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CBI's Forum on

INTERNATIONAL GENERIC DRUGS

Maximize Strategies for Pricing, Competition and Regulations

JANUARY 24-25, 2000 • THE WESTIN GRAND • WASHINGTON, D.C.

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International Journal of Generic Drugs

Generic Line®

— KEYNOTE ADDRESS —

The Honorable Henry A. Waxman,

U.S. Congressman, United States California District 29

"The Waxman-Hatch Act and the Generic Drug Industry"

- ➢ Obtain shares of Big Pharma's protected revenues — Implement aggressive life cycle management (LCM) countermeasures
- ➢ Move your company from domestic to international — Overcome the barriers for entry into Europe, Latin America and Japan
- ➢ Know the impact of recent patent suits in the U.S and the potential impact on international development
- ➢ Increase company value — Stocks, industry deals and financial performance
- ➢ Evaluate pricing and utilize data and benchmarking to identify analogous situations
- ➢ Use a development partner to speed product development and reduce risk
- ➢ Realize the importance of pre-product development planning, GMP systems, PAIs and audits
- ➢ Be innovative — Product line extensions, corporate alliances and niche development can significantly boost your generic drug sales

Plus

Pre-Conference Workshop — Monday, January 24, 2000

Sourcing APIs to Meet Consumer Demand

- Hot markets for sourcing APIs — China & India, Central & Eastern Europe
- Low volume APIs are not insignificant
- API availability
- The U.S. Federal Trade Commission's Role in APIs

MAIN CONFERENCE

Day One — Monday, January 24, 2000

1:30 *Main Conference Registration*

1:45 **Chairperson's Welcome and Opening Remarks**
Ashok Gumbhir, Ph.D.,Professor of Pharmacy Administration, School of Pharmacy, **University of Missouri, Kansas City, Missouri**

★ ★ ★ **KEYNOTE ADDRESS** ★ ★ ★

2:00 **"The Waxman-Hatch Act and the Generic Drug Industry"**
The Honorable Henry A. Waxman,
U. S. Congressman, United States, California District 29

Henry A. Waxman represents California's 29th congressional District. Waxman has been a leader on health and environmental issue, including universal health insurance, Medicare and Medicaid coverage, tobacco, AIDS, air and water quality standards, pesticides, nursing home quality standards, the availability and cost of prescription drugs and the right of communities to know about pollution levels.

Waxman has been involved in health issues since 1969, when he was appointed to the California State Assembly Health Committee. In Congress, Waxman has sponsored a long list of health bills that have been enacted into law. These measures include the Ryan White CARE Act, the Nutrition Labeling and Education Act, the Breast and Cervical Cancer Mortality Prevention Act, the Safe Medical Devices Act, the Patent Term Restoration and Drug Competition Act and the Orphan Drug Act.

2:45 **The Impact of Recent Patent Suits in the U.S. and Potential Impact on International Development**
- 180 Days of Exclusivity
- Provisions to grant first applicant for an Abbreviated New Drug Application (ANDA)
- To commercially sell the drug
- To successfully defend an invalidity or infringement suit (whichever occurs first)

David Rosen,R.Ph., J.D., Partner, **McDermott, Will and Emery**

3:30 *Networking and Refreshment Break*

3:45 **Wall Street Perspective — Improve Market Position and Increase Company Value**
- Major trends in generic drugs
- Stocks, industry deals and financial performance
- What puts a company in a good position?

Darrell Riley, Vice President,
T. Rowe Price Associates, Inc.

4:30 **Counter Branded Strategies that Hinder Generic's Entry to Market**
The results of the very successful life cycle management strategies have been implemented by big Pharma over the past decade. Each strategy is analyzed to discover ways to obtain shares of big Pharma's protected revenues through countermeasures implemented by the generic industry. Applying these counter measures to present and future drugs protected by LCM strategies, will result in a greater share of income for generic companies.
- Use of novel drug delivery systems
- Racemic switches and metabolites
- New indications and new patient populations
- Rx to OTC switches
- USP changes in processes and assays
- In-licensing non-orange book patents
- Switch to orphan drug status
- Payments to generics for no launches
- API ownership
- Patents on stabilizers components

Richard DiCicco,President,
Technology Catalysts International

5:15 *Close of Day One*

5:15-6:15 ***Wine & Cheese Networking Reception***
Join colleagues and friends in a relaxed setting.

