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Case Study:

**Recall of Products in the Pharmaceutical and Medical
Device Industry –**

An Attack on Reputation and Sales

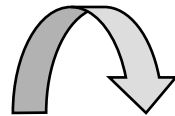
Professor Dr. Dr. Alexander P. F. Ehlers
Attorney at Law and Physician

Change of Reputation Pharmaceutical Companies

- **For many years...**
 - the pharmaceutical industry was highly regarded for its role as a leader in the advancement and improvement of human health.
 - the continuous introduction of new and improved drugs has also driven substantial revenue growth in the industry.

Change of Reputation Pharmaceutical Companies

- But: there have been many product recalls despite well established quality assurance processes and regulatory requirements.



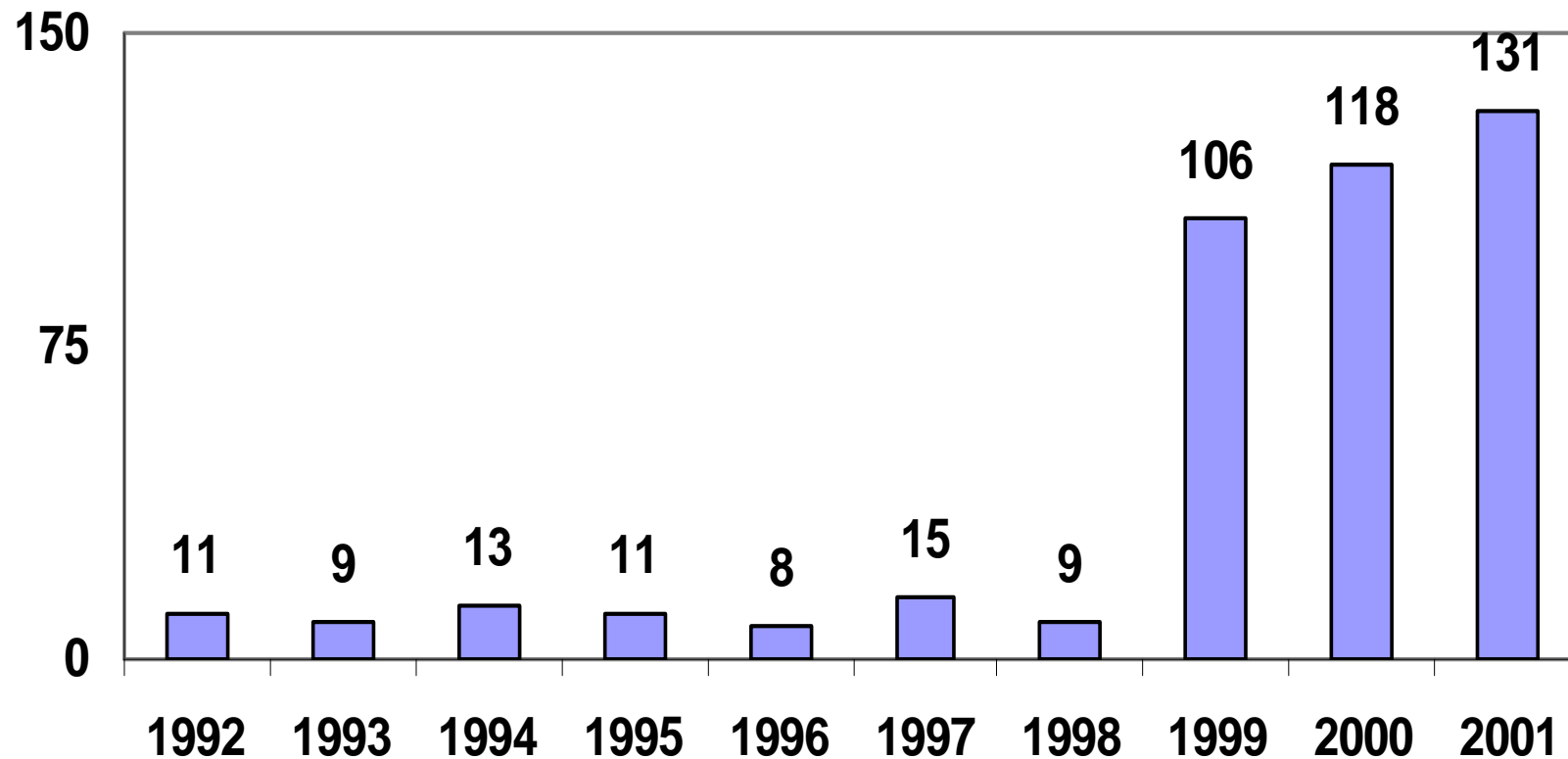
These incidents have led many consumers to believe that pharmaceutical manufacturers have lost sight of their original vision, and instead of focusing on bettering the human condition, are more interested in bettering their profits.

