

WORKSHOP ON THE DEVELOPMENT OF AN EMEA TRANSPARENCY POLICY

22 JANUARY 2009

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Why Transparency?

Secrecy & Concealment breeds suspicion and leaves room to corruption

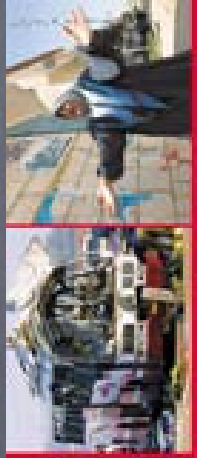
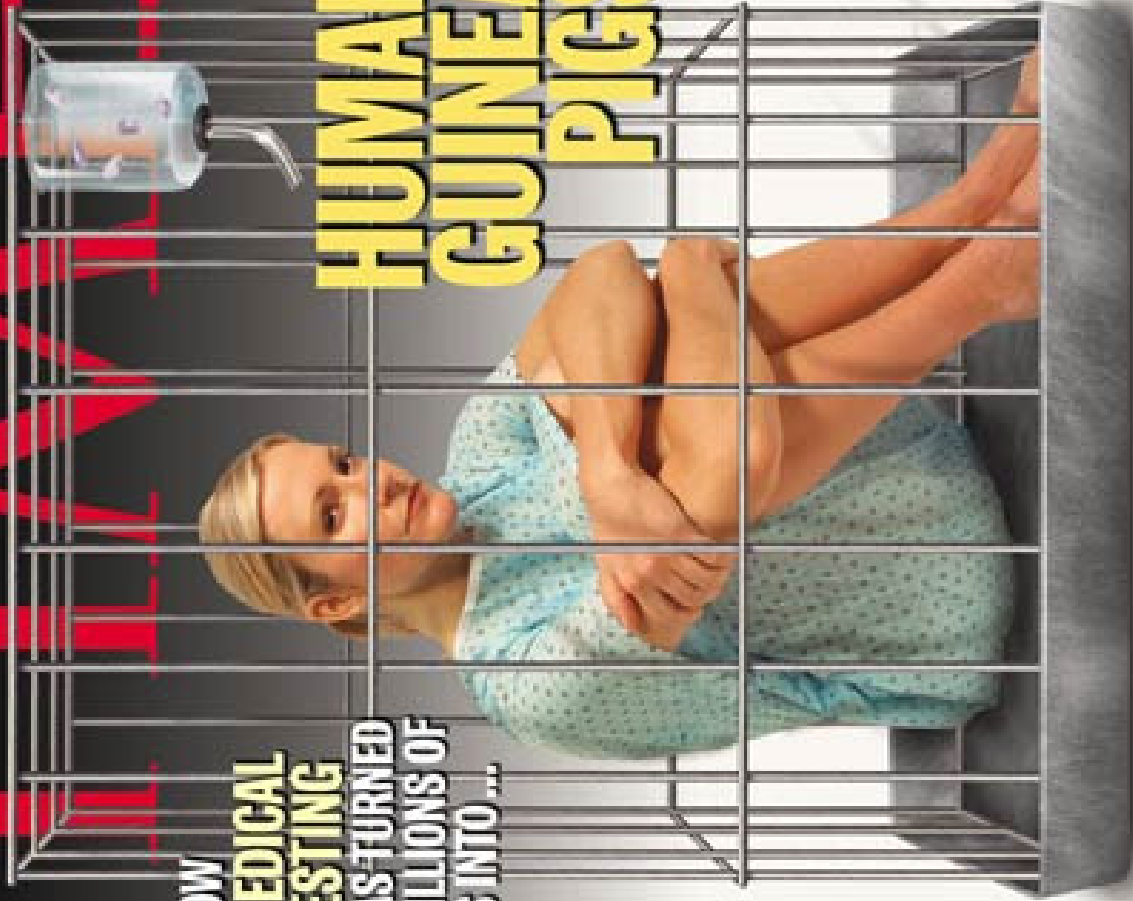
Transparency ensures trust and accountability

APRIL 23, 2002

Powell's Mission Impossible

HOW
**MEDICAL
TESTING**
HAS TURNED
MILLIONS OF
US INTO ...

**HUMAN
GUINEA
PIGS**



Why Transparency?

Access to information leads to the empowerment of the patient and the citizen

Transparency is the first step towards stakeholder involvement and participation

TIME Persons of the Year

2002: The Whistleblowers



2006: You



Transparency Now!

- Government
- Industry
- Doctors
- Researchers
- Medical Journals
- Patient organisations
- Regulatory authorities (EMEA & NCAs)

Real Transparency

Not merely “publicly accessible” upon request
but readily available before the public

Progress in the EMEA

- Withdrawals & Negative opinions
- Access to documents
- Ad hoc Participation/Invitation to SAGs
- Patients' and Consumers' Working Party
 - Simplification of Documents
 - SPC
- Healthcare Professionals WG

Further Steps

- Eudract
- All interventional CT dataset & results
- CHMP agendas, minutes, meetings
- Dossier evaluation
- Clarity on “commercially confidential” information
- Information of safety issues
- Scientific Advice / Protocol Assistance
- Involvement in the discussion of new Guidelines