Day Two — Tuesday, January 25, 2000

8:00 *Continental Breakfast*

8:30 **Chairperson's Review of Day One —**
Ashok Gumbhir, Ph.D.,Professor of Pharmacy Administration, School of Pharmacy,
University of Missouri, Kansas City, Missouri

8:45 **Pricing, Benchmarking and Creating an Overall Strategy**
- Specific case studies involving the introduction of generic molecules into different countries
- Benchmarking — gain perspective and "benchmarks" by looking at the brand erosion and uptake of generic products for specific molecules by country
- Pricing — gain insight from pricing strategies already employed for branded products and generics

* what has worked * what has failed

- Analogues — how we utilize data to identify analogous situations
  * what do we need to consider and evaluate?
- Success — bringing it all together
  * what did it take to succeed in the past?
  * what will it take in the future?

Ken Meier, Strategy Group Specialist, **IMS Global Services**

9:30 **Identify the Strongest Mature and Emerging Markets**

As the generic pharmaceutical industry becomes more global, it is important to identify international "hot" markets in order to capture the maximum market share. How do you identify which markets are saturated, which markets have stringent regulations and which markets look fruitful on the surface, but are actually unstable for generic products?

Case Study

- Moving your company from domestic to international
- Where are the hot spots?
- How does the current global crisis impact the generics international market?

Brian W. Tempest, Ph.D., Regional Director, Europe,CIS, **Africa Ranbaxy Europe Ltd.**

10:15 *Networking and Refreshment Break*

10:30 **Use a Development Partner to Speed Product Development and Reduce Development Risk**

- Cost of failed bio-studies: understanding the real costs
- Value of risk reduction
- Value of competition to internal development efficiency
- Value of increased development capacity
- Using joint ventures/alliances to gain competitive advantage

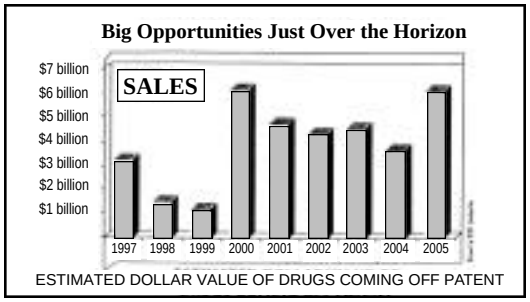
Alan Lanier, Director, Licensing and Business Development, **AAI**

11:15 **Develop a Successful Generic Product Inspection Program**

- Pre-product development planning
- GMP systems
- Internal/external audit programs
- Pre-approval inspections

Thomas E. Needham,Ph.D.,President, **Hancock & Associates**

12:00 *Luncheon*



1:30 **Innovations in Generic Drug Sales and Marketing**

- Full service sales/marketing techniques — present and future
- Research and development consultation
- Manufacturing forecasting, inventory management and supply performance
- Customer satisfaction through superior services
- E-commerce — the cutting edge in technology and communication
- Consumer and professional education via public relations
- Business development — product line extensions, corporate alliances, niche development

Robert J. Gunter, President and CEO, **Pharmaceutical Marketing Partners, LLC**

— INTERNATIONAL FOCUSED SESSIONS —

2:15 **Overcome Barriers to Market Entry for Generics in Europe and Japan**

- First to market exclusivity
- Patent term extension
- Supplementary protection certificates
- Experimental use

William T. Christiansen,Ph.D., J.D.,Attorney at Law, **Seed and Berry, LLP**

3:00 *Networking and Refreshment Break*

3:15 **How Generics Can Contribute to the Access of Drugs in Latin America**

Case Study

- New laws in Latin America
- Overview and strategies
- The future in the Latin American regions
- Pan American Health Organization involvement in the industry

Rosario D'Alessio,Regional Advisor, Pharmaceutical Services, Essential Drugs and Technology Program, **Pan American Health Organization**

4:00 **Case History of a "Greenfield" API Start-up Company in Taiwan**

- Opportunities
- Barriers
- Surprises
- Fund raising
- Commitments

Robert P. Cook,Senior Vice President and Founder, **Scinopharm International, Inc.**

4:45 *Close of Conference*

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Sourcing APIs to Meet Consumer Demand

This workshop reveals crucial information about sourcing APIs to meet consumer demand. Learn where the hot markets are and realize how technology, deals flow and cGMP plant progress adds importance. In addition, find out the value of low volume APIs and the elements of building a successful business. Understand the availability of APIs and the impact of short supplies and keeping within the boundaries of purity.

