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# PRODUCT RISK MANAGEMENT SEMINAR

## *A Product Lifecycle Approach to Identifying, Mitigating and Managing Legal Risks*

**October 19, 2011**
**8:45 am – 4:45 pm**

**Crowell & Moring | 1001 Pennsylvania Avenue, NW | Washington, DC 20004**

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**Product Risk Management Seminar**

October 19, 2011
Washington, DC

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- Scott Winkelman, Crowell & Moring

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# KEYNOTE ADDRESS

## Mark Pryor
United States Senator
for Arkansas

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# CHEMICAL REGULATIONS

## *Trends, Emerging Issues and the Future of Chemical Regulation*

**Panelists**

- Moderators: Warren Lehrenbaum and Kevin Mayer, Crowell & Moring
- Maria J. Doa, Director, Chemical Control Division, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency
- Michael Reilly, Associate General Counsel, FMC Corporation
- Ernie Rosenberg, President and CEO, American Cleaning Institute
- Matt Jaffe, Crowell & Moring
- Lawrence Freeman, Crowell & Moring

United States Environmental Protection Agency

# Enhancing EPA's Chemical Management Program

**Maria J. Doa, Ph.D.**

Office of Pollution Prevention and Toxics

# An Agency Priority

"More than 30 years after Congress enacted the Toxic Substances Control Act, it is clear that we are not doing an adequate job of assessing and managing the risks of chemicals in consumer products, the workplace and the environment. It is now time to revise and strengthen EPA's chemicals management and risk assessment programs."

EPA Administrator, Lisa Jackson

Jan. 23, 2009

# Enhanced Chemical Management

- Program includes:
  - —Getting the information needed to understand chemical risks
  - —Increasing public access to information about chemicals
  - —Targeting priority chemicals for action
    - — EPA has released ten chemical action plans that outline a range of risk management activities
  - —Regulatory and other risk management actions

# Action Plans

- Ten Action Plans issued
- Agency identified an initial list of widely recognized chemicals based on
  - Presence in humans
  - PBTs
  - Use in consumer products
  - Production volume
- Action Plans identify regulatory and voluntary approaches
  - TSCA authorities
  - TRI
  - DfE

# Action Plans

- Benzidine Dyes
- Bisphenol A (BPA)
- Hexabromocyclododecane (HBCD)
- Methylene Diphenyl Diisocyanate (MDI) and Toluene Diisocyanate (TDI)
- Nonylphenol and Nonylphenol Ethoxylates
- Perfluorinated chemicals (PFCs)
- Penta, octa, and decabromodiphenyl ethers (PBDEs) in products
- Certain Phthalates
- Short-chain chlorinated paraffins

# Other Actions Under Development

- Lead
  - Ban the use for wheel weights
- Mercury
  - Phase out or ban the use in switches, relays, measuring devices, and other products
- Formaldehyde
  - Pressed wood products
- Glymes
  - SNUR
    - Any new consumer use of monoglyme. diglyme, and ethylglyme
- Nanoscale Materials
  - SNUR
  - Information gathering rule
  - Test rule

# Chemical Prioritization

- Builds on factors used to identify chemicals for Action Plans
- Identify highest priority chemicals to determine whether risk is significant and whether risk management or other action under TSCA is warranted.
  - Chemicals with extensively reviewed data indicating they are carcinogens, cause reproductive/developmental concerns, or are PBTs.
  - Chemicals to which children and/or the general population may be exposed.
- Release initial group of chemicals for priority review by late fall.
  - Early identification will provide interested parties an opportunity to provide additional relevant information to inform EPA's review.

# Two-Step Prioritization Process

- **Step 1**: Identify priority chemicals for review
  - Identify an initial group of candidate chemicals for review by considering hazard and exposure priority factors
- **Step 2:** Select priority chemicals for assessment
  - Use additional exposure and hazard data sources to further prioritize the chemicals
  - Select chemicals for review and assessment, including possible risk management action

# Step 1

- **Step 1**: Identify priority chemicals for review
  - Identify an initial group of candidate chemicals for review by considering hazard and exposure priority factors
- Prioritization factors:
  - Chemicals identified as potentially of concern for children's health (e.g., chemicals with reproductive or developmental effects)
  - Chemicals identified as persistent, bioaccumulative, and toxic (PBT)
  - Chemicals identified as probable or known carcinogens
  - Chemicals used in children's products
  - Chemicals used in consumer products
  - Chemicals detected in biomonitoring programs

# Step 2

- Use additional exposure and hazard data sources to further analyze the chemicals identified in Step 1
- Select specific chemicals for further assessment, including possible risk assessment and risk management action

# Public Outreach

- EPA conducted a webinar on September 7, 2011
- Also held a face-to-face meeting
  - Industry, NGOs, states, tribal representatives
- Discussion forum on the EPA website
  - Allowed people to share their thoughts online
  - Discussion forum was open until September 21, 2011
  - Information posted to the forum still accessible

# Public Input

- Other factors public would like considered
  - Neurotoxicity
  - Environmental presence
  - Environmental  toxicity
  - Chemicals with no exposure data should not be ranked low
  - Do not focus only on products for children; focus on consumer products
  - Dispersive uses

# Thank You

- For further information

  epa.gov/opptintr/existingchemicals/index.html

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Director

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# Chemical Regulation: Trends and Emerging Issues -- Perspective from Pesticides

*Crowell & Moring Product Risk Management Seminar*

*October 19, 2011*

* * *

*Michael F. Reilly*

*Assistant General Counsel, FMC Corporation*

# FMC Corporation

*LTM ending March 31, 2011 ($ millions)*

| FMC Corporation | |
|---|---|
| Revenue: | $3,155 |
| EBITDA: | $688 |


| Industrial Chemicals | |
|---|---|
| Revenue: | $1,047 |
| EBITDA: | $198 |
| Margin*: | 18.9% |

| Specialty Chemicals | |
|---|---|
| Revenue: | $832 |
| EBITDA: | $223 |
| Margin*: | 26.8% |

| Agricultural Products | |
|---|---|
| Revenue: | $1,281 |
| EBITDA: | $339 |
| Margin*: | 26.4% |

*EBITDA margin

# Ever-increasing chemical regulation is the new reality.

- The rise and influence of the Internet and other communications media, activist groups, and societal concern regarding chemical exposure in food, workplace and the environment – together with real or perceived exposure events/risks and poor industry response -- has led to decreased trust of industry.
- These forces are pushing increased regulation in “developed” nations such as US and EU, as well as “developing” nations.
- “Developing” nations are no longer as deferential to US and EU agencies, and are adopting laws and regulations which are as stringent as, or even more stringent than, US-EU laws. These nations are building regulatory infrastructure of scientists, policy makers and enforcement staff.
- Not to be outdone, US and EU regulators continue developing new rules and expanding existing rules that continue to challenge industry.

# This new reality must be accepted and embraced.

- These new rules touch on the entire business: from product development and testing, to production, import, export, sales and marketing.
- The ever-accelerating evolving nature of chemical regulation places extra burdens on global companies to continue to serve our customers and also comply with applicable law.
- In response, industry – individually and collectively -- must not hunker down and ignore this trend. Rather, chemical companies should seek to engage policy-makers and advocate for science-based application of the rules, particularly educating officials and the public on the ***real*** risks and benefits regarding chemical usage. At the same time, leading companies will factor in regulatory structures to guide R&D toward innovation of new products that still meet customer needs and comply with evolving law.

# Pesticide regulation shows this trend as well underway.

US : EPA re-registration process led to withdrawal/cancellation of over 200 active ingredients; new "registration review" process will look again at same active ingredients and revisit safety data.

EPA's creative use of FQPA to effectively cancel registrations without following the risk-benefit analysis required by FIFRA.

EU: Commission's "Annex 1" process led to withdrawal/cancellation of over 500 active ingredients. Country voting in decisionmaking process adds political dimension.

China: New decree bans Class 1 pesticides; new pesticide law (as proposed) could dramatically impact production and sale.

UN: Implementation and sometimes misuse of international treaties; e.g., Rotterdam Convention on Prior Informed Consent; Stockholm Convention on Persistent Organic Pollutants

# Some personal thoughts on how to respond …

- Make good, safe products and instruct customers on proper use.
- Defend and advocate the science underlying safe use of chemicals to colleagues, family, friends, public, government – but also be willing to listen to those with different views.
- Lobby for good, sensible regulation with policymakers – at legislative and administrative levels.
- Challenge regulatory decisions in the courts.
- Look for the silver lining – new opportunities will emerge for new products.
- Communicate a narrative around use of chemicals to improve the quality of life, to feed the world. Modern life requires chemicals and our industry is a vital contributor to greater prosperity for all.

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October 19, 2011

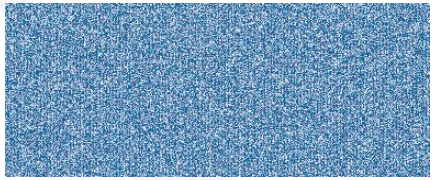
# The Future of Chemical Regulation: Emerging Downstream User Issues

**Ernie Rosenberg**

**American Cleaning Institute®**

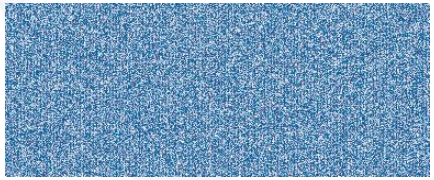
# Use and Abuse of Precaution

- The “Precautionary Principle” is used by activists and some governments to justify control or “deselection” of chemicals in the absence of adequate supporting science
  - Branded downstream products are particularly sensitive to this
- Even without explicit controls, governments can drive “deselection” of chemicals by listing them in ways that assert or imply danger
  - Listing and deselection are not subject to the same discipline or opportunities for challenge as are formal control actions
- Product liability claims can also be based on simple listing



# Downstream “Regulators”

- State agencies
  - Legislative process can be more responsive to activism
  - Regulation at the state level is increasingly fragmenting the U.S. market, e.g., California, Washington State, Maine
    - Wholesale distribution channels preclude state-specific or even regional product formulations
- Activists, federal regulators and some in Congress want to regulate products “downstream” to limit use of chemicals throughout the value chain
- Deselection is also driven by foreign regulations or listing



# Other "Regulators"

- Actors other than regulatory agencies can constrain product formulation or marketing by driving them out of the market via publicity or pressures on others in the value chain
  - Publicity campaigns—"lobbying in the marketplace"—(especially on the internet and via social media) can be very effective, irrespective of the science
  - Deselection can be driven at any point in the value chain, but retailers are the soft spot
    - Some are particularly quick to respond to public or activist pressures; companies putting a high value on their reputation for sustainability can also be quick to deselect
    - Can exclude ingredients from their stores or, in the case of mass retailers, also change product specifications

# Other “Regulators”

- Standards and certification bodies can effectively reduce a product’s market by setting criteria for “environmentally preferable products”
  - Governmental and other institutional purchasers increasingly demand such certification
  - EPA’s Design for the Environment program is an example of product constraints without explicit regulation

# Downstream Users and TSCA Reform

- Because of their sensitivity to the fragmentation of the U.S. market, downstream users are particularly keen to have a credible federal chemical control program
- Activist groups ("NGOs") and their supporters in Congress have proposed "reforms" to TSCA that the business community cannot accept
- For downstream users, provisions that would delay or raise the cost of market entry or inhibit innovation are of particular concern
  - Other issues of concern to chemical producers are also concerns for processors

# Downstream Issues

- Innovation barriers
  - Time to market/product development risk – requirement for prior approval of new chemicals or new formulations
  - Excessive testing costs that cannot be borne by new chemicals or new products
  - Limits on the protection of legitimate confidential business information (CBI)
- Pejorative listing of chemicals
- Targeting of products vs. chemicals
  - Requirements for review and control of mixtures or “articles”
    - Note that TSCA can regulation mixtures and articles, but only if that use must be controlled to prevent unreasonable risk

# Examples of Other Expanding Controls

- European regulation ("REACH")
  - Other REACH-like programs developing around the world, e.g., China, Korea, Turkey
- The Strategic Approach to International Chemicals Management ("SAICM" or the "Dubai Declaration")
  - EU and activists want it to evolve into a global framework convention for the control of chemicals
- Numerous other treaty vehicles
- International treaties and other efforts to force disclosure of product information

# THANK YOU


## Ernie Rosenberg, President & CEO

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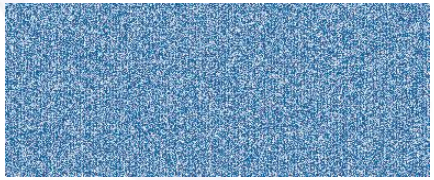


# California's Proposition 65

## Barbarians at the Gate

# Issues

- The Proposition 65 Scheme
- Recent Settlements
  - ***Center for Environmental Health v. Lulu***
    - Lead in Fashion Accessories
      - Approved June 2010
  - ***Held v. Aldo / Moore v. Kate Spade***
    - Phthalates in PVC, vinyl or synthetic leather
    - Approved October 2010, amended March 2011

# Scope of Proposition 65

- Applies only to goods sold in California
- Applies to all businesses with 10 or more employees
- Requires "clear and reasonable warnings" of chemicals that cause cancer or reproductive harm
- Does not "ban" any substances or products
- Warning requirements are not preempted by federal law, including the CPSIA, FHSA or FIFRA
- Warnings often incorporated into MSDSs

# Proposition 65 in Operation

1. State OEHHA publishes a list of chemicals "known to the State of California to cause ***cancer, birth defects, or other reproductive harm.***"
2. Companies subject to Prop 65 may not "expose" people to any chemical on the lists without providing ***clear and reasonable warnings.***
3. Regulations state "safe harbor" language.
4. Companies must determine whether warnings are necessary.

# What is "Safe?"

**For Cancer**

- **"No significant risk"** ("NSR"), assuming lifetime exposure at the level in question

**For Reproductive Toxicity**

- **"No observable effect"** ("NOE"), assuming exposure at one thousand (1,000) times the level in question

# The Latest Warnings:

**WARNING**

**This Facility Contains Chemicals Known To The State Of California To Cause Cancer And Birth Defects Or Other Reproductive Harm.**

**WARNING**

Drilling, sawing, sanding or machining wood products generates wood dust, a substance known to the State of California to cause cancer. Avoid inhaling wood dust or use a dust mask or other safeguards for personal protection.

