



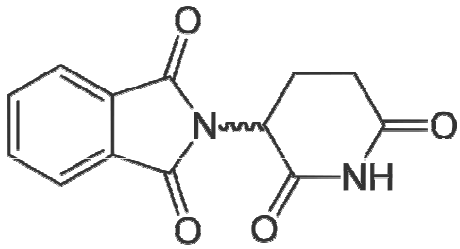
**European Commission
Pharmacovigilance proposals:
patient safety is at risk**

HAI Europe Seminar

23rd of October 2009

Florence Vandevælde

1960: Thalidomide



About 2 500 cases in Germany



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- **1965: EU Directive 65/65/CE**

Marketing authorisation

needed prior to commercialisation

= gatekeeper

1970: DES (diethylstilbestrol)

"Really?"

Yes...

desPLEX®

to prevent **ABORTION, MISCARRIAGE** and
PREMATURE LABOR

recommended for routine prophylaxis
in **ALL** pregnancies . . .

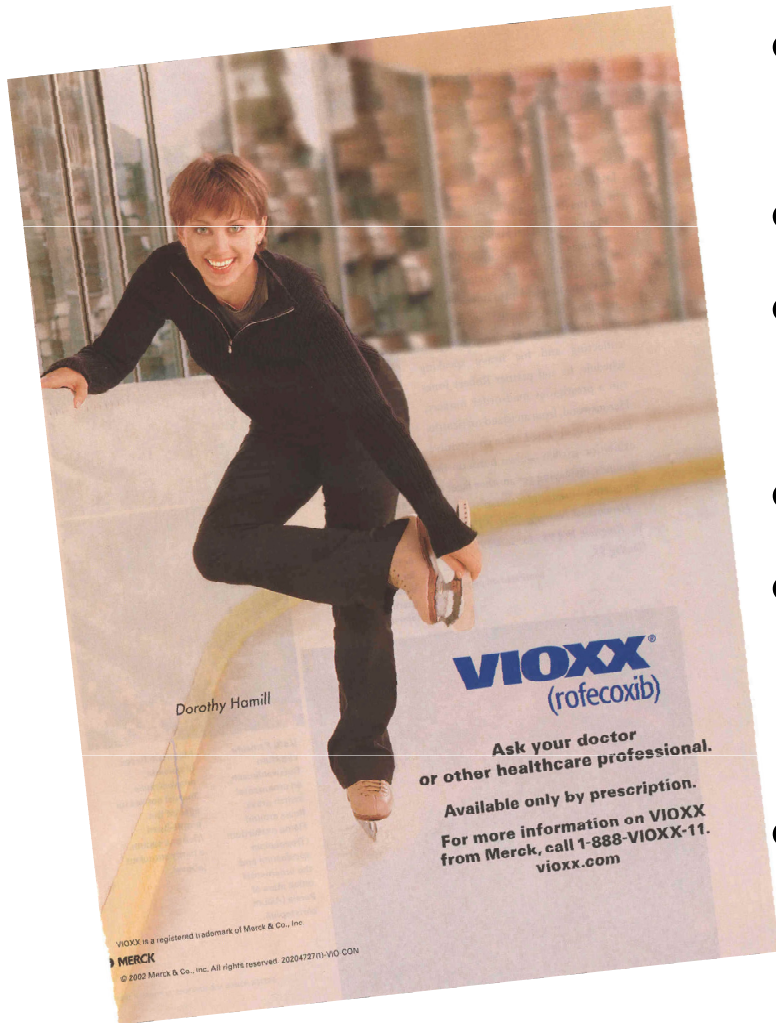
46 per cent live delivery with **desPLEX**
in one series of 1100 patients!™
— bigger and stronger babies, too!™

No genetic or other side effects with **desPLEX**
— in either high or low dosage!™



- Used from 1950 to 1970 (1980 in France!)
- France: 160 000 children exposed
- Daughters: morphologic anomalies of uterus, cancer
- Complications during pregnancy

2004: rofecoxib (ex-Vioxx^o)



- Used from **1999** to **2004**; no therapeutic advance
- **US**: 30 000 strokes
- **2000**: results of Vigor study: increased cardiovascular risks
- **2003**: in France, post-MA study
- **2004**: EMEA conclusions: no therapeutic advantage, probable increased risk... no withdrawal!
- **2004**: 2nd study: withdrawal by the pharmaceutical company

