-based companies
- Why screen?
  * legal prohibitions
  * reputational harm
  * business implications
- Who should be screened?
- How to screen?

Sylwia A. Lis, Associate, **Baker & McKenzie LLP**

3:15 *Networking and Refreshment Break*

3:45 **Compliance Considerations when Supplying Clinical Trial Materials into Eastern Europe and Emerging Markets**

In today's challenging environment of drug development and the need for large global clinical trials, the process for providing drug supplies to patients in a timely manner has become increasingly complex. With large numbers of the targeted patient populations located in many areas around the globe, there is a need to increase our knowledge and develop processes for supplying Eastern Europe and other emerging markets. Exporting to these countries presents many cultural, regulatory and environmental challenges. This presentation offers a comprehensive view of compliance considerations across these markets.

- Overview of benefits and challenges of conducting studies in Eastern Europe and emerging markets
- Mitigate compliance risks associated with these countries
- Hear best practices to streamline your process

Donna McDermott, MS, Associate Director, Global Regulatory Operations Team,
Sharp & Dohme Corp., A subsidiary of Merck & Co. Inc.

4:30 **Ensure Compliance with International Trade Sanctions while Taking Advantage of Its Opportunities**

Navigating U.S. trade sanctions and embargoes can be tricky, with different rules applying to different countries and jurisdiction split between two separate agencies. Each sanctions program is different and understanding how each works can be a competitive advantage. While many companies approach sanctions compliance by strictly prohibiting business with embargoed countries and requiring their foreign subsidiaries to do the same, careful companies in certain industries — including pharmaceuticals — can find opportunity among the restrictions. This session provides an overview of U.S. sanctions and embargoes and the current enforcement landscape and discusses how smart companies with strong compliance systems can work within the law to find opportunities that their competitors might unnecessarily decline.

- Hear an overview of U.S. sanctions, embargoes and current enforcement landscape
- Analyze how strong compliance programs can offer a competitive advantage

Carrie F. Fletcher, Counsel, **Crowell & Moring LLP**

5:15 *Close of Conference*

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All travel arrangements are subject to availability.

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