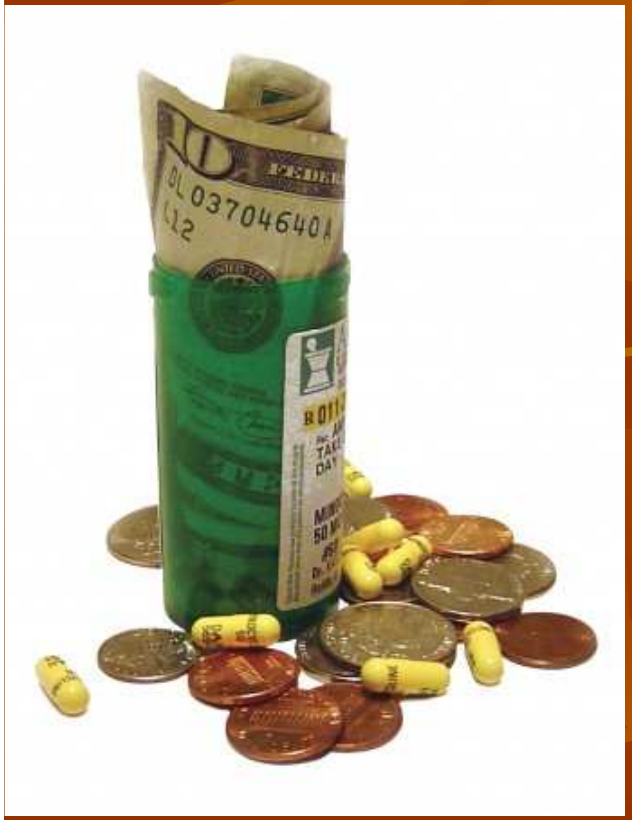
CONFLICTS OF INTERESTS FOR MARKETING AUTHORIZATION OF A MEDICINE



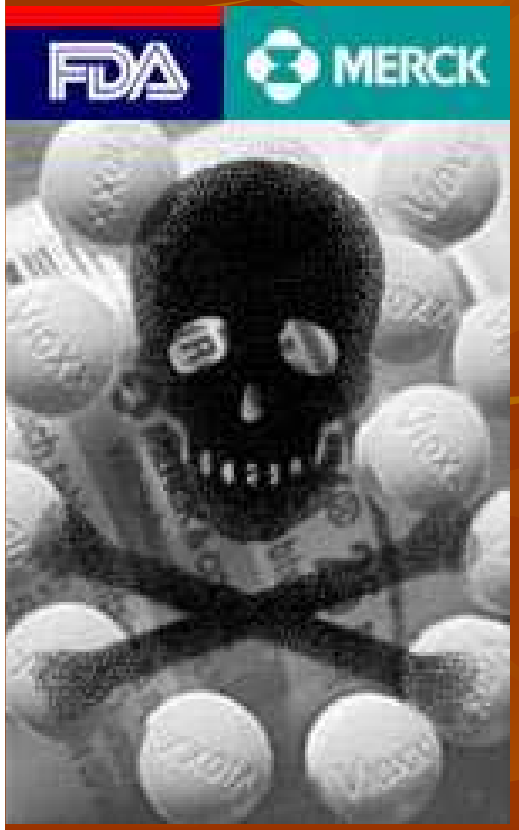
NECESSITY OF A NEW JURISDICTION

G Delépine, NDelépine

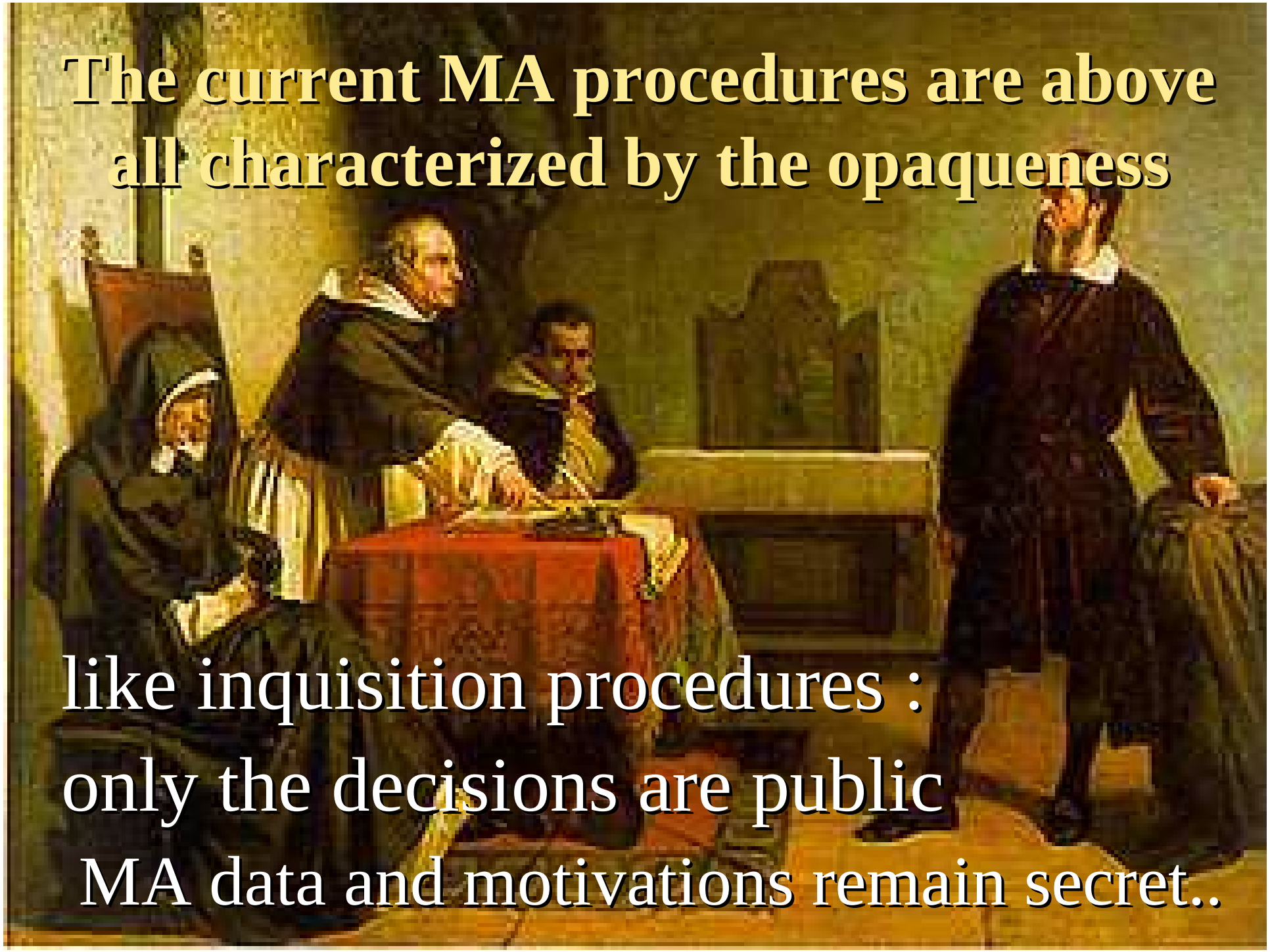
Hôpital Raayond Poincarré Garches France