„Fewer than half of U.S. consumers have a favorable view of the drug industry – and according to the latest Reputation Quotient study, only tobacco ranks lower in the public's estimation.“ (Business week December 8, 2005)

Product Recalls in the Pharmaceutical Industry

- Number of recalls is permanently increasing.
- 16 product recalls between 1997 and 2007 in Europe (15 prescription drugs, 1 Vaccine).
- In 26 years prior to 1997, there were only 8 product recalls.

Example: Annual Complaints Received by FDA



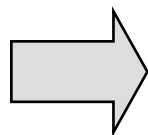
Source: FDA Office of Compliance, CenterWatch

Why are Pharmaceutical Companies so attractive?

- Pharmaceutical companies are seen as „deep pockets“ => Attractive target for lawsuits
- Reputation: View that pharmaceutical companies are more concerned with profits than with people
=> „That is how we do things here“ attitude“

Effect on Profitability

- costly settlements on pricing and promotional practices.
- difficulty in obtaining clinical trial subjects.
- Since 2000, pharmaceutical companies have paid a total of almost \$4 billion in settlements and fines.



Raising the total costs!

Effect on Reputation

- Recall and liability litigations

= Negative brand reputation

Why is there an Increase in Issues?

- More complex drugs.
- Rush to be the first to get a product on the market.
- Patent expiration on existing drugs.
- Information on side effects are known much faster.

Product Recalls - Vioxx

- COX-2 selective inhibitor NSAID marketed by Merck.
- Used in the treatment of osteoarthritis, acute pain conditions and dysmenorrhoea.
- Worldwide, over 80 million people have been prescribed Vioxx.
- Withdrawn in 2004 because of concerns about increased risk of heart attack and stroke.

Product Recalls – Vioxx (cont)

- Merck had Vioxx sales of \$2,5 B in the year before recall.
- There were over 10.000 cases and 190 class actions filed against Merck due to Vioxx.
- In the US cases settled, in Germany the lawsuits are ongoing.

Other Publicized Events

- **Ambien**
 - Reports of sleepwalking, sleep driving & sleep eating
- **Bausch & Lomb**
 - Renu contact solution possibly causing eye infections
- **Pfizer's Viagra**
 - May cause blindness
- **Merck's osteoporosis drug Fosamex**
 - May cause rare disorder that causes patient's jawbone to rot and die
- **Zocor / Crestor**
 - May cause muscular degeneration

Communication Lessons from Vioxx

- Creating a crisis communication plan (a rapid response media plan)
 - Identify key individuals to be involved, their roles and responsibilities.
- Persistence and long-term view
 - Press releases, corporate statements, conferences, paid advertisement, letters to editors in response to misleading or inaccurate articles, frequent communication with employers, internal and external websites.

Communication Lessons from Vioxx – The Importance of Information

- Consumers perception was:
 - FDA forced Merck to withdraw the drug.
 - Merck has hidden information about the drug.

Communication Lessons from Vioxx - Educating the Public

- Identify which facts people need to know about the Company.
- Address those needs in order to correct misconceptions.
- „...If people understood the facts about Merck’s actions with regard to Vioxx, they had more favourable opinions of the company. (...) Our strategy was to educate the public solely about the facts – the messages included no spin, no emotions.“ (Wainwright, Vice President of Public Affairs at Merck & Co., Inc.).

Legislative Measures in Germany by the Competent Authorities

Sec 64 Arzneimittelgesetz (German Medicinal Product Act):

- The competent authority may order the recall from the market the medicinal products.
- The competent may also seize the medicinal products.
- The competent authority may issue a public warning.

Strategies

- regulatory compliance
- risk management
- performance improvement

Questions?

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