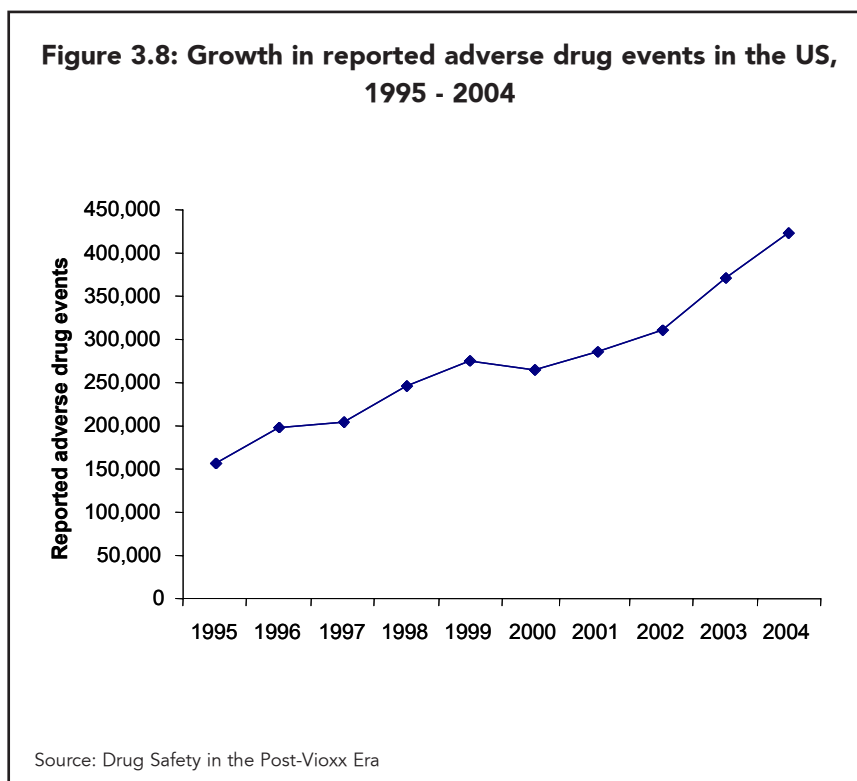


# Drug Safety in the Post-Vioxx Era

New legislation, regulation and company strategies in Europe and the US



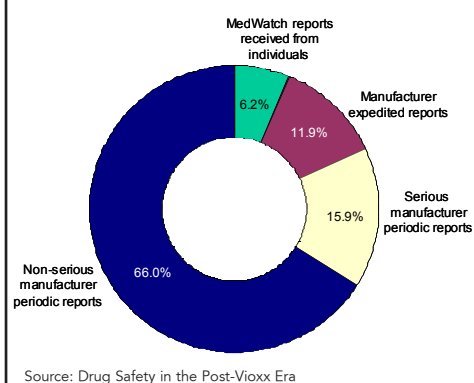
**How is your company addressing the issue of drug safety...?**

**Assess the new drug safety strategies your competitors are using in this latest report...**

## Drug Safety in the Post-Vioxx Era

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**Figure 2.4: Sources of FDA-reported adverse events**



"In 2004, the FDA received more than 422,000 reports of suspected drug-related adverse events, as shown in Figure 2.4. The FDA's Adverse Event Reporting System (AERS) is a computerized system that combines the voluntary adverse drug reaction reports listed on MedWatch with required reports from manufacturers..."

Merck's voluntary withdrawal of Vioxx in September 2004 and the ensuing investigation of regulatory checks and balances have raised awareness of safety issues to unprecedented levels. Although Vioxx represents the most severe safety scare to date, similar problems could occur again given the commercial availability of various products that have been linked to widespread severe reactions and the lack of sufficient regulatory controls.

**Drug Safety in the Post-Vioxx Era: New legislation, regulation and company strategies in Europe and the US**, is a new report which examines the actions taken by legislative and regulatory bodies in response to recent drug safety concerns surrounding the COX-2 inhibitors and antidepressants. Implement a variety of proactive management, marketing, distribution and technological strategies to ensure the safety of your products and prevent exposure of drug safety issues for the public.

**Develop a tighter drug safety strategy by analyzing nine case studies describing safety issues encountered by pharmaceutical companies and examine the predictions for the future of drug safety regulation in the US and EU.**

## Key findings of the report

**Table 1.1: Potential safety risks of popular drug classes**

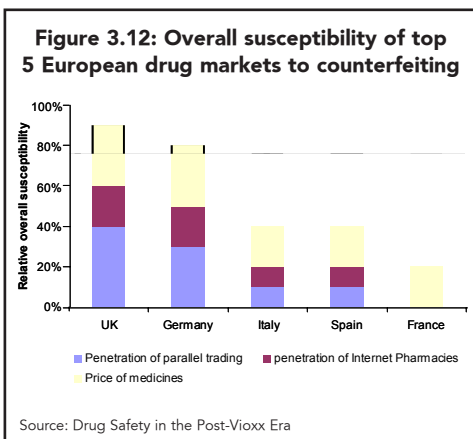
Drug Class	Indication	Potential Reactions	Safeguard
COX-2 inhibitors	Pain relief	Risk of stroke, heart attack	Expanded labeling, recalls
Statins	Cholesterol reduction	Liver toxicity	Liver tests
NSAIDs	Pain relief	Ulcers	Expanded labeling, contraindications
Bisphosphonates	Osteoporosis	Gastrointestinal effects	Expanded labeling, contraindications
Hormone replacement therapy	Symptoms of menopause	Cardiovascular effects	Expanded labeling, contraindications
Leukotriene receptor antagonists	Asthma	Liver toxicity	Expanded labeling, contraindications, liver tests
Triptans	Migraine	Cardiovascular effects	Expanded labeling, contraindications
ACE inhibitors	Hypertension	Renal impairment	Expanded labeling, physician supervision