The scandal of the VIOXX

- Illustrates the inefficiency of the current procedures of market approval



- 1999-2004 Vioxx gave 2,5 bllions $ benefit every year
- Doctor D.Graham 17/11/2005 « a realistic and likely range of estimates for the number of victims in the US was between 88,000 and 139,000. Of these, 30-40 percent probably died. »


The current MA procedures are above all characterized by the opaqueness
like inquisition procedures :
only the decisions are public
MA data and motivations remain secret..

Trials data are the exclusive property of the laboratory

- which can decide the scheme of the trial,
- The end point,
- The type of analysis
- To publish or not, or partially
- Can alter data, include ghost patients or exclude some patients with complications
- without any independent control

All trials should be published

- **Many results are never published, especially when clinical trials show that a drug or treatment didn't work or have unexpected toxicity. So the medical community remains in the dark over what was learned.**
- **« less than 1 in 5 Cancer Trials Are Published.. »« In trials sponsored by industry, the rate was even lower: Just 1 in 20 is published.. »**

  Ramsey in the onologist 2008

The investigators

- The investigators are motivated by high fees which often distort their conclusions
- 8th april 2008, Kassirer in le *Los Angeles Times* published Tainted Medicine showing the importance of conflicts in Financial interest
- « can we trust in medical research? »

Demonstrate that my drug is effcient and you receive 200,000$

And for whistle blowers investigators

En avril 1993, le docteur Nancy Olivieri, de l'Hôpital des enfants malades de Toronto, signe avec la société Apotex Research Inc. un protocole de recherche sur une nouvelle molécule, la déféripronе,. Deux ans après le début des essais thérapeutiques et la publication de premiers résultats encourageants, elle suspecte ce médicament d'aggraver la fibrose hépatique de certains de ses malades

Elle décide alors de faire signer à ses patients une nouvelle lettre de consentement,. Aussitôt, le laboratoire met fin au contrat (sans annuler les recherches en cours dans d'autres hôpitaux) et menace le médecin de poursuites si elle enfreint la clause de confidentialité. Ignorant les pressions, au nom de son devoir envers ses patients, elle présente ses résultats lors d'un colloque..;

Experts of the committees of MA

No experts of the committees of MA are independent from firms.

This situation is the result

- of the faith that medical research "would be motivated only by interest of the patients or science" .

"today profits are tomorrow medicines"

assertions denied by objective analysis : the profits of firms especially served for increasing dividends while credits allocated to research and number of real new medicines decreased

MA is a judgment on the harmlessness and the efficiency of the product.

- But if democratic justice bases on
- the contradictory and
- public examination of all the elements of proof

Propositions for transparency.

- The clinical trials intended to support a file of MA have to recover from a **particular legal regime to have convincing value**

A new regime of property

- **Their regime of property will be the one of a shared co-ownership** enter
- the laboratory which finances,
- the patients who take the risk and
- the State or the welfare organization which will pay the future medicine

Authentic data

- The medical data of the trials have to be authentified
- With a **registration of main data at the health Autority every year** (as we do for commercial firms)
- and to be published with **independent rewievers** even in case of interruption of the trial.

Recommandations de Transparency International

Base de données publiques sur les essais cliniques des médicaments

Publications des éventuels conflits d'intérêts

Code de conduite : Un Code de Déontologie pour les professionnels de santé, les administrations de santé, les organes de contrôle, intégrant des sanctions.

- **Code de conduite pour les industries pharmaceutiques et de DM pour ne pas verser des pots-de-vin.**
- **Implication et rôle de surveillance de la société civile**
- **Protection des dénonciateurs**