

Consumer Healthcare Products Association

Where are Global Regulatory Trends Pointing?

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Overview

1. Case studies from the U.S.
 - Reminder of where our mutual legal framework came from
 - Hallmarks over time
 - Swings in the risk pendulum
2. Do pediatric cough/cold discussions point to a trend?
3. Comparisons/ contrasts with other countries
4. Who drives the issues
5. What this may mean for prescription-to-nonprescription switch

Case studies from the U.S.

- U.S., U.K., Australia, Canada
 - All Common Law countries: Negative law
 - In that construct, nonprescription as default status. Prescription status defined.

Case Studies from U.S.:

Hallmarks over time

- 1938: Safety
- 1951: Prescription-nonprescription clarity
- 1962: Effectiveness
- 1970s and on: FDA review of established ingredients for effectiveness, and included safety (GRAS/GRAE)

Case Studies from U.S.:

Hallmarks over time

- 1997 and 2002: Best Pharmaceuticals for Children Act and Pediatric Research Equity Act
 - BPCA applies to new drugs
 - PREA goes through a listing process
 - Neither specific to OTCs nor an all-encompassing mandate *but* they do color attitudes and expectations

Case Studies from U.S.:

Hallmarks over time

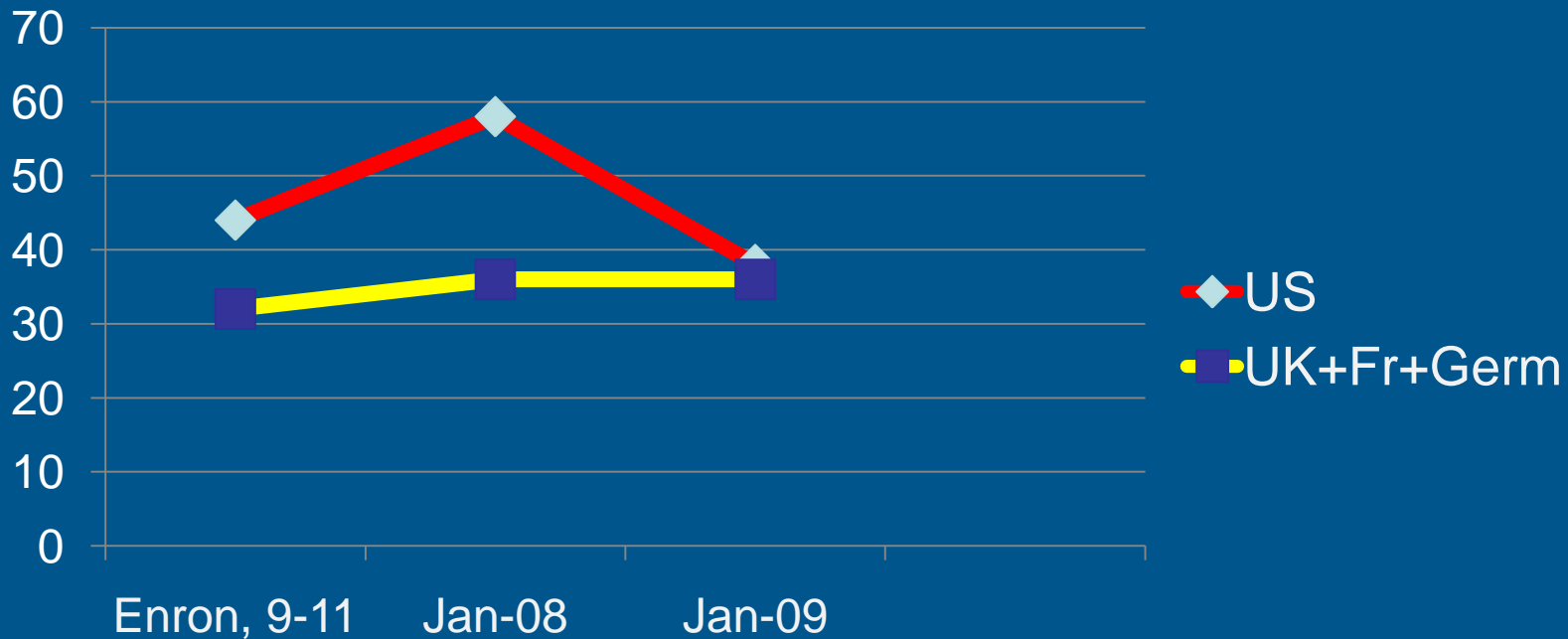
- 2007: *Prescription* risk evaluation and mitigation strategies (REMs)
 - Prescription new drugs, *not* OTCs, including switches
 - *But*, do they color attitudes? Should they color attitudes?

Swings in the risk pendulum

- 1980s/early 1990s: Concerns of a ‘drug lag’
 - AIDS/HIV community
 - Cancer patients
- 2006-08: Trust in FDA down. Charges drug approvals “too fast”
 - *But*, continuing interest in access to prescription drugs in trials prior to approval
- 2009?