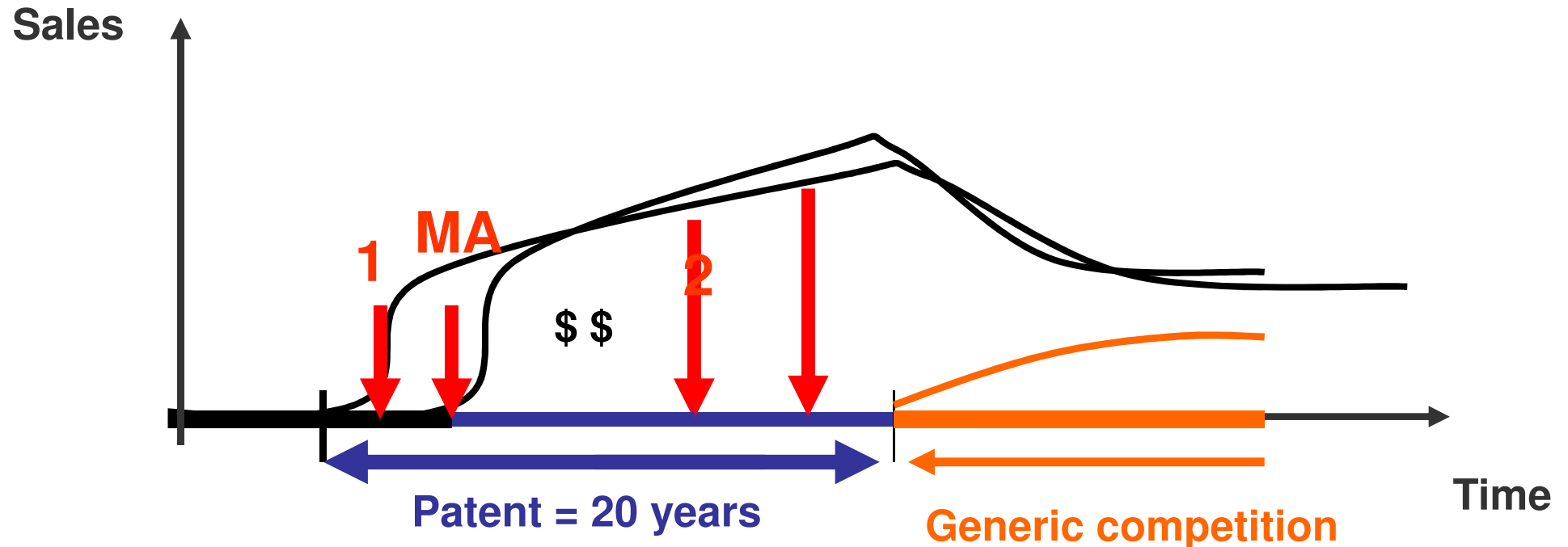
In the 2000s

Multiplication of litigations

- Rofecoxib (Vioxx^o)
- Olanzapine (Zyprexa^o)
- SSRI (Seroquel^o)
- Rosiglitazone (Avandia^o)

-> dissimulation of adverse drug reactions data

Three reasons to amend the proposals



1. Premature marketing authorisations

2. Dissimulation of adverse drug reactions data

3. Biased decision-making & secrecy

1. Premature marketing authorisations

*The illusion of “risk management systems”
and of post-authorisation studies*

- Marketing authorisation:
quality, efficacy, safety
- The EC aims to:
 - generalise **Risk Management Systems**;
 - favour **authorisations with conditions**, even with no public health justification
- **Risk Management Systems = false “good idea”**
 - Remove health authorities’ responsibilities;
 - EU citizens to become “guinea pigs”