**CALIFORNIA HEALTH AND SAFETY CODE SECTION 25249.6**

# Your "Choice"

- Comply by giving warnings, or
- Non-compliance risks:
  - Lawsuits from public and private enforcers
    - $2,500 per day penalty, per violation
    - Restitution, plaintiff attorneys' fees and costs, and expert fees
    - Injunctive relief for formulation and warnings

# The Enforcers

- State Attorney General
- County District Attorneys
- City Attorneys
- "Citizen Enforcers," aka Bounty Hunters

# The Enforcement Process

- 60-day Notice to company, Attorney General, and district attorneys
- Certificate of Merit
- Suit filed, discovery conducted
- Expert analysis of exposures and effects
- Burdens of proof reversed
  - Plaintiff need not prove actual exposure or harm
  - Defendant must prove absence of risk or exposure below "safe" levels
- Settlement by consent decree
- Trial and Appeal

# Elements of a Settlement

- Public Record
- Formulation limits on specified chemicals in covered products
- Specific warning requirements
- $$ to State of California
- $$ to private enforcers
- $$ to a "non-profit"
- $$ to private attorneys
- Possible criminal fines
- Possible opt-ins

# Recent Settlements

- ***Center for Environmental Health v. Lulu***
  - Lead in fashion accessories
  - Alameda County Superior Court
  - Approved June 2010

- ***Held v. Aldo / Moore v. Kate Spade***
  - Phthalates in PVC, vinyl or synthetic leather
  - San Francisco County Superior Court
  - Approved October 2010, amended March 2011

# Lulu Settlement – Lead

- Lead in wallets, handbags, purses, clutches, totes, belts, and footwear
- Manufacturers, importers, distributors & retailers
- Section 2.6: "***The Parties intend this Consent Judgment to set new industry-wide standards*** *for lead in various components of Fashion Accessories that are feasible for manufacturers, importers, distributors, and retailers to implement, and that comply with Proposition 65."*

# Lulu Formulation Requirements

- Paint & Surface Coatings: 90 ppm lead in accessible paint, and other surface coatings on accessible components by 12/1/2010
- Leather: 600 ppm lead in accessible leather components by 12/1/2010; 300 ppm by 12/1/2011
- PVC: 300 ppm lead in accessible PVC by 12/1/2010; 200 ppm by 12/1/2011
- Most other Components: 300 ppm lead by 12/1/2010

# Lulu Compliance Phase-In

- Applies only to "accessible components"
- Formulation limits apply to purchasers, importers, manufacturers, and suppliers as of stated dates
- Retailers have one year from purchase, import, manufacture, and supply deadlines to eliminate non-compliant stock
- Retailers may use warnings on pre-12/1/2010 goods until 12/1/2011
- Belts and footwear compliance dates extended one year, except as to lead paint

# Lulu Enforcement

- Judgment applies only to settling parties
- Base settlement payment $32,500 with various add-ons
- Non-parties may
  - Opt-in, pay money and get release
  - Comply with formulation requirements
  - Use Warnings
  - Any combination of above

# Aldo Settlement – Phthalates

- Broader Scope than Lulu
  - (i) Wallets and other coin or bill holders; (ii) handbags, purses, clutches, and totes; (iii) belts; (iv) footwear; (v) apparel including gloves and headwear (and excluding sauna suits); (vi) jewelry; (vii) key holders, key chains, and key caps; (viii) luggage tags and ID cases; (ix) bag charms and zipper pulls; (x) eyeglass cases; (xi) coverings/cases for mobile electronic devices (e.g., for telephones, cameras, MP3 players, CDs/DVDs, and laptops); (xii) coverings for journal/address books; (xiii) cosmetic cases/bags; and (xiv) toiletry cases/bags.
- Excludes products primarily for 12 & under

# Aldo – A New "Industry Standard"

- Section 1.5 "*The Parties intend for this Consent Judgment to set an industry-wide 3P Standard* … of Fashion Accessories that manufacturers, importers, distributors, and retailers will implement following the time schedule set forth herein, and which will obviate the need for Proposition 65 warnings …" with regard to such Fashion Accessories.

# Covered 3P Phthalates

- DEHP, BBP &DBP – plasticizers that make PVC and other "plastics" soft and pliable (vinyl, synthetic leather)
- Alleged to cause reproductive harm, but before being banned in EU and U.S., EU regulators and CPSC declined to regulate it
- But there are 5 phthalates on the Prop 65 list (BBP, DBP, DEHP, DIDP and DnHP)
- DnHP is not regulated by the CPSC
- DINP and DNOP are regulated by CPSC, but are not on the Prop 65 list

# Aldo Requirements

- 1,000 ppm: DEHP, BBP and DBP
- Accessible components only
- No warnings alternative offered

- May not purchase, import, manufacture or supply after 12/15/2011
- May pay more $$$ to extend this deadline

# Aldo Instructions to Vendors

- Must provide 3P Standard to vendors and instruct each vendor to use reasonable efforts to provide Fashion Accessories that comply with the 3P Standard

- Must not "employ statements that will encourage a vendor to delay compliance with the 3P Standard"

# Aldo Enforcement

- $43,000 base payment, but actual payments can vary
- Opt-in window was closed, but then re-opened and extended to November 1, 2011
- Post-judgment enforcement procedures involve notice and additional payments

# What Should You Do?

- Identify your at-risk products
- Meet settlement formulation levels
- Carefully select and educate your suppliers
  - Specifications
    - Raw material controls
    - Warranties
    - Indemnities
    - Test Certificates (merge into COC's)
- Label products accordingly

# Retailers

- Act like a manufacturer or importer
- Post warnings
  - General store warnings
  - Consent decree warnings may be specific
  - On-product or on-shelf warnings
  - Online and catalog warnings

# California

## "Green Chemistry"

# What is "Green Chemistry"?

- Regulatory scheme designed to be protective (over-protective?) of human and environmental health
- Design products and processes that reduce or eliminate the use or generation of "hazardous" chemicals
- Applies across life cycle, including the design, manufacture, use and disposal of consumer products
- Approach to pollution prevention because it applies "scientific solutions" to real-world environmental situations

# Should Businesses Worry?

» "Applies to products sold, offered for sale, manufactured, imported, marketed or distributed in California"

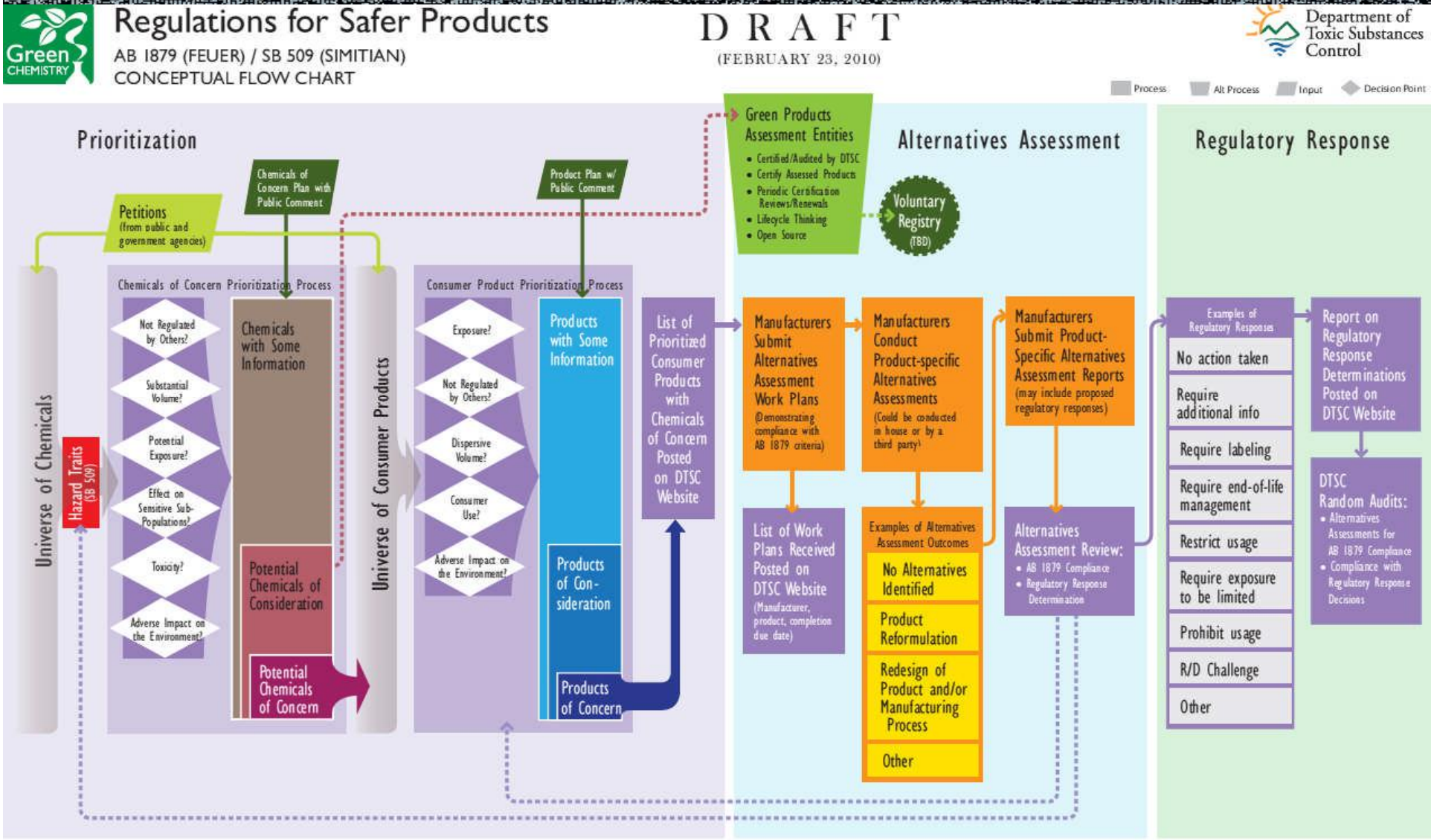
» "One in every eight U.S. consumers lives in California. "[S]o we're going to use our power as a big state, as a major consuming entity, to drive the design market"

» Effective Date: Was January 1, 2011 -- **POSTPONED**

– December 31, 2012 – date Priority Products identified for
  • children's products,
  • personal care products,
  • household cleaning products

– January 1, 2016 – date Priority Products could be identified for other products

# How Does It Work? – 1st and 2nd Draft Regs



# How Does It Work? – 3rd Draft Regs

- Step 1: Chemicals of Concern List (12-31-11)
- Step 2: Priority Products List (12-31-12)

Anyone may petition to evaluate a product that is, or that contains, a chemical for inclusion in the prioritization process.

**But** . . .

There is no formal process to petition for removal of a chemical or product from the lists

- Step 3: Alternative Assessment Plans and Reports (no deadline set)
- Step 4: Regulatory Response
  - None
  - Labeling
  - End-of-Life Management
  - Restrict Usage
  - Restrict Exposure
  - **Prohibit Sale**

# And If Businesses Don't Cooperate?

» Failure to Comply List – responsible entity failed to comply with one or more requirements for a specified chemical or product

» Failure to Respond List – manufacturer or entity acting on its behalf did not respond to request for information

# How will Hazardous Chemicals be Defined in California?

» Office of Environmental Health Hazard Assessment (OEHHA)

- Mission: "Protect and enhance public health and the environment by scientific evaluation of risks posed by hazardous substances."
- Current Regulatory Proposal: "Green Chemistry Toxics Information Clearinghouse Identification of Hazard Traits, Endpoints and Other Relevant Data for Inclusion in the Toxics Information Clearinghouse"

» What do businesses think of OEHHA's Regulatory Proposal?

- ACC: "[T]he Proposed Regulation is both unnecessarily resource-intensive in terms of creation and implementation"
- GMA: "The proposed establishment of a unique to California system of hazard trait nomenclature will substantially increase the difficulty, cost and time of populating and deploying the Toxics Information Clearinghouse."
- RMA: "[T]he proposed hazard traits approach was inappropriate, not supported by sound[] science, inconsistent with general principles of administrative law, and arbitrary and capricious."

# Not Just California

Already Enacted Similar Legislation

- » Connecticut
- » Maine
- » Michigan
- » Minnesota
- » Washington

2011 - 30 States Announce Upcoming Bills to Protect Kids/Families from Toxic Chemicals, including:

- » Ban BPA in certain products
- » Ban hazardous flame retardants in consumer products
- » Ban cadmium in children's products
- » Ensure safety of chemicals in children's products
- » Calls for the federal government to reform Toxic Substances Control Act (TSCA)

# EPA and Green Chemistry?

» EPA to Identify Priority Chemicals

- Getting information needed to understand chemical risks
- Increasing public access to information about chemicals
- Targeting priority chemicals for action – EPA has released 10 chemical action plans that outline a range of risk management activities
- Regulatory and other risk management activities

» EPA Region 1 - New England Green Chemistry Challenge:

The overarching goal/mission for the New England Green Chemistry Challenge is to broaden the understanding and adoption of green chemistry practices and principles in business, education, government, health care, and society as a catalyst to grow a sustainable economy in New England and beyond

http://www.epa.gov/region1/greenchemistry/index.html

» EPA Upgrades "Enforcement and Compliance History Online (ECHO)" database

# Understanding the New EU Chemical Substances Legislation: REACH

# Agenda

- REACH - The Basics
- Why is it needed?
- Registration
- What are the deadlines?
- Evaluation
- Authorization
- What's excluded?
- Industry Responsibilities
- Downstream Users
- Protecting Confidential Business Information
- REACH Guidance Documents
- Divisions of Responsibility
- Comparing Previous System and REACH
- International Chemical Safety Initiatives
- The CLP Regulation

# REACH: The Basics

- Came into effect June 1, 2007
- Establishes integrated system for Registration, Evaluation, Authorization of CHemical substances.
- Ensures gaps in existing information on hazardous properties of approximately 30,000 chemical substances are filled
- Ensures necessary information on safe use of chemical substances transmits along industrial supply chain to reduce risks for workers, consumers, and environment.
- Reverses burden of proof so that producers and importers of chemical substances, rather than public authorities, must demonstrate that chemical substances can be used safely.

# REACH: Why is it needed?

- Pre-REACH legislation distinguished between "existing" and "new" chemical substances
  - All chemical substances put on market before 1981 were called "existing chemicals" (amounting to around 100,000)
  - Chemical substances introduced after 1981 were termed "new" chemicals (amounting to around 4300)
- Under pre-REACH legislation, new chemicals had to be notified and tested in production volumes as low as 10kg per year
  - Volumes above 1 ton per year required extensive testing: stifling research, development and innovation and encouraging continued use of existing untested chemical substances

# REACH: Registration

» Manufacturers and importers required to register with central database all chemical substances which they produce or import in EU in volumes of 1 ton or more per year (around 30,000 marketed chemical substances) + registration of substances contained in Articles

» New independent European Chemicals Agency ("ECHA") based in Helsinki, Finland receives dossiers and manages registration of chemical substances through a database

» Registration involves providing chemical safety report (volumes > 10 t/y) and technical dossier with information on:
  – intrinsic properties and hazards of each chemical substance (*i.e.*, physicochemical, toxicological, eco-toxicological properties)
  – use of chemical substance identified by importer or manufacturer or by their customers

» Failure to register where necessary means chemical substance **cannot be manufactured in or imported to** EU market

# REACH: What are the deadlines?

» Chemical substances already on the market phased-in gradually:
» First obligation: pre-registration: took place from June 1, 2008 to November 30, 2008 – still possible in certain circumstances under section 28(6)
» Applied to "phase-in substances", *i.e.*:
  - chemical substances listed in EINECS list;
  - chemical substances manufactured in EU but not placed on EU market in last 15 years; or
  - so-called "no-longer" polymers placed on market in one of current EU-member States before REACH came into effect.

» Registration deadlines depend on volume of chemical substance on the market or hazard
  – 1 December 2010 for high production volume chemical substances (1,000+ tons per year per manufacturer or importer), CMRs (in volumes of 1+ ton), and chemical substances classified as very toxic to aquatic organisms (in volumes of 100+ tons);
  – 1 June 2013 for production volumes in range of 100 – 1000 tons;
  – 1 June 2018 for low production volume chemical substances (1 – 100 tons).
» Chemical substances which are not already on the market need to be registered before they are placed on the market
  – Registration started June 1, 2008

# REACH: Evaluation

- Evaluation provides a means for the authorities to require registrants to provide further information
- Two types of evaluation
  - Dossier evaluations
    - ECHA will perform compliance check on registration dossier and check for proposals for animal testing
  - Substance evaluations
    - Performed where ECHA or EU Member State competent authority has reason to believe that chemical substance may present a risk to human health or environment

# REACH: Authorization

- All chemical substances of very high concern will be subject to authorization
  - CMRs (carcinogenic, mutagenic or toxic to reproduction)
  - PBTs (persistent, bio-accumulative and toxic)
  - vPvBs (very persistent, very bio-accumulative)
  - Chemical substances identified as having serious and irreversible effects to humans and environment equivalent to other three categories, *e.g.*, certain endocrine disrupting substances
- Granted only if producer or importer can show
  - Risks from use in question can be adequately controlled, or
  - Socio-economic benefits of using chemical substance outweigh risks and suitable alternative chemical substances do not exist
- EU Commission able to introduce restrictions at EU level for any chemical substance that poses unacceptable risks
  - Restrictions include: banning uses in certain products, banning uses by consumers or even complete bans

# REACH: What's excluded?

» Intermediates which are non-isolated are fully exempt
  – Intermediates = chemicals used to make other chemical substances
  – Non-isolated = not separated from mixture of other chemicals inside chemical system
» Isolated intermediates must be registered, but with simplified information requirements

» Polymers exempt from registration and evaluation
  – Polymers = large molecules consisting of repeated chemical units (monomers) joined together, *e.g.*, plastics
» Chemical substances occurring in nature
  – such as minerals, ores and ore concentrates which are not chemically modified
» Basic elemental substances of low risk such as noble gases

# REACH: Industry Responsibilities

» Manufacturers and importers of chemical substances will
  - supply data on properties of their chemical substances to ECHA
  - prepare Chemical Safety Reports (production volumes >10t/y)
  - implement risk management measures
  - supply safety information to downstream users and distributors who will need to pass safety information onto customers

» Substance Information Exchange Fora ("SIEFS") or "consortia" may need to be formed by companies with the same interests in the same chemical substances for registration purposes

# REACH: Downstream Users

- Provide information to assist in preparation of registration e.g finance the testing etc for preparation of registration dossier to ensure that critical substance is registered
- Make use known to supplier to make this identified use in registration dossier;
- Prepare Chemical Safety Reports for uses outside conditions described in exposure scenario (where use >1 ton)
- Apply risk management measures for chemical substances identified on Safety Data Sheets and Chemical Safety Reports;
- Report certain information to ECHA before commencing or continuing with particular use of chemical substance registered by actor up supply chain.