Swings in the pendulum

- Low level of trust not unique to FDA, not unique to U.S.
- “How much do you trust business to do what is right?” – Edleman Trustbarometer

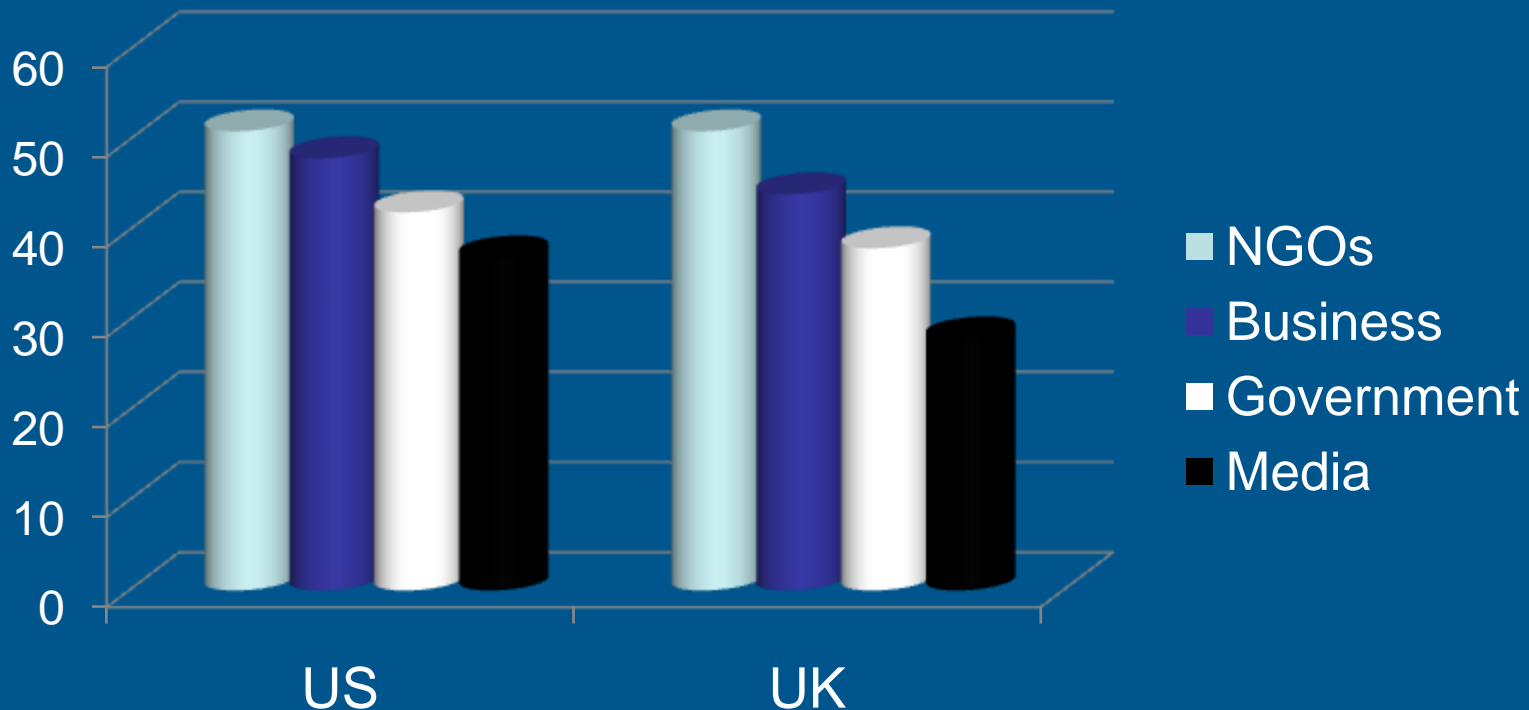


Swings in the pendulum

- *But*, “how much do you trust business to do what is right?” response +12% from January to July 2009 in U.S.
 - Edelman Trustbarometer

Trust, continued

- From Edelman Trustbarometer, July 2009
- “How much do you trust each institution to do what is right?”



Trust, continued

“66 percent of voters nationwide [U.S.] say they’re at least somewhat angry about the current policies of the federal government.”

– Rasmussen Reports as quoted in Politico
Sept. 24, 2009

Do pediatric cough/cold discussions point to a trend?

- Maybe, maybe not
- Baltimore Health Commissioner and academic pediatricians drove initial consideration in U.S.: Outside FDA, not within
- Was a *lack of trust* a driver – in industry, in FDA? Arguably yes

Pediatric cough/cold discussions

- And yet parents *do* want to treat their children's cold symptoms
- 74% of care-givers of children under 12 use OTC medicines for coughs and colds
 - “On this occasion [child's most recent cold within past 6 months], did you consider giving your child any type of over-the-counter medicine?”
 - Nielsen for CHPA, April 2009

Comparisons/contrasts with other countries

- Note while pediatric cough cold discussions moved from U.S. to U.K., Canada, and Australia, no reconsideration in continental Europe nor Japan

Who drives the issues?

- Repeating: Restoring trust as a driver
- FDA Commissioner Dr. Margaret Hamburg:
 - Restoring public confidence in FDA as goal #1
- Agencies are not monolithic
 - Office of Surveillance and Epidemiology role within FDA contrasted with Office of New Drugs and reviewing divisions under it

What this may mean for prescription-to-nonprescription switch

- Safety emphasis clearly up worldwide
- Studies in pediatric populations up, generally worldwide
- Switch fairly slow in U.S. in 2008-2009, but barriers around the world modestly down
 - First 2 EU-wide centralized switches – Alli for weight loss, Pantozol Control for frequent heartburn
 - Clamelle for chlamydia in UK

What this may mean for prescription-to-nonprescription switch

- Opportunities to design or use tools to address specific switch challenges *up*
 - Websites with algorithms for personalized advice
 - In-store kiosks or mobile applications
 - Pharmacist training or support

Conclusion

- Yes, challenges up.
- Yes, trend toward 'more'
 - More safety emphasis
 - More information through labeling and other means
- An evolution
- Switch can, must, and will continue