



Public Perception on Industry and Drug Safety: Implications on the Culture of Safety

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Disclosure

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Retired Wyeth Pharmaceuticals

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Opinions expressed are my own

The Consumer Survey*

Harris Interactive

Pharmaceutical Safety Institute

*Supported by a grant from Quintiles, Inc.

Consumer Survey Development and Analysis

Harris Interactive

UNC School of Public Health

Quintiles

Pharmaceutical Safety Institute

Survey Details and Demographics

Conducted entirely online October 2006

Analyzed November 2006

Demographics

1726 respondents, over 18

853 Male, 873 Female

Survey Details and Demographics

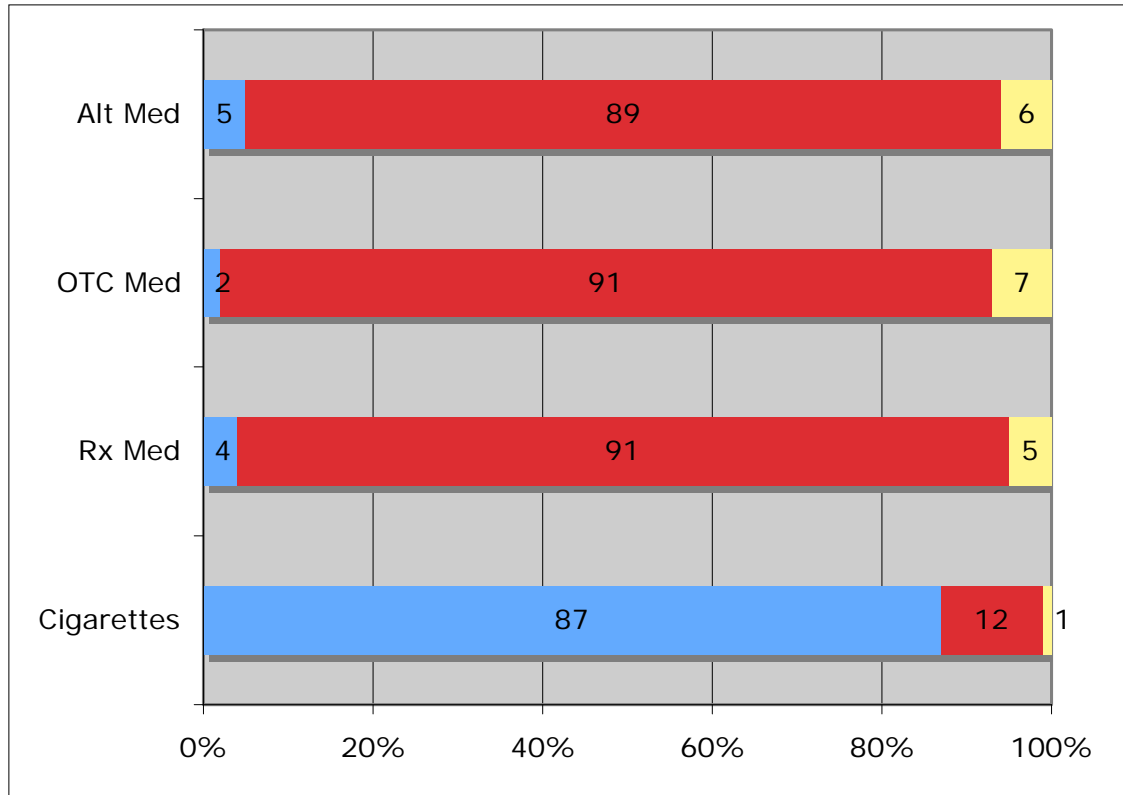
Demographics

<u>N</u>	<u>Age Bands</u>
454	18 - 30
356	31 - 40
641	41 - 60
275	61+

Results

Baseline Understanding and
Experience

How safe are these products?