# Protecting Confidential Business Information

- Appointment of third party representative at pre-registration to keep identity secret towards other potential registrants
- Use of confidentiality agreement to specify that information shared within consortium is used solely for the consortium
- Use of independent third party to make judgment as to suitability of document for supporting registration of other consortium members
- Use of opt-out to submit certain information to ECHA separately from consortium
- Provision of justification to ECHA as to why information contained in registration be kept confidential
- Listing of chemical substance under Annex IV

# REACH Guidance Documents

- ECHA develops detailed Guidance Documents and specific IT tools to make transition to new system as easy as possible
- IT tool for submitting on-line registrations is IUCLID5
- ECHA maintains a website http://guidance.echa.europa.eu/guidance_en.htm which details status of Guidance Documents

# REACH: Divisions of Responsibility

| | Industry | Agency | Member States Authorities | European Commission |
|---|---|---|---|---|
| Registration | Collects and submits data.<br>Assesses risks and identifies risk management measures.<br>Keeps registrations updated. Proposes testing schemes. | Receives registration dossiers.<br>Checks them for completeness. Maintains the database and provides information to the public. | Enforcement. | |
| Evaluation | Provides further information if required. | Coordinates work of the member state authorities, develops evaluation criteria, takes decisions on requesting more information from industry if member states agree. | Review individual dossiers.<br>Prepare, carry out rolling substance evaluations plans.<br>Prepare draft decisions on further information requirements. | Takes decision on requesting more information from industry if member states don't all agree |

# Divisions of Responsibility

(Continued)

| | Industry | Agency | Member States' Authorities | European Commission |
|---|---|---|---|---|
| Authorization | Submits application dossier | Publishes application on its website. Recommends priorities. Committees draft opinions. Supports Commission in decision-making. | Submit proposals for chemical substances considered to pose serious irreversible effects equivalent to CMRs, PBTs and vPvBs | Takes decisions on priority setting (step 1) and on granting authorizations (step 2) |
| Restriction | Provides socio-economic assessments . | Provides opinions and comments. Publishes the member state restriction proposals and its Committee's draft opinions on Internet. | Submit proposals | Takes decisions on restrictions of production, marketing and use. |

# Comparing Previous System and REACH

| | Previous System | REACH |
|---|---|---|
| Notification Requirements | Requirements for new chemicals started at production level of 10 kg. Already at this level, one animal test was needed. At 1 ton, a series of tests including other animal tests had to be undertaken. | Registration will be required when production/import reaches 1 ton. As far as possible, animal testing will be minimized. |
| Innovation and Costs | It was relatively costly to introduce a new chemical substance on the market. This encouraged the continued use of "existing", untested chemical substances and inhibited innovation. | Innovation of safer chemical substances will be encouraged under REACH through: more exemptions for R&D; lower registration costs for new chemical substances; and the need to consider substitute chemical substances for decisions on authorization and restrictions. |
| Responsibility of Risk Assessment | Public authorities were obliged to perform comprehensive risk assessments that were slow and cumbersome. | Industry will be responsible for assessing the safety of identified uses, prior to production and marketing. Authorities will be able to focus on issues of serious concern. |

# Previous System and REACH

(Continued)

| | Previous System | REACH |
|---|---|---|
| Knowledge Gaps | There are gaps in our knowledge about many of the chemical substances on the EU market. | REACH will close the knowledge gaps by providing safety information about chemical substances produced or imported in volumes larger than 1 ton/year per manufacturer/importer. |
| Burden of proof | The burden of proof was on the authorities: they needed to prove that the use of a chemical substance was unsafe before they could impose restrictions. | The burden of proof will be on industry. It has to be able to demonstrate that the chemical substance can be used safely and how. All actors in the supply chain will be obliged to ensure the safety of the chemical substances they handle. |

# International Chemical Safety Initiatives

» United Nations Environment Program
  - World Summit on Sustainable Development in Johannesburg in September 2002 agreed by 2020 chemical substances should be used and produced to minimize significant adverse effects on human health and environment
» OECD co-operative action program for testing and assessing High Production Volume Chemicals
» Rotterdam Convention 1998 on Prior Informed Consent regulating trade in certain dangerous substances
» Stockholm Convention on Persistent Organic Pollutants ("POPs")
  – Aims to control production, use, import, export, disposal and release of 12 POPs
» European Commission
  – Participates in UN negotiations on a Global Harmonized System for classification and labeling of chemical substances – EU CLP Regulation 1272/2008
  – Participates in Intergovernmental Forum on Chemicals Safety which promotes chemical risk assessment and environmentally sound chemical substance management

# CLP Regulation 1272/2008

- Manufacturer's and importers had to report certain substances to the C&L Inventory by January 3, 2011 including:
  - Substances subject to registration under REACH and placed on the market;
  - Substances classified as hazardous under the CLP Regulation and placed on the market, irrespective of the tonnage band; and
  - Substances classified as hazardous under the CLP Regulation and present in a mixture above certain concentration limits, which results in the classification of the mixture as hazardous, and where the mixture is placed on the market.

# CLP Regulation 1272/2008

» Obligation to classify, label and package substances

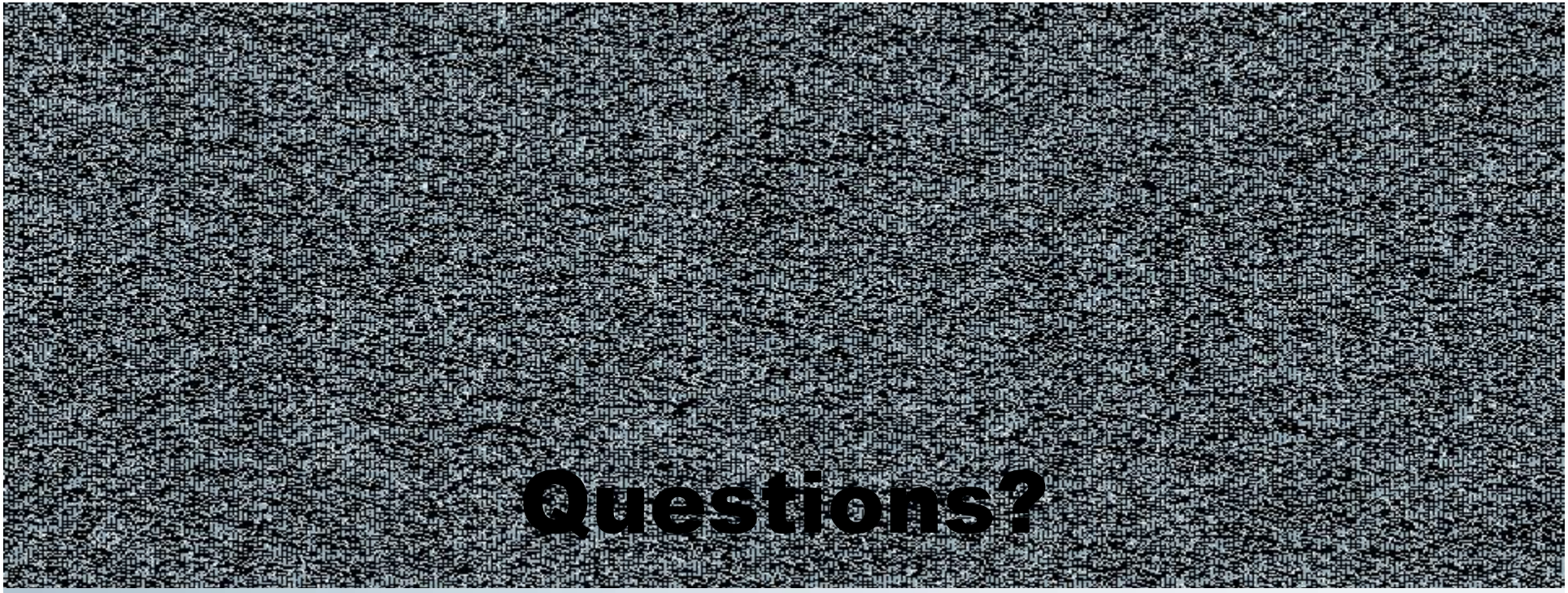
– Since December 1, 2010, substances must be classified using the provisions of the CLP Regulation

Until June 1, 2015, a classification under the DSD Directive must also be provided alongside any CLP Regulation classification.

– Since December 1, 2010, substances must be labeled and packaged in accordance with the CLP Regulation only.

– From June 1, 2015, mixtures must be classified, labeled and packaged using the provisions of the CLP Regulation only.

Prior to June 1, 2015, mixtures must continue to be classified, labeled and packaged in accordance with the DPD Directive. However, mixtures may also be classified, labeled and packaged in line with the CLP Regulation before that date in which case the provisions regarding labeling and packaging within the DPD Directive will not apply.


Questions?

crowell moring

**Product Risk Management Seminar**

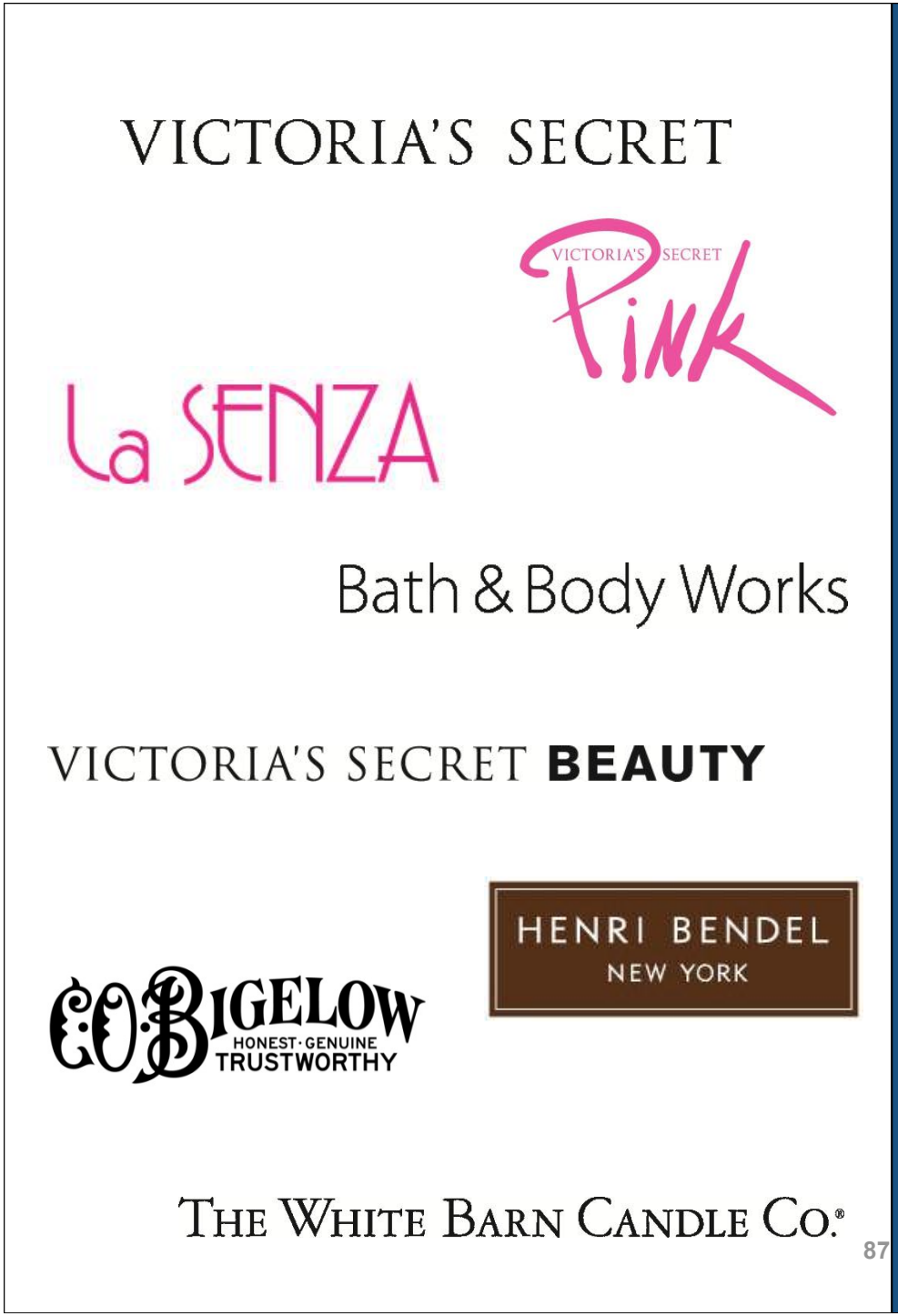
October 19, 2011
Washington, DC

# CUSTOMS AND TRADE

## *The Price of Admission: Managing the New Import Regulation Model and Avoiding Pitfalls at the Border*

**Panelists**

- *Moderator*: Laurent Ruessmann, Crowell & Moring
- Leigh A. Schmid, Senior Vice President, Global Trade Compliance, Limited Brands
- Alex Schaefer, Crowell & Moring




**Product Risk Management Seminar | Oct. 19, 2011**


**Leigh A. Schmid**
**Senior Vice President**

**Limited Brands**

**Global Trade Compliance**

# Customs Enforcement

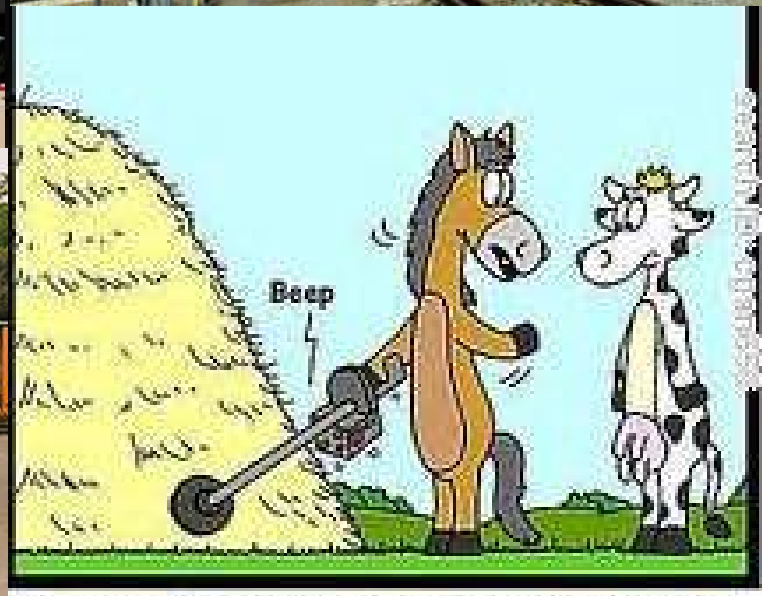
»Finding contraband is like "looking for a needle in a haystack"