Source: Drug Safety in the Post-Vioxx Era

"Medications with identified but manageable risks, which comprise the bulk of prescription drugs sold today, are subjected to expanded labeling requirements advising patients and healthcare providers of potential safety issues. These labels contain contraindications for use in certain patient populations or require regular physician monitoring of use. The small number of drugs that have not been associated with significant or severe side effects are not subject to these restrictions..."

- Lawsuits due to Vioxx are likely to cost Merck at least \$10bn to \$15bn, the most of any drug lawsuit to date.
- Reported adverse drug reactions are at an all time high and are expected to continue to grow at a double-digit pace, in part due to the high susceptibility of the growing senior population to adverse events.
- The latest EU-level proposals address various issues including pediatric testing, the manufacture of active pharmaceutical ingredients (APIs) according to Good Manufacturing Practice (GMP), and labeling.
- In February 2005, Senators Christopher Dodd (CT) and Charles Grassley (IA) introduced a bill to the US senate to require the public disclosure of all new clinical drug trials by pharmaceutical companies - the 'Fair Access to Clinical Trials Act' of 2005.
- Several pharmaceutical companies have recently withdrawn drug applications in order to collect more comprehensive safety study data, particularly for candidates with questionable safety profiles or those belonging to classes associated with heightened risk.
- Counterfeiting is a growing area of concern in the EU and US and is another factor compromising drug safety for pharmaceutical companies. Several bills have been proposed in the US Congress to expand the FDA's powers to address counterfeit drugs.

## Key questions answered in this report



"The purchase of medicines through Internet websites by European residents continues to grow both as a convenience and as a means to obtain less expensive products from low cost producing countries like China, Russia and India. Since Internet pharmacies are a large source of counterfeit medicines, this trend significantly increases the associated safety risks posed to consumers..."

- Which manufacturers have had significant safety breaches and how did they occur?
- How are your competitors responding to safety challenges and how does your organization compare?
- How could legislative changes boost regulators' authority over the industry and how will this affect your company?
- What regulatory changes have been proposed in the US and EU, and how do these differ?
- How are managed care organizations and retailers responding to recent safety concerns regarding the COX-2 inhibitors and the issue of drug counterfeiting?

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**Table 3.8: Pending US legislation**

Bill	Sponsors	Status
Pharmaceutical Market Access and Drug Safety Act	Senators Byron Dorgan (ND), Olympia Snowe (ME), Charles Grassley (IA), Edward Kennedy (MA), John McCain (AZ) and Debbie Stabenow (MI)	30 co-sponsors
PhRMA Act	Rep. Fortney Stark (CA)	9 co-sponsors
The Fair Access to Clinical Trials Act (FACT Act)	Senators Christopher Dodd (CT), and Charles Grassley, (IA)	3 co-sponsors
Food and Drug Administration Safety Act	Senators Christopher Dodd (CT), and Charles Grassley, (IA)	2 co-sponsors
Counterfeit Drug Enforcement Act	Rep. Steve Israel (NY)	No co-sponsors
Strengthen FDA's authority	Senators Mike Enzi (WY) and Edward Kennedy (MA)	Not yet introduced
Legislation requiring public disclosure of all later-stage clinical trial information	Reps. Henry A. Waxman (CA) and Edward J. Markey (MA)	Not yet introduced

Source: Drug Safety in the Post-Vioxx Era

"In April 2005, Senators Dodd and Grassley introduced a bill that would re-structure the FDA to eliminate conflicts of interest in the drug oversight function. The bill would create a proactive, independent Center for Post-market Drug Evaluation and Research that reports directly to the FDA Commissioner..."

- **Anticipate regulatory and legislative changes in Europe and the US that may impact how you address drug safety issues** and assess potential changes that may need to be made to your current drug safety strategy.
- **Analyze new trade group initiatives and proactively work with trade organisations** to provide more transparent information to physicians and patients and highlight drug safety concerns early.
- **Discover how managed care organizations and retailers are reconfiguring their business models** to improve the safety of drugs they provide to consumers.
- **Benchmark your drug safety strategy against your competitors** by analyzing management, marketing and technological strategies companies are pursuing.
- **Develop innovative future strategies** by utilizing the report's nine case studies of leading pharmaceutical companies including GlaxoSmithKline, Pfizer, AstraZeneca, Eli Lilly and Merck & Co.

# Drug Safety in the Post-Vioxx Era

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# Drug Safety in the Post-Vioxx Era

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