

Practical Challenges Implementing Global Recalls

**February 28, 2007
ICPHSO 14th Annual Meeting**

**Peter L. Winik, Esq.
Latham & Watkins LLP**

Recalls Span The Globe

- Globalization = Worldwide Distribution
- Recall analysis can no longer be limited to single country.
- In addition to Europe, regulatory regimes developing in Asia and elsewhere.
- Over past three years implemented recalls in over 50 Countries.
- Assembled Worldwide Team of Lawyers



Identifying the Geographic Scope of the Recall

- Where product sold vs where used
- If sold worldwide, must recall be worldwide?
- Differing risk profiles? Cultural and market factors
- Announcing the recall in countries where the product was not sold

Reporting Considerations

- Confidentiality Concerns
- Timing Considerations
- Identifying Product Safety Regulators
- Whether to Report If No Legal Obligation Exists or Cannot Be Determined

Practical Considerations

- Different regulators may reach different conclusions about the hazard
- Preparing Worldwide Recall Materials
- Differing Notice Requirements
 - Press Release vs. No Press Release
 - Paid Advertising

Practical Considerations

- Website Notification
 - What to Post
 - When to Post
 - Need to Ensure Notice Posted in Relevant Languages
- Managing the Press
 - Local Counsel or Local Representatives Are Essential for Country-Specific Inquiries
 - Company Desire to Centralize Responses to Press Inquiries

Practical Considerations

- Retaining Local Counsel
- Translations
- Need for Centralized and Coordinated Approach with Regulators
- Establishing and Managing a Toll-Free Hotline
- Issuing Refunds
- Returning Product

Need for Central Management

- Major Coordination Effort
- Big Picture Issues to Consider When Handling Country-Specific Details
- Logistical Hurdles
- Cultural and Language Challenges
- Managing the Demands of Differing Regulatory Regimes Around the World