- Trade Statistics demonstrate the challenge
  - $2 Trillion of imports in 2010
  - 28.3 Million entries filed
  - Average duty rate on goods entered 1.2%
  - Truck: 42%; Air: 28%; Ocean: 25%; Rail: 4%: Other: 1%

- CBP is looking for ways to address the challenge of finding the "bad guys"
- Solutions:
  1. Technology
  2. Shrink the Haystack

# Customs Enforcement

- Technology Solutions:
  1. Non-Intrusive Inspections
  2. Electronic Surveillance
  3. Data Screening

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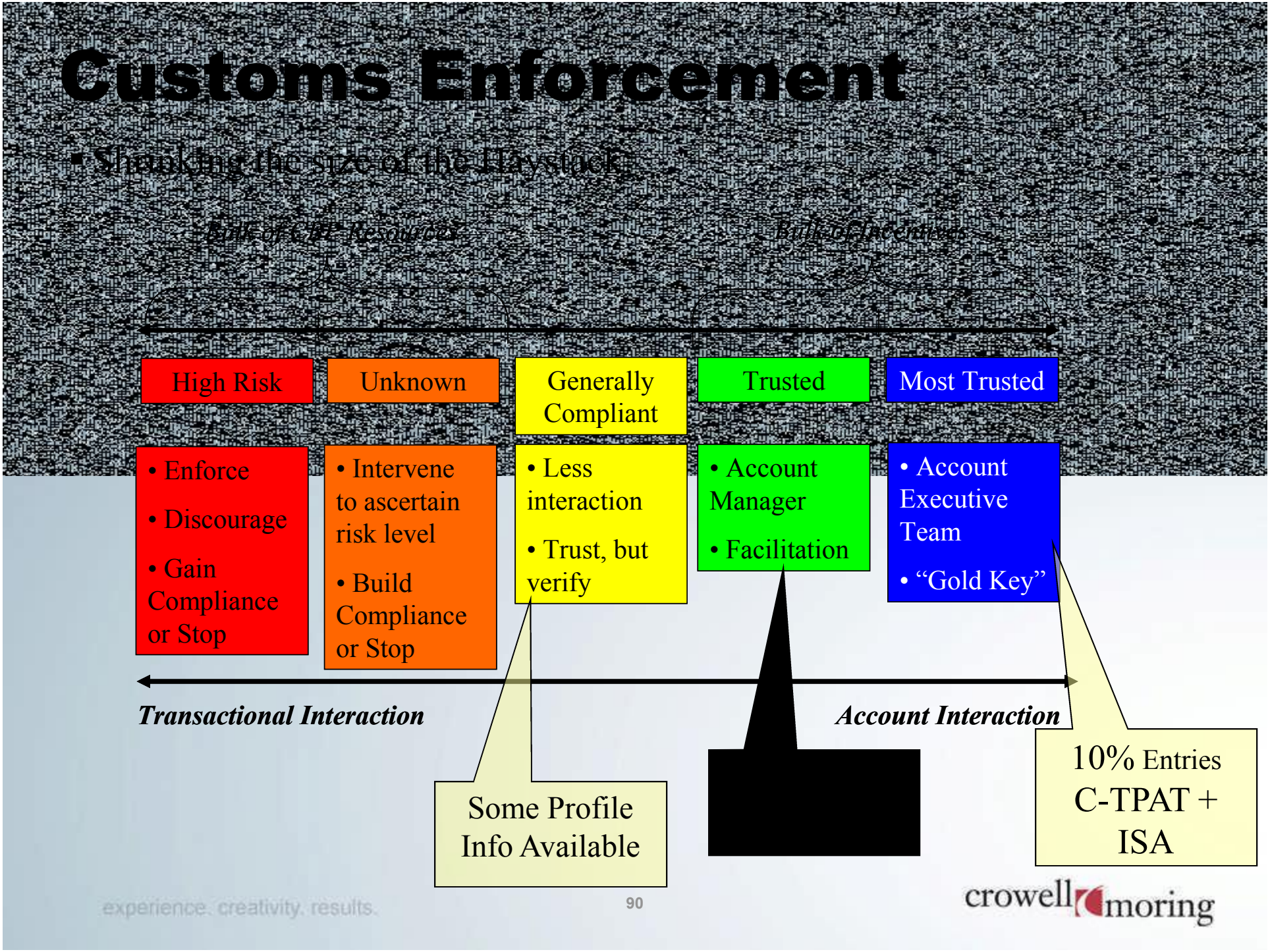
# Customs Enforcement

- Shrinking the size of the Haystack



# Account Executive Functions

» Serve as a central point of contact for trade partners in the industry sector

» Create an engagement plan with trusted partner to gauge compliance while minimizing touch points

» Described as a "National Account Manager on steroids"

» Leon Hayward, Assistant Director, Field Ops, Trade and Cargo Security in NYC is the pilot Account Executive for the electronics industry

» Pilot started Nov. 1, 2010

# Center of Excellence & Expertise

Exploration of a Center of Excellence & Expertise (CEE) concept of operation was initiated by the COAC.

Goal of this industry-focused sub-organization will interweave "Management By Account" throughout its operational and decision-making processes.

- promote trade collaboration to achieve greater transparency;
- recognize trusted partner commitments; and
- embrace the overall trade strategy

CBP will consolidate industry expertise to provide uniform treatment in the application of the law, regulations, processes, and procedures, and manage risk

# Risk-Based Account Management

» Engage and manage entities regardless of size, value or volume

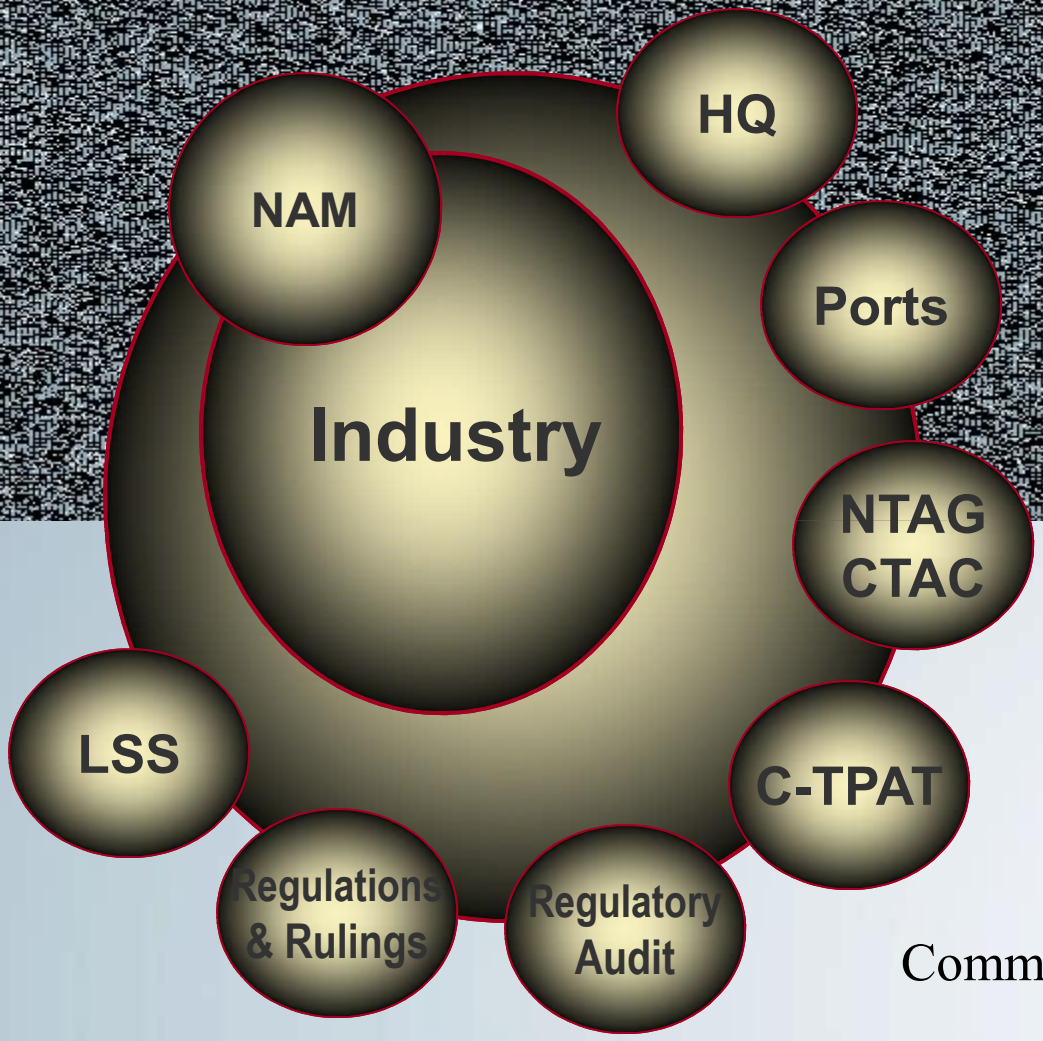
» Collect and analyze information to identify areas of risk

» Lead activities and develop comprehensive strategies to manage risk

» Initiate and carry out compliance and enforcement actions

» Track and report performance results

# Collaboration




National Account Managers
Entry Specialists
Import Specialists
Program Managers
Paralegal Specialists
Drawback Specialists
Headquarters
CBP Officers
CBP Attorneys
Regulatory Auditors
National Import Specialists
International Trade Specialists
Supply Chain Security Specialists
National Targeting Analysis Group
Laboratories and Scientific Services
Commercial Targeting and Analysis Center

# CEE Pilot

- Pilot to develop comprehensive strategies to facilitate trade and manage risk in the pharmaceutical industry began on Nov. 1, 2010.
  - Anne Maracich, Asst. Port Director, Los Angeles International directs the pilot center.
  - Authority extends to advice and coordinating activities that impact port operations.

# Simplified Entry – A Collaboration

**Current environment**

» Entry, Summary, and financial requirements are misaligned with industry, resulting in a lack of uniformity, increased costs, and inefficient trade facilitation and enforcement

» Redundant paperwork requirements, archaic policies, procedures, and technology slow the trade process and cause unnecessary delays

» Current processes are stuck within old laws and regulations and differentiating between trusted and suspicious importers is difficult

**Proposed environment**

» A viable Simplified Entry, Summary, and Financial solution that is business- and CBP-friendly to streamline and remove administrative burdens

» 21st century, world-class trade environment that will free the U.S. from 18th century laws, regulations, and thinking that is no longer compatible with a global economy

» Facilitating trade of CBP's trusted partners, while focusing on importers of concern

# Proposed Model: Overview

**The Simplified Processes Workgroup is proposing a model that will:**

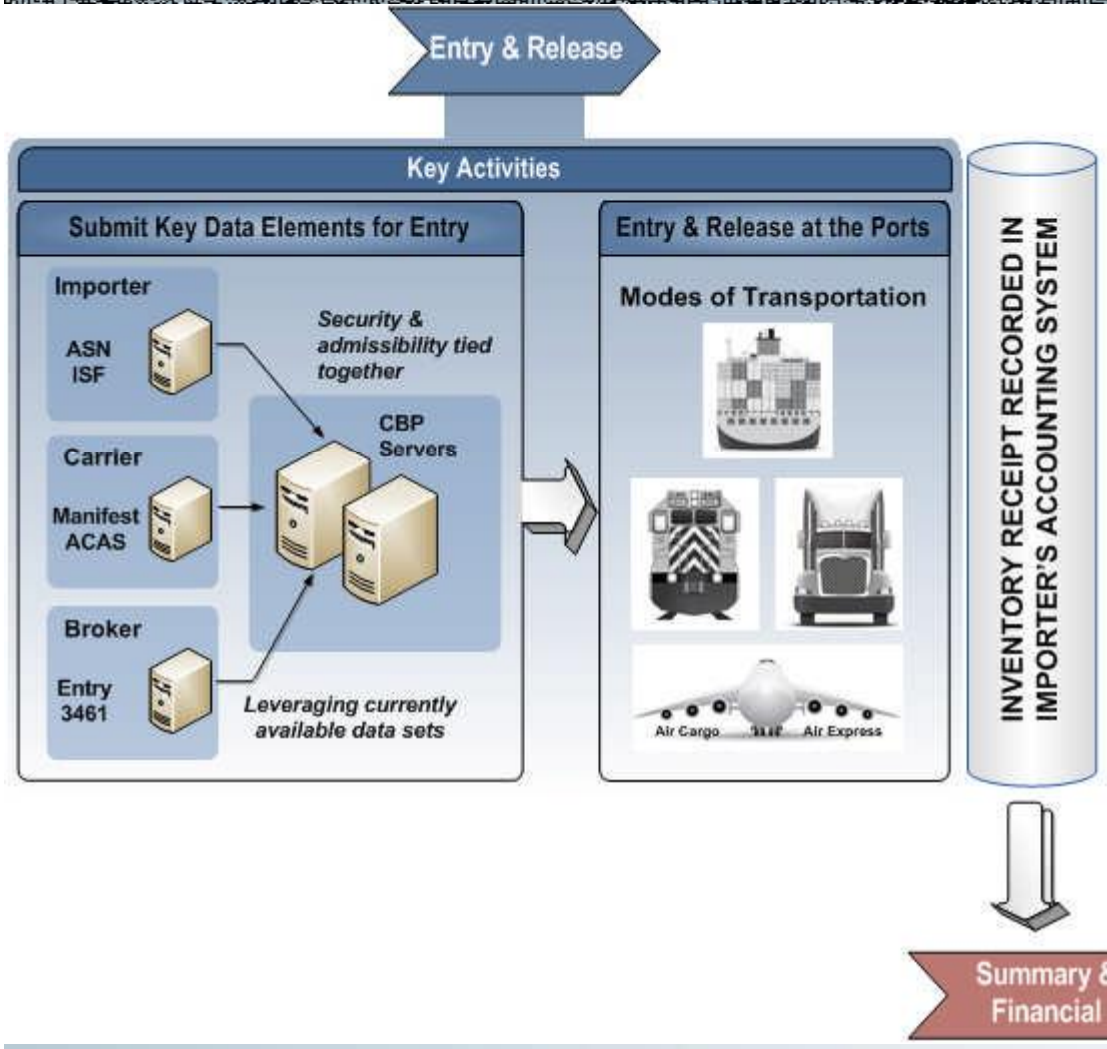
» Reduce filings involved in obtaining release for low risk companies

» Decrease release timeframes by satisfying CBP requirements and obtaining release preferably before arrival

» Align summary requirements with importer business models

» Link summary and financial submissions, expands the timeframe for submitting entry summary, and allow users to consolidate the payment of duties, taxes, and fees