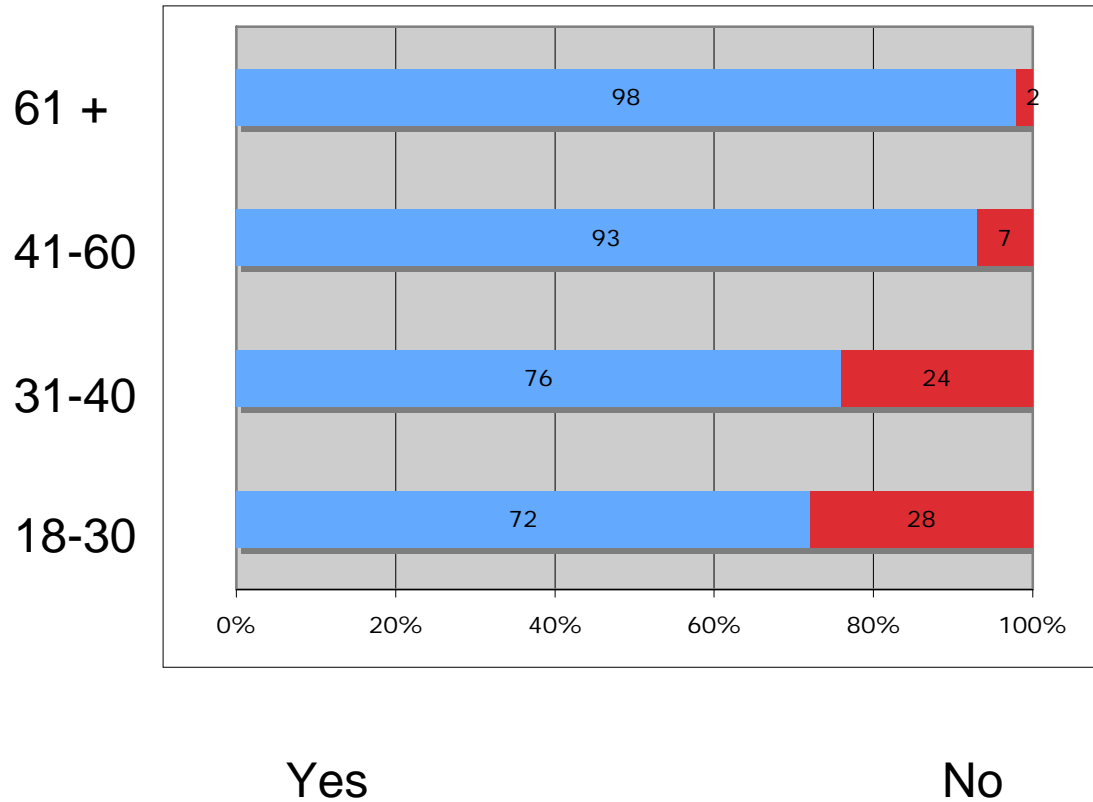


Not safe at all

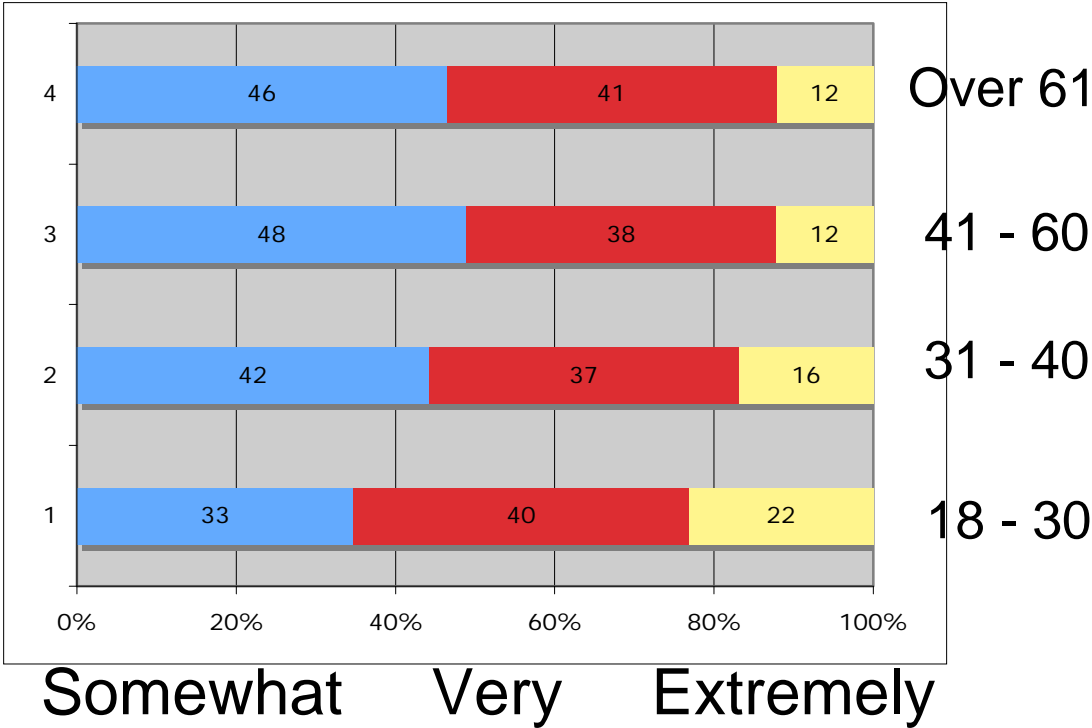