8:00 *Workshop Registration*

8:30 *Workshop Leader's Welcome and Opening Remarks*

I. The Hot Markets for Sourcing APIs — China and India, Central and Eastern Europe
- A. Technology base
- B. Deal flow and optimizing relationships
- C. cGMP plant progress

II. Low Volume APIs Are Not Insignificant
- A. The value chain from manufacturer to wholesaler
- B. Manufacturing issues
- C. Elements of building a successful business

III. API Availability
- A. Impact of current short supply
- B. Staying within the boundaries of purity

IV. The U.S. Federal Trade Commission's Role in APIs
- A. The U.S. generic company perspective
- B. The U.S. brand company perspective
- C. The FTC perspective
- D. The international perspective

12:00 *Close of Workshop*

There will be a 30 minute networking and refreshment break at 10:15

— About Your Workshop Leaders —

H. Robert Koch is the President of **API, Inc.** and has over 35 years of experience in the manufacture of chemicals at **Hoffman LaRoche,** which included both active pharmaceutical ingredients and vitamins. His manufacturing experience ranges from junior chemist on the Chlordiazepoxide (librium),in the mid 1960's,to Director of the Chemical Production Department at the Roche Nutley, NJ, in the 1980s and 1990s. As Director, he was responsible for all chemical manufacture at the Nutley, NJ site, which included active pharmaceutical ingredients, biotech products and vitamins. This experience provides him with an excellent background in cGMP manufacturing, regulatory issues and validation.

Richard DiCicco, is the founder and President of **Technology Catalysts International,** the largest multinational consultancy in the pharmaceutical and chemicals industry specializing in licensing and business development. Since 1979,TCI has been helping the pharmaceutical industry acquire the products or technology they need to achieve a greater than 30 percent on their investment after taxes. TCI has focussed on helping the global generic industry over the past ten years, with either the first launched generic to a brand, or countering life cycle management strategies through pre-emptive dealmaking or drug delivery technology sourcing.

Edward M. Cohen,Ph.D., Vice President,Science Advisor, **Schein Pharmaceutical,Inc.** Current responsibilities include providing technical support for new business ventures for Schein's Strategic Development Group. Dr. Cohen has been with the Schein group since January of 1989. His responsibilities with the firm have included Research and Development,Quality Assurance/Quality Control, and Regulatory Affairs. Prior to joining Schein, Dr. Cohen was head of the Pharmaceutical Research and Development Group at the Squibb Institute For Medical Research,from 8/85 to 12/98. From 1965 to 1985, Dr.Cohen was employed by **Merck** (West Point, PA) in the Pharmaceutical R&D group. A portion of his Merck career was spent as Director of **Merck's French Pharm. Development Group** (1978 to 1981). His industry career started as an Analytical Chemist at Johnson & Johnson in 1962, following completion of the work towards the receipt of a Ph.D. degree in Pharmaceutical Chemistry from Rutgers.

UPCOMING CBI PHARMACEUTICAL EVENTS

Online Pharmacies
October 21-22, 1999, Chicago, IL

Pediatric Drug Development
October 21-22, 1999, Washington, DC

Electronic Publishing
October 28-29, 1999, Philadelphia, PA

Pharma InfoTech Forum '99
November 4-5, 1999, New Orleans, LA

SUPAC
November 18-19, 1999, New Orleans, LA

Contract Labs
December 2-3, 1999, Miami, FL

CRO-Bio/Pharmaceutical Contracting, Pricing and Risk Sharing Arrangements
December 6-7, 1999, Coral Gables, FL

Manufacturing APIs
December 6-7, 1999, Atlanta, GA

Pharmacogenomics Impact
December 6-7, 1999, San Francisco, CA

Pharmaceutical and Medical Device Packaging
December 8-10, 1999, Washington, DC

Online Retail Pharmacies
January 27-28, 2000, Scottsdale, AZ

Marketing Pharmaceuticals over the Internet
January 27-28, 2000, Washington, DC

Drug Development for Women
January 27-28, 2000, Washington, DC

Stability Data Management
January 30-February 1, 2000, Philadelphia, PA

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U.S. Congressman, United States California District 29

"The Waxman-Hatch Act and the Generic Drug Industry"

Pre-Conference Workshop—Monday, January 24, 2000

Sourcing APIs to Meet Consumer Demand

Hot markets for sourcing APIs — China & India,Central & Eastern Europe
Low volume APIs are not insignificant • API availability

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Fortunately -- if you **can't attend** -- you can still be informed of the latest developments in **International Generic Drugs** by purchasing the Conference Compendium.Simply check the appropriate box on the registration form and send it with your payment of just $298. Your copy of the proceedings will be mailed immediately following the conference.

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- **Substitution & Cancellation:**
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