# Proposed Model: Entry and Release



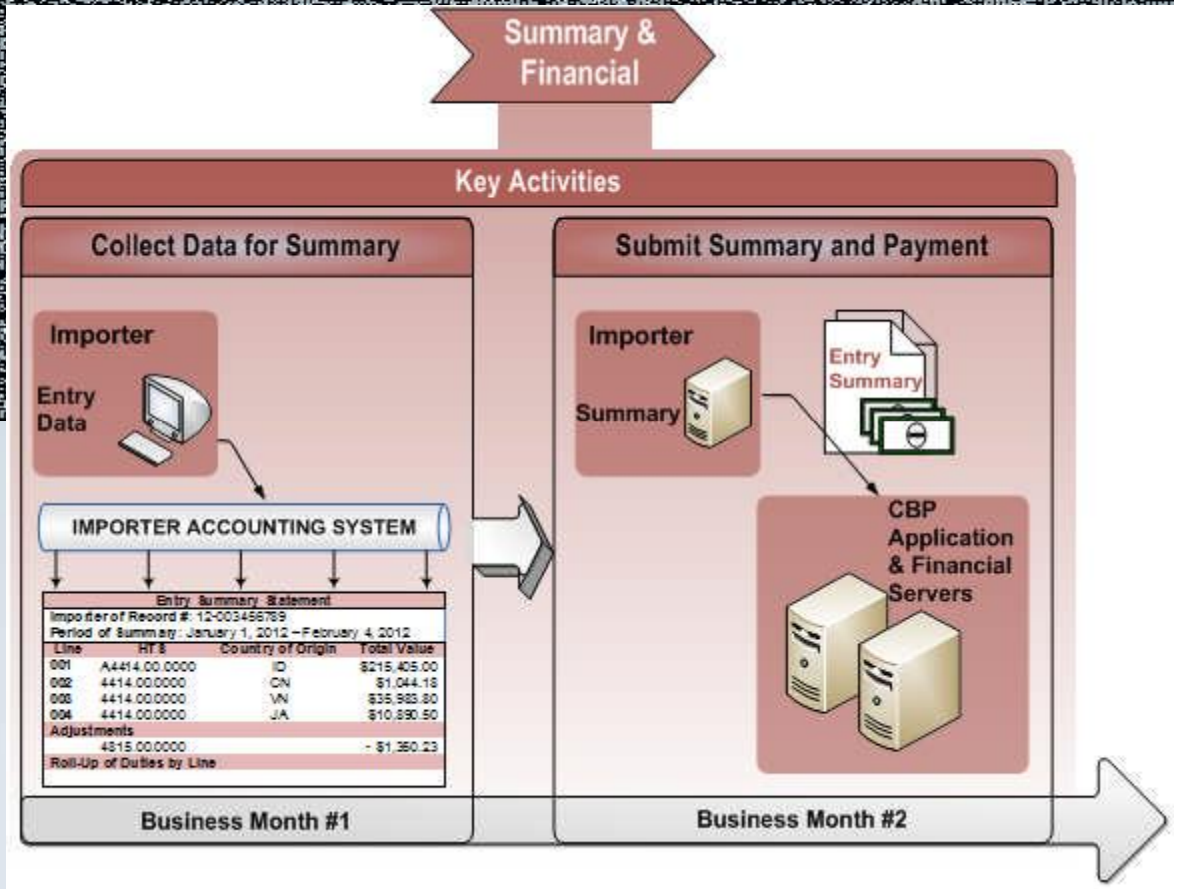

**Key Process Changes**

- » Admissibility is tied to 10-14 key data elements transmitted to CBP
- » Process can be mode-specific
- » Standardizes filing requirements across industries
- » Streamlines current CBP paperwork forms, as necessary, required for filing
- » Reduces entry data requirements to prevent duplication and repetition
- » CBP policies and business rules will be revised as necessary to accommodate changes

# Proposed Model: Summary & Financial

**Key Process Changes**

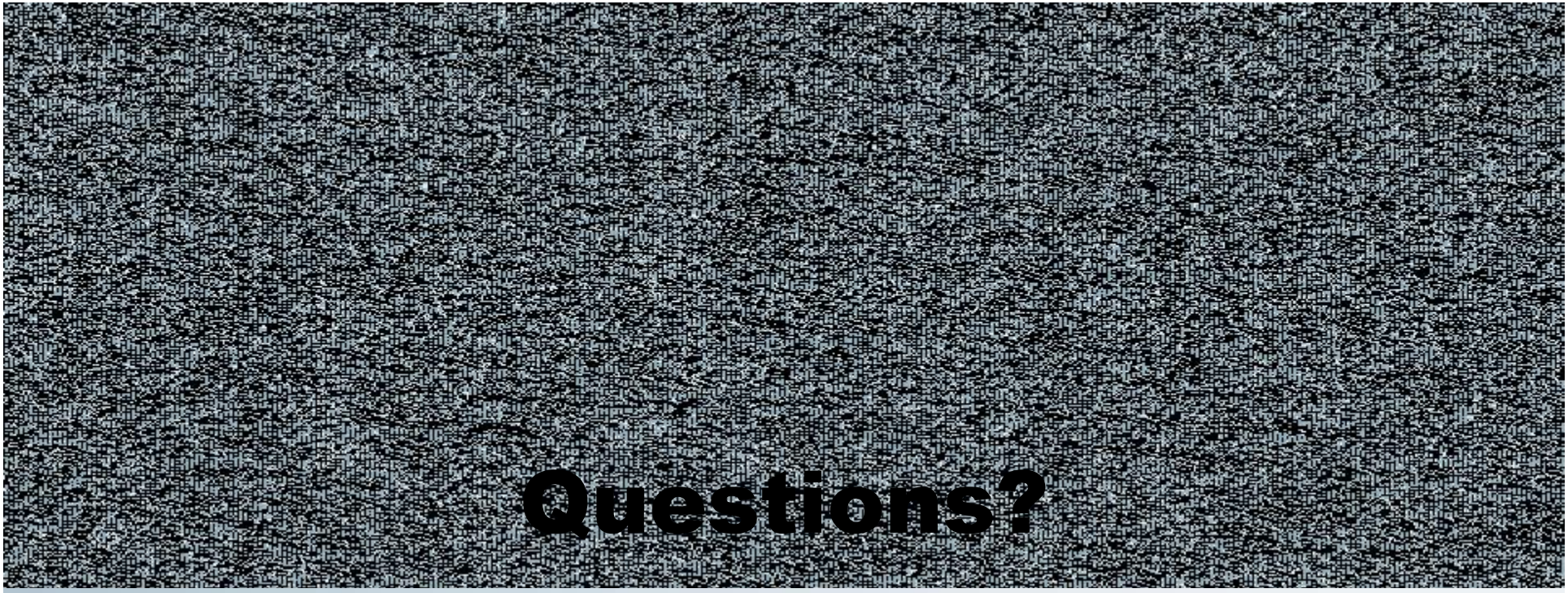
- » Free management by account
- » Summary and payment are linked and happen simultaneously
- » Entry summary and payment are no longer tied to release
- » Instead, process is specific to importer's business model and account practices
  - ➢ Importer will summarize all entries that hit inventory within its "business month" on one entry summary
  - ➢ Importer will have up to 30 days after close of that business month to make necessary amendments to entries, then file summary and financial at the same time



# Key Challenges and Considerations

| | Simplified Entry | Simplified Summary and Financial |
|---|---|---|
| **Key Considerations** | ✓ Linking security and admissibility to release of shipments<br>✓ De-linking release from summary<br>✓ Requiring only those data elements necessary to determine security and admissibility<br>✓ Efficiencies gained from both a CBP and industry perspective<br>✓ Compatibility with participating government agency models | ✓ Management by account<br>✓ Decoupling summary and financial requirements from release transactions<br>✓ Reducing repetitive data filings<br>✓ Aligning summary and financial submissions to importer business models<br>✓ Increasing accuracy of data submissions |
| **Key Challenges** | ✓ Qualifications for participation<br>✓ Required statutory and regulatory changes, including penalty regime<br>✓ Technology adjustments and enhancements<br>✓ Aligning participating government agency (PGAs) data requirements with streamlined entry and release<br>✓ Addressing non-standard or low value shipments<br>✓ Change management requirements across CBP and business | ✓ Qualifications for participation<br>✓ Required statutory and regulatory changes, including penalty regime<br>✓ Technology adjustments and enhancements<br>✓ Calculating interest payments<br>✓ Liquidation<br>✓ Merchandise Processing Fees |

U.S. Customs and Border Protection


Questions?

crowell moring

**Product Risk Management Seminar**

October 19, 2011
Washington, DC

# SOCIAL MEDIA AND ADVERTISING

## *Managing Your Reputation and Liability in the Age of Consumer Product Reviews, Astroturfing, and Blogger Endorsements*

**Panelists**

- *Moderators*: Dina Epstein and Lauren Patterson, Crowell & Moring
- Stacey Ferguson, Senior Attorney, Division of Advertising Practices, Federal Trade Commission
- Brian Falbo, Counsel, Product Group, Dell
- Bridget Calhoun, Crowell & Moring

# What We Will Cover

- Company-Directed Behavior
- Company-Linked Behavior
- Independent Behavior

# COMPANY-DIRECTED BEHAVIOR


## iTunes App Reviews

- "Amazing new game"
- "ONE of the BEST"
- "[*Game developer*] hits another home run with [*game being reviewed*]"
- "Really Cool Game"
- "GREAT, family-friendly board game app"
- "One of the best apps just got better" and
- "[*Developer of gaming application being reviewed*] does it again!"

# Reverb Communications, cont'd.

- PR/Marketing Company had employees pose as disinterested consumers to post public reviews endorsing clients' gaming applications ("astroturfing").

- FTC Complaint: Failure to disclose facts material to purchasing decision was a deceptive practice.

- Consent Decree: Company to remove posted endorsements, barred from future postings without disclosure of material connection.

# Legacy Learning

# Legacy Learning, cont'd.

- Company promoted guitar lesson courses via an online "review ad" affiliate program
- Affiliates received substantial commissions on the sale of each product resulting from referrals

- Complaint: Company represented that endorsements were made by independent reviewers or ordinary consumers and failed to disclose affiliate relationship
- $250,000 disgorgement

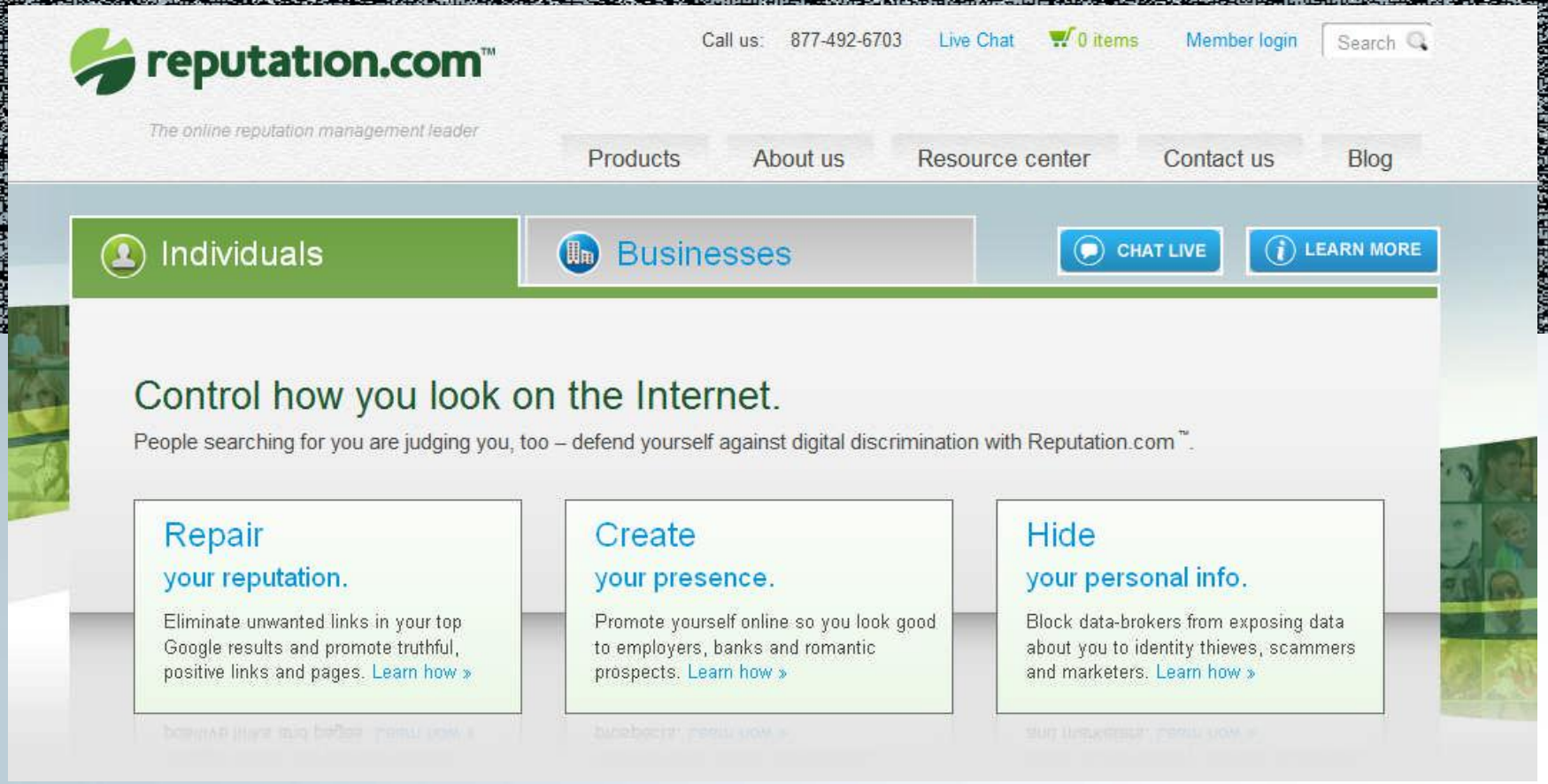
LEGACY LEARNING SYSTEMS

# Communications Decency Act

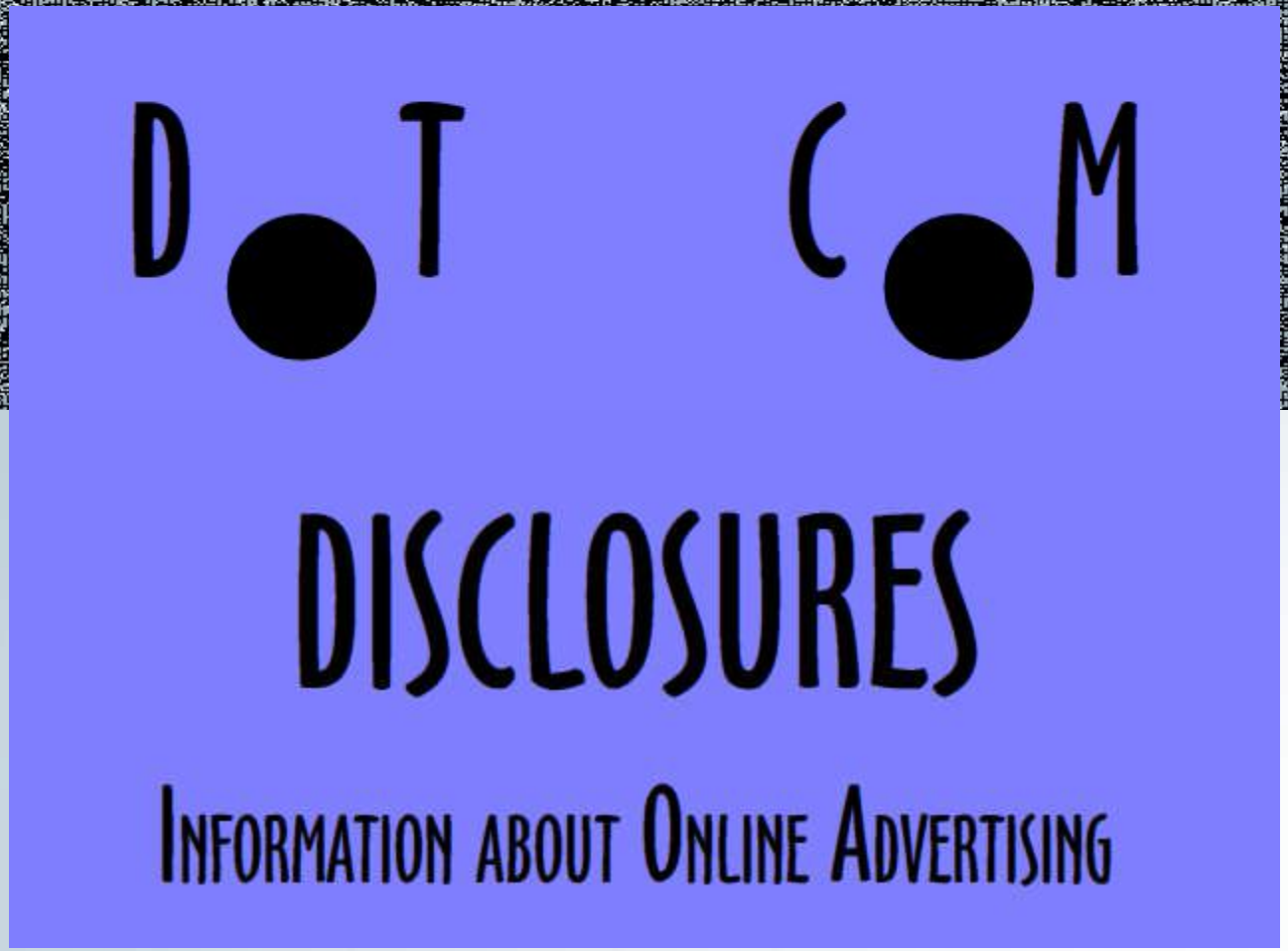
» 47 USC §230(c): No provider or user of "interactive computer service" shall be treated as the publisher or speaker of any information provided by another information content provider.