Somewhat

Completely

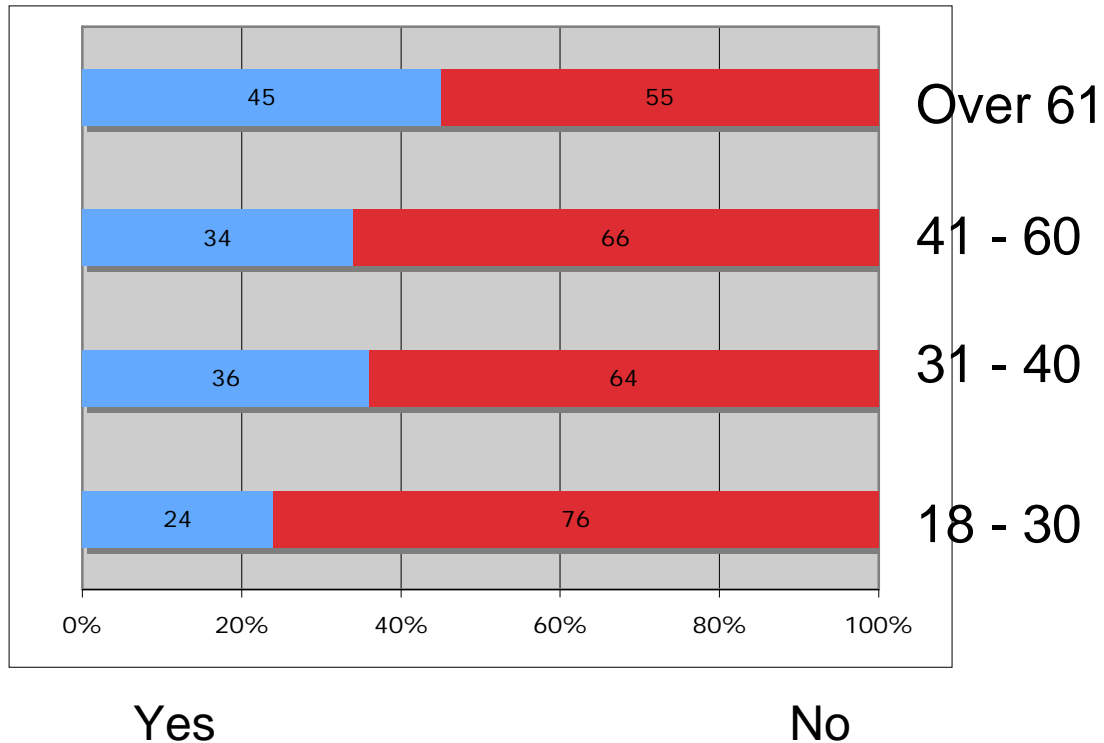
Have You Ever Taken an Rx Medication?