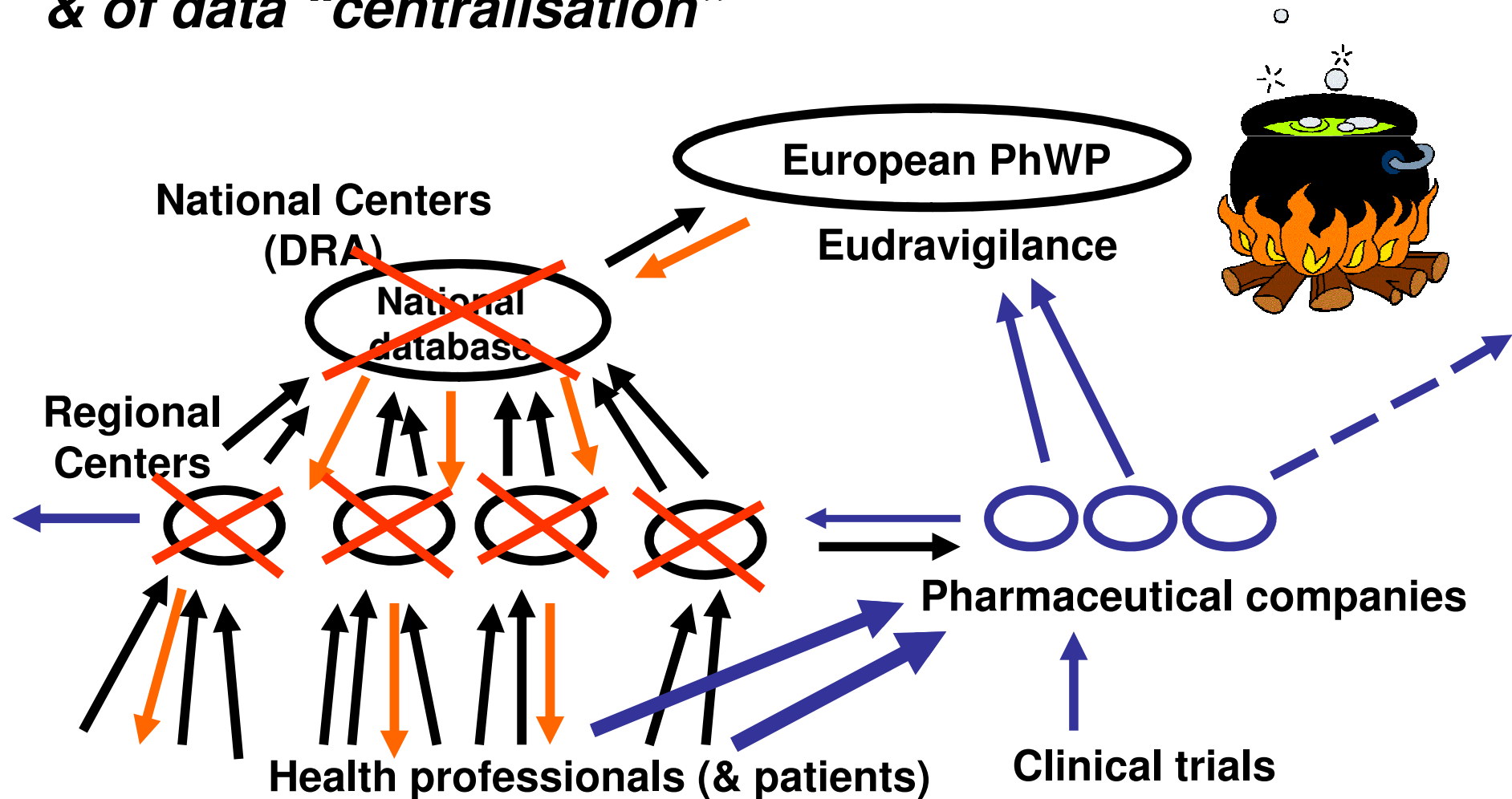
1. Premature marketing authorisations

Our recommendations

- Marketing authorisation:
quality, **therapeutic progress**, safety
- To preserve the meaning of **marketing authorisation** (protection)
- To help patients to recognise “intensively monitored” medicines
- Make **RMS** become **proactive pharmacovigilance tools**

2. Dissimulation of adverse drug reactions data (1)

*The illusions of shifting “responsibilities” to pharma
& of data “centralisation”*



2. Dissimulation of ADR data (2)

Our recommendations:

- Preserve and **strengthen Member States' pharmacovigilance systems**
- Really encourage **patient notifications** to Regional or National pharmacovigilance Centres (not just a web portal)
- Guarantee **quality of Eudravigilance**: registration of data by the Member States' pharmacovigilance systems
- More **transparency**:
 - Public access to National databases and to Eudravigilance
 - Patient leaflets adapted to users

3. Biased decision-making & secrecy (1)

Consequences of Health authorities' financial and political dependence on pharmaceutical companies

- **Current situation:**
 - delayed decision-making process,
 - dissimulation of data
- **Why?** Conflict of interests ++
 - **Data interpretation** by pharma (PSURs)
 - **Hierarchy:** Marketing authorisation committees (directly funded by pharma companies fees + inherent conflict of interest) with more power than Pharmacovigilance systems

3. Biased decision-making & secrecy (2)

- **The EC proposals:**
 - **The end of pharmacovigilance public funding**
 - **Pharma companies** in charge of report follow-up and of their products **evaluation**
 - **PSURs:** more secrecy, not if "well-established use"
 - **Pharmacovigilance Risk Assessment Advisory Committee (Praac):**
no authority, no autonomy, no resources
 - **Pharmacovigilance driven by MA Committees:**
 - CHMP (Committee for Medical Products for Human Use)
 - CMDh (Coordination group for Mutual recognition and decentralised procedures)

3. Biased decision-making & secrecy (2)

- **Our Recommendations**

- **Maintain** pharmacovigilance **public funding**
- **Health authorities** in charge of report follow-up and of evaluation on the basis of all available data
- **PSURs:** list of individual cases; at least every 5 years
- **European pharmacovigilance Committee**
Same authority as CHMP; members independent from pharma and from MA committees
- **Separate Pharmacovigilance from MA**
 - Creation of a Coordination group for risk assessment (equivalent to the CMDh)

3. Biased decision-making & secrecy (3)

- Develop a **proactive pharmacovigilance** (clinical trials meta-analyses, post-authorization observational studies run by Health authorities)
- More **transparency**:
 - of pharmacovigilance data (clinical data belongs to the public);
 - during every step of the decision-making process

Conclusion: Take home messages

Therapeutic progress: to avoid useless exposure

Marketing autorisation: last gate keeper (look out for RMS!)

Conflict of interests: pharma companies, MA committees

Quality of pharmacovigilance data: strenghten role and responsibilities of pharmacovigilance centres (look out for industry bypassing!)

Independency: public funding, separating Marketing Autorisation from pharmacovigilance

Proactivity

Transparency: clinical data belongs to the public, health authorities are to be held accountable