» Immunity for publication of user-generated content.

# Manipulating Search Results & Reputation Management

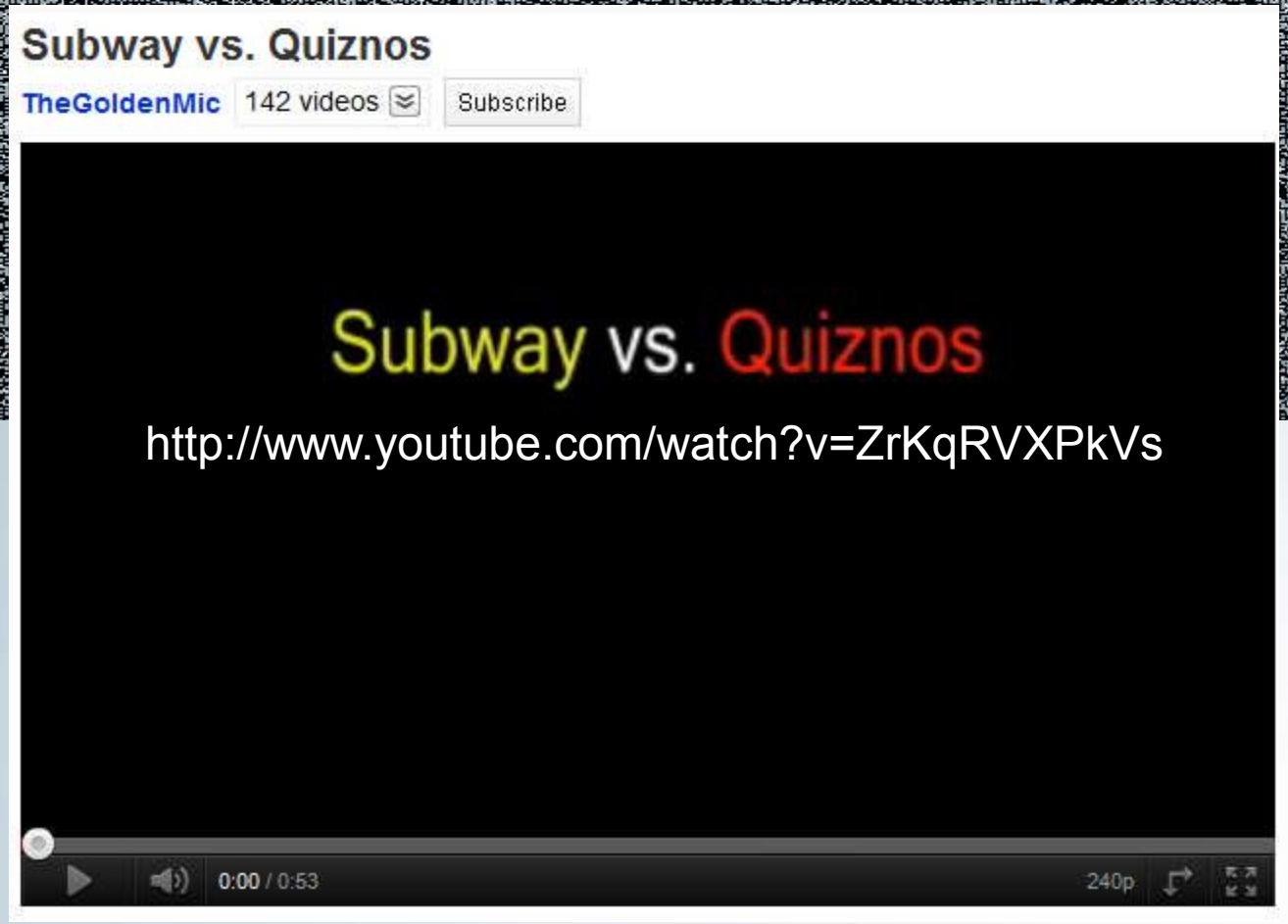


# Dot Com Disclosures



# COMPANY-LINKED BEHAVIOR

# Subway v. Quiznos



# FTC Closing Letter to Ann Taylor


"EXCLUSIVE BLOGGER PREVIEW"

THE INVITATION: **"Bloggers who attend will receive a special gift, and those who post coverage from the event will be entered in a mystery gift card drawing where you can win up to $500 at LOFT!"**

THE FINE PRINT: **"Please note all bloggers must post coverage from our event to their blog within 24 hours in order to be eligible. . . . Gift card amounts will vary from $10 to $500."**

# Company-sponsored blogs

FISKARS

fisk-a-teers

CRAFTING AMBASSADORS

CHERYL angela TAMI Rebecca

categories archives authors history

TAMI

## October Color Challenge

posted by: Tami posted in: Challenges, Color Challenge on: October 6, 2011

I've been feeling pulled in two directions for the color challenge this month. On the one hand, the leaves are turning, and the colors of fall foliage are beckoning. On the other hand it's Breast Cancer Awareness Mo in front of me. We have dogwood trees with leaves that turn a lovely shade of pink right next to the orange leaves of the oak trees. **Pink and Orange together!** If you were around last year, you may remember

As with all color challenges, please create something handmade just for this challenge. Post a photo in the gallery and link it back to this thread. I have a lovely pair of pink Breast Cancer Awareness Scissors and a along. The deadline for this challenge is October 31st at midnight PST. Can't wait to see your beautiful pink and orange projects.

BCA1.jpg

facebook

**Dell**

The upcoming XPS 14z is thin and powerful, especially when compared to the PC Convertible from 1986. An amusing comparison of technologies from different eras - let us know what you think in the comments: http://del.ly/6034RVIk

**Dell Slims Down with the XPS 14Z**

del.ly

In only 25 years technology has grown from the 1986 PC Convertible to the 2011 Dell XPS 14Z. Consider this, the PC Convertible weighed over 12 pounds and slightly smaller than a suitcase. Not exactly what our idea of portable is; the Convertible couldn't have been too stylish either. Fast forward...

Like · Comment · Share · 22 hours ago via Sprinklr

132 people like this.

**David Pat** The XPS 17 is the best laptop I have ever owned. High hopes for the 14

22 hours ago · Like · 1 person

**Maa'n Al Dirani** I want one :(

22 hours ago · Like

Tweets

**about 3 hours ago** Sorry, Zuck: Facebook pioneer Parker is on Twitter #cnn http://t.co/fxni2Id1 #Twitter

by DinapixStudio

**about 3 hours ago** A new social web order - @bsaren @bleland @JohnBStevens just off with @radian6 preparing LitleCo for new...

by LitleCo

**about 3 hours ago** RT @FullSocialMedia: Are You Blogging Just Like Everyone Else? http://t.co/F9NP2ckV - #social #media #sm

by WimgoPersuasion

**about 3 hours ago** Six Social Behavior Tenets to Make or Break Your Social Marketing ...: To see the six social behavior...

by Capital_direct

1 2 3 4 5

**Dell**

Like

Computers

# INDEPENDENT BEHAVIOR

# Reviews on Third-Party Sites

711 of 733 people found the following review helpful:

★★★★★ **Cuisinart DCC-1200 easily trumps Krups 180-46 Aroma Control**, December 1, 2001

By **Pawel Fludzinski** - See all my reviews

**Amazon Verified Purchase** (What's this?)

**This review is from: Cuisinart DCC-1200 Brew Central 12-Cup Programmable Coffeemaker, Black Stainless (Kitchen)**

Two weeks ago, I needed a new coffee maker. The Krups Aroma Control maker is in all the stores and catalogs, so I bought one in the local mall BEFORE reading the Amazon reviews. BIG MISTAKE. Lesson learned - read the reviews - many negative comments. I used it for 3 days, and readily understood the description (...) of "eye candy" (looks nice, but seems like cheap plastic) and weak coffee (what they describe as a feature - allowing the coffee to steep - is really a euphemism for a poorly designed system that is guaranteed to give you a weak cup of coffee). One redeeming feature - the carafe is very nice.
Within 2 days of having the Krups, i was on Amazon looking for a replacement coffee maker (a good cup of coffee is critical in the morning!). I went out on the risk curve and ordered the new Cuisinart - no reviews yet. The Cuisinart has a more classic brewing system (water goes through grinds via gravity), yields a delicious cup of HOT coffee, has a variable temperature hot place, and looks and feels solid. We happen to have stainless steel appliances (refrigerator, freezer, stove), and it matches beautifully. Best news - excellent coffee!. I would highly recommend the Cuisinart.

**Help other customers find the most helpful reviews**

Was this review helpful to you? Yes No

Report abuse | Permalink

Comments (3)

# Consumers Claims

## Reebok EasyTone Shoes: Better Butt or a Lotta Hype?

5 | 5 tweets | Share | retweet | Submit

POSTED BY KATHY ON 11/12/2009

TAGS: EASYTONE, MY REVIEWS, REEBOK / 5 COMMENTS AND 5 REACTIONS

14 | +1 0


P>The latest athletic shoe **'innovation'** to hit the mainstream market and media: **Reebok's EasyTone** shoe. The edgy commercial promises **'a better butt'** as well as more toned calves and thighs. At around **$100** a pair, you have to ask yourself: will these shoes buy me a better butt? Or is it just a whole lotta hype? **My analysis ahead...**

**The Claim:** "Get a better butt and legs with every step". Emulates walking on sand.

first time I've seen a mainstream brand like Reebok

## Pear Micro Laptop!

- Consumers apply to install a webcam in their house for 4 weeks and record their use of and musings about Pear's new micro laptop.
- Consumer video clips are streamed live on Pear's website.
- Company officials do not tell the consumers what message they want to convey or otherwise influence the consumers'

The *new* Pear Micro Laptop

# Questions?

crowell moring

**Product Risk Management Seminar**

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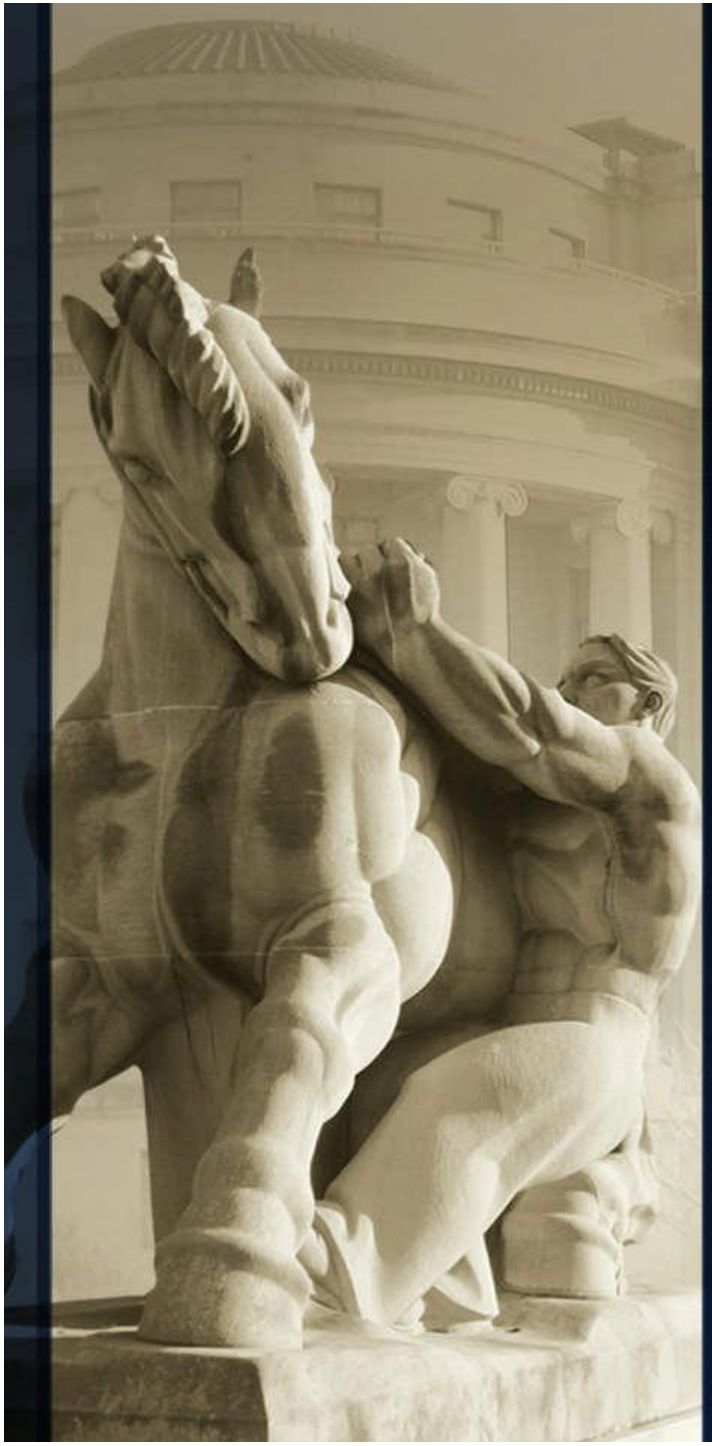
# ANTITRUST DISTRIBUTION

## *Up All Night: Distribution Risk as a Leading Cause of Insomnia*

**Panelists**

- *Moderator*: Ryan Tisch, Crowell & Moring
- Melanie Sabo, Federal Trade Commission
- Laura Jones, Corporate Counsel, Avaya
- Sean-Paul Brankin, Crowell & Moring
- Robert Lipstein, Crowell & Moring



# Product Risk Management Seminar Crowell & Moring

Melanie Sabo
Assistant Director, Anticompetitive Practices Division
October 19, 2011

BUREAU OF COMPETITION
FEDERAL TRADE COMMISSION

# DISCLAIMER

THE COMMENTS TODAY ARE MY OWN. PLEASE DO NOT ATTRIBUTE THEM TO THE FTC OR ANY COMMISSIONER.