How confident are you it was safe?



Have you ever had an Adverse Reaction to an Rx Medication*



* 482 or 98% stopped taking Rx Med due to ADR

Most Rx drugs are safe when taken as directed

n = 1726	18 - 30	31 - 40	41 - 60	61+
Disagree	11	13	16	19
Neutral	28	24	19	15
Agree	60	63	66	66

How confident are you about the release of safety information as soon as known

n = 1726	18 - 30	31 - 40	41 - 60	61+
Not at all	19	23	37	42
Somewhat / Confident	61	62	53	49
Very / Extremely	20	15	10	9

Situation

- **Mass-scale use of a prescription drug is now measured in months, rather than years**
 - A recent assessment of pharmacovigilance by the European Commission concluded: “with the globalization of the pharmaceutical market, products often enter different global markets simultaneously with exposure of large numbers of patients occurring in a short period of time.”
- **Global efficiencies:**
 - Clinical Development
 - Marketing authorization
 - Manufacturing & Distribution
 - Financial Systems
- **What is missing - Global Culture of Safety**

A Flawed System

- Safety Methods and Communication
 - Cox-2 inhibitors
 - Pediatric antidepressants
 - rosiglitazone maleate (Avandia®)
- Implications of Morbidity and Mortality
 - The impact of emerging safety information and product labeling on use by those who should receive benefit
 - Withdrawal removes the product from all who may benefit
- Social Responsibility
 - To communicate risk by setting expectations and not entitlement
- A Culture of Safety and Not Blame
 - A higher level of effort to eliminate the silo behavior

The Media

- **Partners in Communication**
 - Not dysfunction
 - Need broad understanding of the clinical research enterprise
- **Global Reach**
 - US is not alone
 - United Kingdom
 - Germany
 - Others
- **Quality Investigative Journalism**
 - Credibility
 - Balance

The Public

- 96% felt that drugs should “remain under close review” by the FDA and drug companies after they have come to market;
- 95% of the survey respondents had some level of concern about adverse reactions to prescription drugs that are taken as directed;
- 80% of the respondents were concerned about the agency’s ability to make independent decisions;
- 80% of consumers thought it was important to be more knowledgeable about serious safety events associated with drugs;

A 2006 Harris Interactive/Wall Street Journal Poll. Becky Bright. Americans growing less confident in FDA's job on safety, poll shows. Wall Street Journal Online. May 24, 2006.

The Public

- 76% were concerned about the agency's ability to effectively communicate safety concerns about marketed drugs to doctors and the public;
- 76% of these respondents were fairly to extremely concerned about adverse reactions;
- 74% of respondents were fairly, very, or extremely confident that drugs in the US are safe when taken as directed, only 7% were not confident of this;
- 29% thought drugs were safer than 5 years ago, while only 19% thought they were less safe.

Healthcare Providers

- **Critical to the effectiveness of the safety system**
 - Are relied on for interpreting and reporting key safety information to the patient
 - Understanding and conducting Clinical Research
 - Reporting safety data
 - A Continuum of Processes and Technology
 - Under constant deluge of information

The Industry

- 38% of respondents somewhat or very strongly trust clinical trials.
- 44% of respondents very strongly distrust or somewhat distrust pharmaceutical companies that develop drugs.
- 45% of respondents somewhat or very strongly trust the FDA.
- 69% of respondents are confident that drug companies will release any information they have about adverse drug reactions as soon as they have the information. Younger respondents seem to be more trusting and optimistic about the integrity and ethical behavior of drug companies.
- 71% of respondents are confident that drug companies will eventually disseminate all info (positive or negative) regarding safety of their drugs.