# AGENDA

## EXCLUSIVE DEALING

*In the Matter of Transitions Optical, Inc.*

Docket No. 091-0062

Next Exclusive Dealing Consent Agreement

Next Exclusive Dealing Complaint

## RETAIL PRICE MAINTENANCE

*In the Matter of Nine West Group, Inc.*

Docket No. C-3937



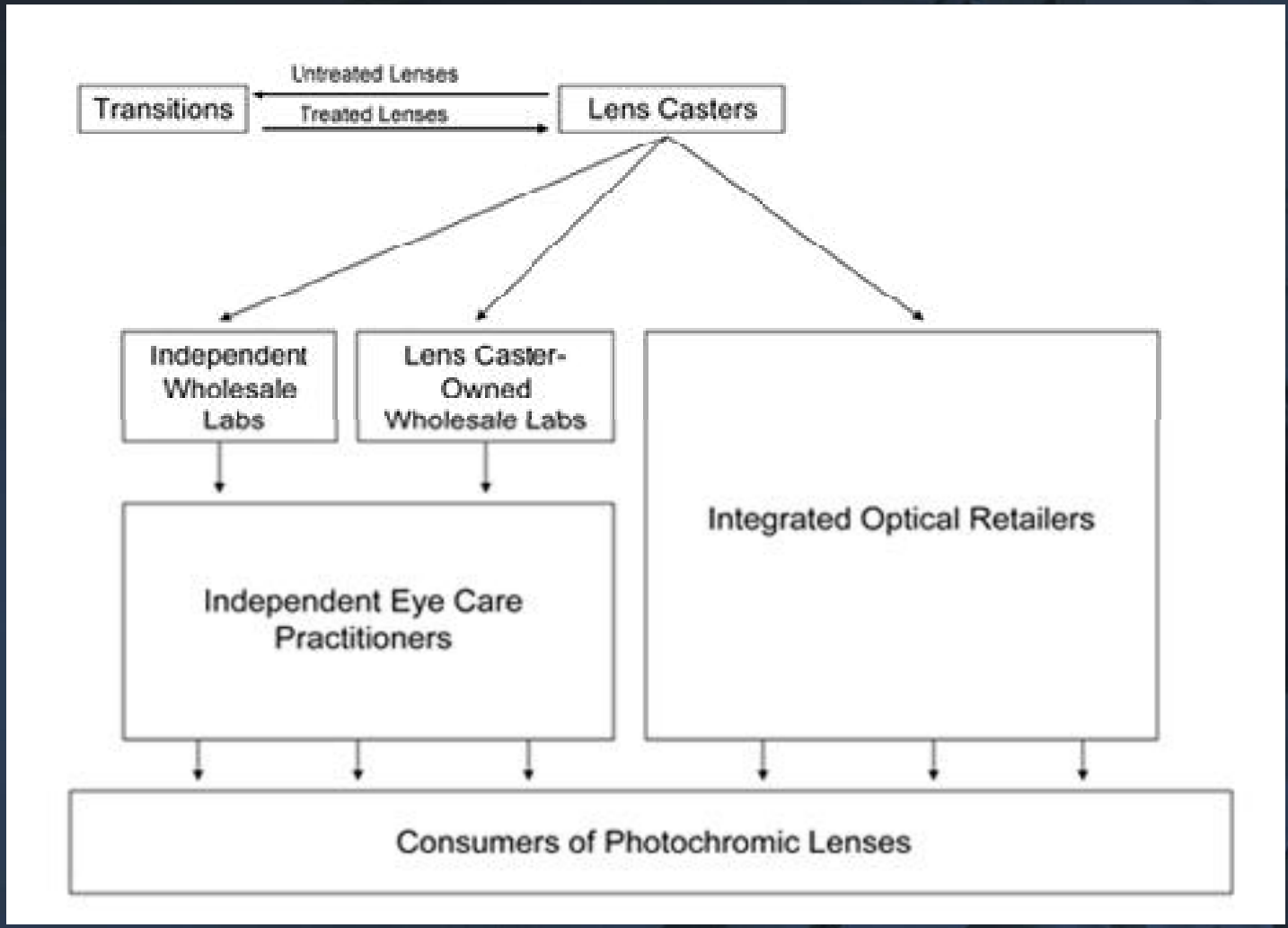
# EXCLUSIVE DEALING in *Transitions Optical*

- Facts
  - Transitions Optical, Inc. is the nation's leading manufacturer of photochromic darkening treatments for eyeglass lenses.
  - In 2008, photochromic lenses constituted 18-20 % of all corrective lenses sales in the U.S.
  - From 2003 to 2008, Transitions enjoyed an 80% market share of the photochromic lens market, and more than 85% in 2008.

# EXCLUSIVE DEALING in *Transitions Optical*

- FTC Complaint:
  - Transitions illegally abused its dominant position through exclusive dealing agreements.
  - Maintained agreements with:
    - Manufacturers of corrective lens (lens casters)
    - Optical retail chains and wholesale labs.
  - Locked out rivals from ~85% of the lens casters market and up to 40% or more from the retail and wholesale market.
  - Deals restricted output and led to higher prices.

# *Transitions Optical, Inc.*



# *Transitions Optical, Inc.*

- Transitions aimed exclusionary tactics at both lens casters and distributors further down the supply chain:
  - Lens Casters:
    - General policy of refusal to deal with lens casters that declined to sell Transitions' lenses exclusively.
    - Corning, Inc. introduced SunSensors® in 1999.
    - Transitions retaliated by terminating its supply relationship with the first lens caster to sell SunSensors®.
    - Transitions later terminated a second lens caster, Vision-Ease Lens, which had developed a competing product, LifeRx®.
    - Fearful of losing high volumes of profits, the lens casters agreed to Transitions' exclusivity requirements.



# *Transitions Optical, Inc.*

- Retailers and Wholesale Labs:
  - Long-term exclusive arrangements with over 50 retailers, including most large optical retail chains.
  - Required wholesale labs to promote Transitions' lenses as their "preferred" brand.
  - Agreements forced customers to buy many Transitions products as part of a bundle.
  - The breadth of this product line effectively precluded Transitions' rivals from competing on the merits.

# *Transitions Optical, Inc.*

- Harm to Competition
  - Transitions is not a firm without high market share.
  - Its conduct likely reduced output and increased prices.
  - Because Transitions does not face effective competition, it has been able to ignore consumer demand.
  - Exclusionary practices also harmed consumers by depriving rivals of the incentive to develop competing photochromic technology.
  - No pro-competitive efficiencies justified Transitions' conduct.



# *Transitions Optical, Inc.*

- Legal Analysis
  - Section 2 of the Sherman Act, 15 U.S.C. § 2, condemns exclusive dealing by a monopolist when its conduct effectively prevents rivals from competing with it.
    - *See, e.g.*, *United States v. Microsoft Corp.*, 253 F.3d 34, 68-71 (D.C. Cir. 2001) (condemning exclusive agreements because they prevented rivals from "pos[ing] a real threat to Microsoft's monopoly").
  - Agreements that foreclose key distribution channels are often found to have this anticompetitive effect.
    - *See*, Richard A. Posner, ANTITRUST LAW 229 (2d ed. 2002) (noting that exclusive dealing may "increase the scale necessary for new entry, and . . . increase the time required for entry and hence the opportunity for monopoly pricing").



# *Transitions Optical, Inc.*

- Legal Analysis
  - Transitions' policy of requiring exclusivity from its lens casters foreclosed its rivals from over 85% of available sales opportunities.
    - Significant because nearly all photochromic lenses are first sold by lens casters.
  - Exclusionary practices with retailers and wholesale labs amplified the harm to competition.
    - Foreclosed rivals from as much as 40 percent or more of these downstream distribution channels.
  - Transitions could not show that the exclusive arrangements were necessary to achieve a procompetitive benefit, such as protecting Transitions' intellectual property or technical know-how, or preventing interbrand free-riding.



# *Transitions Optical, Inc.*

- Settlement and Order
  - Most of the provisions will be in effect for 20 years.
  - Generally prohibits Transitions from restricting customers' ability to buy or sell a competing product or requiring customers to give more favorable treatment to Transitions' products.
  - Limits Transitions' ability to offer certain types of discounts (10 year expiration date).
    - Market share discounts
    - Retroactive discounts
    - Bundled discounts
  - Forbids Transitions from retaliating against customers that buy/sell Transitions' lenses non-exclusively.

# Follow-On Private Litigation

- Actions were filed in C.D. Calif., N.D. Calif., D.C., S.D. Florida, N.D. Texas, W.D. Washington, E.D. Wisconsin, and possibly elsewhere
- More than 20 cases have been consolidated in the Middle District of Florida
- U.S. District Judge James D. Whittemore rejected Transitions four-year Statute of Limitations Defense because pattern of anti-competitive conduct started in 1999 and ran until the company settled claims with the FTC in 2010
- Trial is likely to begin in early 2013

# Other Similar Conduct

- In *Transitions*, the company used "all or nothing" threats to exclude other photochromic manufacturers from a key method of distribution: lens manufacturers
- We are also investigating complaints about dominant firms at the distribution level using "all or nothing" threats to exclude distribution rivals from the upstream manufacturing market



# Example:

- A dominant distributor ("D") has distribution facilities throughout the United States and represents 30-50% of major manufacturers' total sales
- D also has a monopoly in multiple local geographic markets
- A new distributor rival tries to enter a local geographic market where D has monopoly power
- In response, D threatens to cut off all of its purchases from the major manufacturers -- across the United States -- if the manufacturers also supply the new entrant
- A new entrant in one local geographic market cannot offer an economic incentive to the manufacturers that would offset the risks posed by D's threats
- The manufacturers therefore do not supply the new entrant, and foreclose the distributor from an input necessary to compete: products to distribute



# Competitive Harm

- Even in distribution markets that would otherwise be characterized as having low entry barriers, D's conduct significantly increases barriers to entry: you cannot operate as a distributor if you cannot buy the products to distribute

- D's conduct would therefore unlawfully maintain and enhance its monopoly power in local markets where its dominance would otherwise be threatened by new entrants – likely resulting in higher prices and reduced output.



# Resale Price Maintenance

In 2000, the FTC charged Nine West with a Section 5 violation for allegedly entering into vertical agreements with its dealers in order to restrict price competition in the sale of women's shoes.

The FTC alleged that, over a period of 11 years, Nine West and its dealers engaged in unlawful resale price maintenance.

Specifically, the FTC challenged Nine West's adoption of certain pricing policies that determined which shoes dealers could not discount or promote outside of specified times, and its agreements with dealers on future prices.

The FTC concluded that these agreements with dealers had the effect of restricting competition among dealers and increasing prices to consumers.

# Nine West Revisited

Following the Supreme Court's decision in *Leegin Creative Leather Products, Inc. v. PSKS, Inc.* (2007), Nine West petitioned the FTC to reopen and modify its previous order to allow Nine West to take actions to maintain resale prices, other than unilaterally terminating a dealer.

Nine West argued that implementation of minimum resale price agreements – currently prohibited by the order – would allow Nine West to "develop and maintain favorable brand integrity" and, thus, enhance inter-brand competition.

Nine West suggested that, if evaluated under the rule of reason, the order's prohibitions were unjustifiable because of the myriad of pro-competitive benefits that stemmed from RPM.

# The FTC's Decision

In 2008, in reliance on *Leegin*, the FTC granted Nine West's petition to reopen and modify its previous order on the ground that its potential use of RPM agreements was not likely to harm consumers at this time. Specifically:

- The FTC agreed that Nine West did not have market power. Where no market power exists, "the forces of inter-brand competition will discipline any supra-competitive pricing."
- The FTC accepted Nine West's assertion (without corroborating evidence) that the implementation of RPM agreements would "increase consumer demand for its products and thereby enhance competition."

However, the FTC required Nine West to file a periodic report with the FTC providing information describing Nine West's use of RPM and its effect on prices and output.

# Factors Suggesting Higher Scrutiny of RPM

- The FTC cited factors suggestive of conditions in which RPM poses a greater anticompetitive potential:
  - Retailers as the impetus for adoption of RPM
  - RPM programs that are "ubiquitous" in a given industry
  - RPM program initiated by "dominant player in the market"

- Note that the FTC concluded that none of these factors were present with regard to Nine West.



# ACP Division handles CONDUCT cases

- Multiple Case Leads in the Pipeline
  - Receive a Complaint a Week on Average
- Your Competitors/Customers Complain
  - Letters, emails, phone calls, presentations
- Congressional inquiries
- Academics, Colleagues
- Self-generated
- Referrals from Other Competition Agencies (DOJ, EC, OFT, State Attorneys General)



# POINTERS FOR DEALING WITH FTC

- Cooperate with Investigative Staff
  - Redaction Issues compromised CEO's credibility in a recent case
  - Frequently enlist OGC's assistance with Subpoena Enforcement in Federal Court
  - Bullying or Insulting Staff Doesn't Help

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# Distribution Issues Under EU Antitrust Rules: Internet Sales

Sean-Paul Brankin
Crowell & Moring
*October 19, 2011*

# EU Antitrust and Distribution

- A more interventionist approach to distribution issues
- Because
  - intra-brand competition a real concern
  - market integration objective
- An example:  Internet sales

# Territorial Restrictions

- Generally prohibited subject to limited exceptions
- 'Active sales' restrictions safe harbored in certain circumstance
  - to exclusively allocated territories
  - subject to market share thresholds (30%)
- 'Passive sales' restrictions treated as object (~ per se) violations

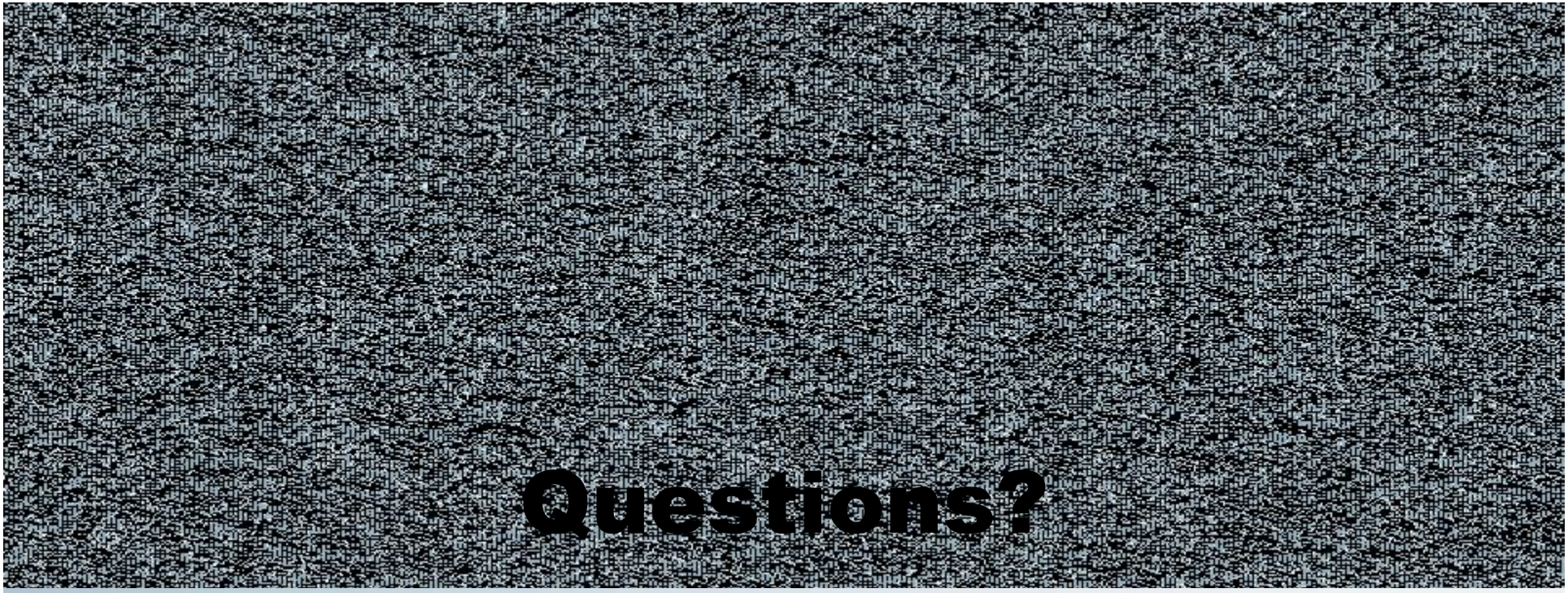
# Internet Sales

- Internet sales generally treated as passive
  - having a web site is not active marketing
  - nor is offering different language option on site
- Per se violation (in effect) to
  - prohibit Internet sales/restrict language options
  - charge higher prices for products resold on-line/offer discounts for off-line sales
  - require distributors to
    - block/redirect customers from outside their territory
    - refuse transactions made on foreign credit cards
    - limit the % of total sales made on-line

## Not per se

- Refusing to supply on-line only distributors
- Requiring a minimum volume (but not %) of off-line sales
- Requiring quality standards for web-sites

- Prohibiting sale on branded 3rd party sites
- Restricting active marketing
  - direct email campaigns (unsolicited)
  - banner ads on foreign websites
  - search engine optimization targeting foreign searchers


Questions?

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**Product Risk Management Seminar**

October 19, 2011
Washington, DC

# GLOBAL CONSUMER PRODUCT SAFETY

## *Strategic Issues in Compliance, Reporting and Negotiating with Multiple Product Safety Regimes*

**Panelists**

- *Moderator*: Bridget Calhoun, Crowell & Moring
- Marc Schoem, Deputy Director, Office of Compliance and Field Operations, U.S. Consumer Product Safety Commission
- Sean Beckstrom, North American General Counsel, Graco Children's Products
- Laurent Ruessmann, Crowell & Moring
- Laura Walther, Crowell & Moring

# UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION UPDATE

# EUROPEAN UNION: UPDATE REGARDING GENERAL PRODUCT SAFETY DIRECTIVE & TOY SAFETY DIRECTIVE

# Overview

- General Product Safety Directive
- Toy Safety Directive
- Interplay of GPSD and TSD provisions
- General observations

# General Product Safety Directive

» Revision of RAPEX management guidelines
  – Background re guidelines & late 2009 revision (Commission Decision 2010/15)
  – Major element: revision of risk assessment annex (which relates to risk assessment for most products)

» Current revision of General Product Safety Directive
  – Commission Green Paper followed by public consultation
  – Main issues
  – Next steps

# Toy Safety Directive

- 2009 revision implemented by Member States by July 2011 (2013 for chemical provisions)
- June 2011 revision of the toy safety standard EN 71-1 (Mechanical & physical properties)
- Continuing work on standards & guidance & international cooperation

# Interplay of GPSD & TSD provisions

» Series of recent and pending revisions – both were due and now GPSD "catching up"

» 2010 revision of RAPEX management guidelines: applies to toys as well

» Classification issues
  – Toys versus sports equipment
  – Toys versus vehicles for transport

» Standards to apply

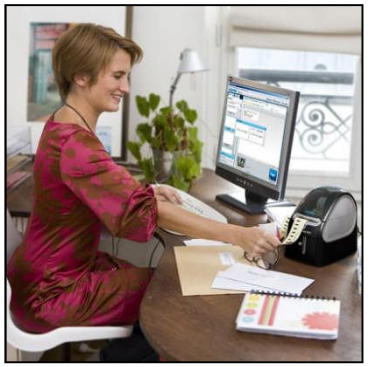
# General observations

- Move toward more comprehensive obligations
  - Highlights need for communication within supply chain
  - Underscores importance of investment in relations with regulatory authorities
- Implications for cross-border trade
  - Increases risk of barriers to trade
    - Authorities understand and are working to avoid: improving communications at international level
    - Operators need to be alert and not be taken off guard
  - Puts premium on mutual recognition, if not harmonisation (e.g. risk assessments)
  - Need rapid response to rapid (and increasing) ad hoc actions of the regulators
    - Huge increase in use of EU RAPEX
      (see, e.g., recital 8 of Commission Decision 2010/15: fourfold increase in notifications between 2004-2009)
    - Products not necessarily more unsafe but more communication about products
    - Mistakes can be made & sometimes RAPEX appears to be used for non-serious risks

# CANADA CONSUMER PRODUCT SAFETY ACT HIGHLIGHTS

Newell Rubbermaid™
Brands That Matter

# Manufacturer's Perspective



# My Perspective

NewellRubbermaid
Brands That Matter


Sharpie · IRWIN · Goody · Rubbermaid · GRACO · Calphalon · WATERMAN
LENOX · PAPER MATE · LEVOLOR · PARKER · DYMO · TC technical concepts · Aprica

# Global Village

NewellRubbermaid
Brands That Matter

- Global Products
- Global Customers
- Global Communication
  - Consumers
  - Agencies

It's true – look it up on the internet!

# What's a Manufacturer to Do?

NewellRubbermaid
Brands That Matter

Monitor

Communicate

Sharpie IRWIN Goody Rubbermaid GRACO Calphalon WATERMAN
LENOX PAPER MATE LEVOLOR PARKER DYMO TC technical concepts Aprica

# Monitor

NewellRubbermaid
Brands That Matter

- Listen to consumers worldwide
- Consumers will talk to manufacturers by:
  - Telephone
  - Email
  - On-line Product Reviews and Blogs
  - Lawyer letters/lawsuits
  - Social Media
- It's important to have resources in the country (or experienced with the country) to communicate with consumers

# Monitor

NewellRubbermaid
Brands That Matter

- Manufacturer's need to monitor blogs, Facebook, Twitter, YouTube and product reviews for safety issues
- Companies need to have a process to fold that information into their consumer database
- Consumer databases need to be set up to aggregate data in the quickest manner possible and to give early alerts and be able to interact around the globe

# Communicate

NewellRubbermaid
Brands That Matter

- Reporting obligations
  - Determining when to report
  - What to whom
- Globalization of recalls
  - Where does a manufacturer sell similar products
  - Capture all jurisdictions
  - What are the differences in products from country to country
  - Outreach to non-acting jurisdictions

# Communicate

NewellRubbermaid
Brands That Matter

- Manufacturers need to work with more than the primary recalling authority
- Manufacturers need to alert other jurisdictions in which the product is sold
  - Europe
  - Latin America
  - Asia
    - Japan
- Manufacturers need to determine whether these other jurisdictions will require a recall (i.e. Brazil)

# Practice Tips

NewellRubbermaid
Brands That Matter

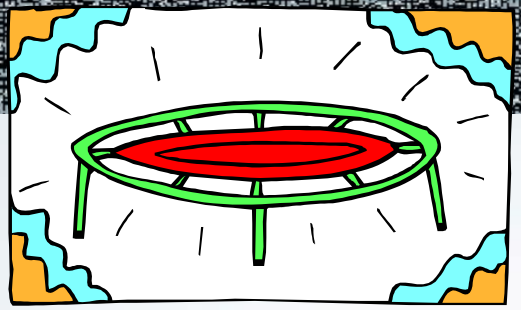
- Be concerned about your brand/image on a global basis
- Avoid looking as if you apply different safety standards and recall thresholds to different countries
- Be prepared with crisis communications for consumers, retail and media
- Be culturally sensitive
- Remember messing up on global recall could result in fines, loss of business or jail time.

# Let's Have Some Fun!

- Mogulicious manufactures innovative specialty skis for sale to ski resorts for rental and demo by professional skiers in a number of countries.
- A number of resorts have complained over several months that the new skis are so fast that some skiers have lost control and injured themselves on the slopes.
- One young former X-Games winner suffered a concussion and a black eye and then posted about the incident on the CPSC's public database.
- The CPSC succeeds in persuading Mogulicious to voluntarily retrofit the skis to provide more speed control.

# The Inventor

» A former Crowell & Moring lawyer turned fitness junkie has developed a revolutionary new mini trampoline that works your core, burns calories, ***and*** is really fun. Everyone in her family is enjoying the workout.



» She wants to market the product for sale and asks you whether the product is subject to any mandatory regulatory standards in the U.S., Canada and the E.U.

# Questions?

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# MOTOR VEHICLE SAFETY / NHTSA

*Steering in the Right Direction*

**Panelists**

- *Moderators*: Dan Campbell and Rebecca Baden, Crowell & Moring
- O. Kevin Vincent, Chief Counsel, National Highway Traffic Safety Administration
- James Chen, Director of Public Policy & Associate General Counsel for Regulatory Affairs, Tesla Motors
- Joe Stancati, Managing Attorney and Director of Litigation, Dana Holding Corporation

# Enforcement

» Recall Statistics

» Recent Trends

» NHTSA's Current Emphasis

» "Lessons To Be Learned"
  – NHTSA
  – Manufacturers
  – Suppliers

# Electric Vehicles

» Our President: State of the Union

» Products In The Marketplace Now . . .

» Products Coming

» Get your popcorn ready . . .

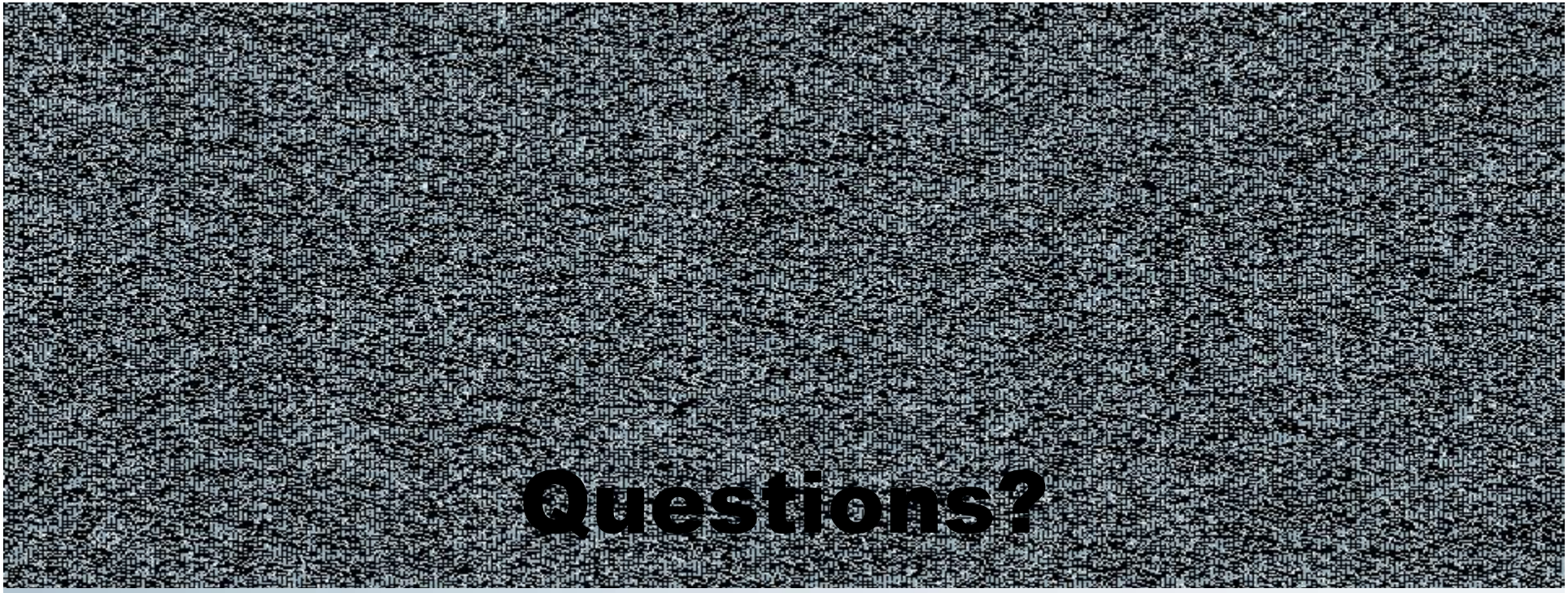
# Electric Vehicles

» Current Efforts, Future Challenges

– NHTSA

– Manufacturers

– Suppliers


Questions?

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# LITIGATION RISK MITIGATION

*Getting Inside the Mind of a Plaintiff's Lawyer*

**Panelists**

- *Moderator*: Lynn Parseghian, Crowell & Moring
- Andrew Kaplan, Crowell & Moring
- Tracy Roman, Crowell & Moring

# How Do Plaintiffs' Lawyers Identify New Cases?

- Governmental action (or proposed action) on high-visibility issue – federal or state
- Governmental inaction
- Old wine in new bottles: plaintiffs settle a class action and then, years later, sue again
- Copy-cats of suits against your competitors

# What Are Some Of Their Favorite New Targets?

- Food
  - statements regarding nutrition
- "Green" or "natural" claims
- Toys, sporting goods
- Customer interactions
  - billing practices

# How Do They Fund Their Cases?

» Joint Ventures
  – Capital Contributions
  – Shared Expenses / Other Costs
  – Decision Making
    • Financial
    • Strategic
  – Allocation of Fees

» Other Funding Methods

# What Are Some Of Their Tactics Aimed At Early Settlement On Favorable Terms?

- Pressing broad theories of liability that sound compelling but lack scientific (or other real-world) support
- Developing fraud/deceptive practice theories that avoid the need to prove a product defect
- Playing "gotcha" in discovery, especially with e-discovery
- Using anecdotal customer reports and social media to color the factual story

# How Can Your Company Avoid Becoming A Target?

- » Evaluate the terms of your warranties
- » Make sure you have an enforceable arbitration agreement
- » Evaluate your QC practices
- » Evaluate your product return process and study trends in your return rates
- » Monitor your anecdotal customer reports
- » Take care with Government communications

# Questions?

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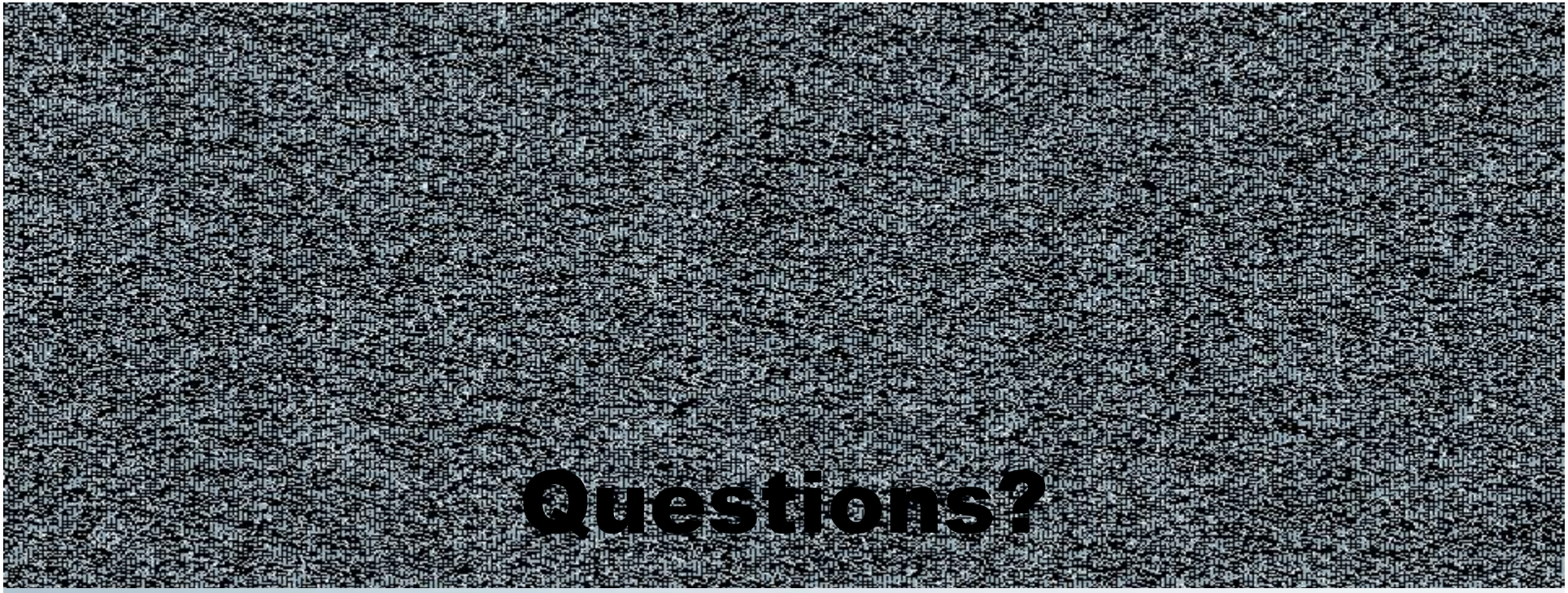
# RESPONDING TO INVESTIGATIONS AND ENFORCEMENT ACTIONS BY REGULATORY AGENCIES

**Panelists**

- *Moderator*: Ann Mason Rigby, Crowell & Moring
- Mark Josephs, United States Department of Justice, Consumer Protection Branch, Assistant Director
- Phil Inglima, Crowell & Moring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# CONCLUDING REMARKS

- Scott Winkelman, Crowell & Moring

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# THANK YOU!