Current Public Perception

Based on what you know or have heard, how good a job do you think the FDA does on

Ensuring the safety as well as efficacy of new prescription drugs (excellent or good)

2004 - 56%

2006 - 36%

2007 - 45%

Ensuring that truly innovative prescription drugs come to market more quickly (excellent or good)

2004 - 29%

2006 - 22%

2007 - 34%

Current Public Perception

The US Senate recently passed a bill that would provide the FDA with new responsibilities. How confident are you that the following measures would help improve drug safety?

Establishing a computerized network to scan insurance and pharmacy records for indications of safety issues with new prescription drugs - 52% (confidence)

Increasing fines for Pharma companies that fail to comply with FDA requests for label revisions or additional studies - 52%

Allowing the FDA to fine Pharma companies for false or misleading ads. - 54% (confidence)

Towards an Agenda for Change

Overview

- What you have heard so far emphasizes systemic, rather than transactional, means of dealing with reform
- What follows summarizes a proposed working agenda, heavily indebted to this superstructure of experience and insight, and transforming what is currently in place
- An integrated and holistic approach to reform

1. Systematic Reform: A safety culture in the life sciences sector needs to be system wide

- The pharmaceutical safety dialogue has been too often limited to being between industry and regulators
- A much larger group of stakeholders, including patients, providers, and payers, needs to be engaged
- Realignment of the whole system needs to take place, rather than attempts made to fix its parts

2. Accountability: including strong public and private leadership needs to be committed to organizational and cultural change in order to implement a safety culture.

- Executives throughout the Life Sciences Sector, must act as champions for a safety culture
- Chief Safety Officer
- Leadership includes a broader range of decision-influencers and decision-makers with a vision of safety guiding principles that integrate into daily organizational functioning and support implementation and adherence

3. A blame-free culture.

- A reporting and learning culture
 - Human factors
 - Root cause analysis
- Empowerment to correct safety issues. In fact, it is easier to spot violations in a blame-free culture since errors are not hidden
- Protection of 'on-the-ground' safety champions contributes to a higher level of accountability

4. Transparency

- All communication, not just regulatory-related information, is risk communication
- There is currently poor adoption of the extensive literature on risk communication by the life sciences sector
- Fully integrated processes including all elements of the organization
- Evidence-based Practice Centers (EPCs), 1997 by the U.S. Agency for Healthcare Research and Quality
- The public accepting responsibility
- Public disclosure systems must collect truthful, unbiased data

5. Public understanding

- The media is involved with translating and interpreting the complexities of safety issues in the life sciences to the public and are rarely intimately familiar with the dynamics and complexity of safety issues
- There is a need for credible, neutral resources
- Inform without over-complicating or over-simplifying
- Why? Governance of scientific and technological progress is no longer an exclusive domain. Inclusiveness in dealing with regulations and guidance is a viable norm

6. Professional Development: Safety education and training are in need of revision

- Academic curricula
- Role specific safety culture programs
- Fundamental knowledge of what the safety system is, the role one plays in it; and the range of inter-related issues
- Safety and risk management processes
- Executive roundtable discussions
- Organizational learning

7. Social Responsibility and Profitability: Financial Community Responsibility

- Fuller disclosure of benefit/risk information strengthens a company's credibility and assets rather than weakens them
- The venture capital and financial communities equate safety cultures with business efficiency
- Return on investment (ROI) considerations for new chemical entities with undefined safety profiles

8. New methods to improve the safety of marketed drugs: Three examples

- Large trials that are publicly funded
 - Special populations
 - Long term safety assessment
- Electronic health records and database technology
 - Evidence based decision making
 - Real time appropriate use assessment
- Limited commercial release
 - Continuous improvement in benefit / risk assessment

Conclusion

an integrated and holistic approach

- A “safety culture throughout the entire health system” that learns from near misses and adverse events but does not concentrate on blame
- Bring together all the pertinent stakeholders to contribute to working within the legislative framework to create a positive environment to implement a safety culture throughout the life sciences sector; industry, payers, providers, advocacy groups and patients
- Over the past thirty years, the advances in global regulatory approvals and commercial distribution have outpaced improvements in therapeutic product safety. The need for reform is overdue