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Contre le Lyell et le Stevens-Johnson

Clinical trials or no clinical trials:
what about Adverse effects?

2016, September 30th

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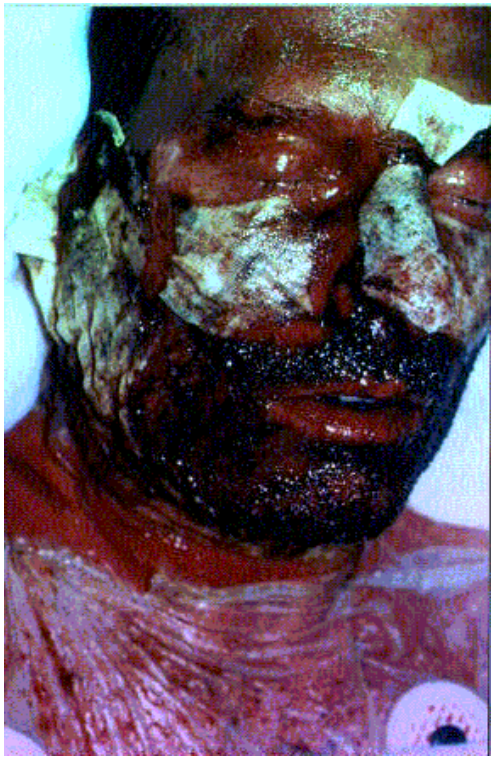
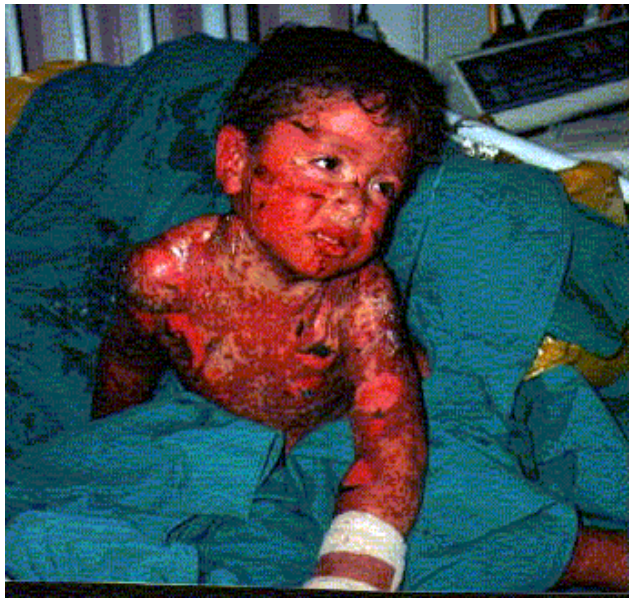
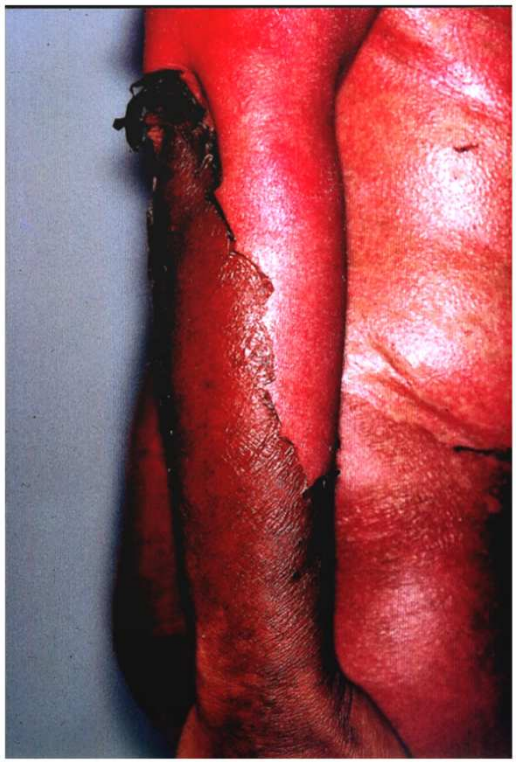
Stevens-Johnson’s syndromes







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What's the role of clinical trials?

- Clinical trials aim to prove the benefit of a candidate drug to market but also to check if the potential risks are acceptable.
  - One of clinical trial's main purposes is to detect serious adverse drug reaction (ADR) that could question market authorization or limit indications.
- ADR detection relies on the number of persons exposed to the drug…. which takes time!
  - Earlier marketing of a drug means that serious and rare ADR will be detected after the clinical trial
- What would be the liability regime for the multiple steps after clinical trials in the adaptative pathway procedure ? No mention of this issue in the current debate…
- What will be the consequences for potential unexpected ADR victims after the clinical trial? Are patients fully aware of the impact of earlier drug marketing on their rights?

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Drug side effects liability regimes in Europe

- Outside clinical trials, unexpected ADR victims are not aware of participating to risk detection … and they get rarely compensation for their damages.
- **ADR falls under the EU liability regime of defective products** (*Directive 85/374/ECC),* the common liability regime for consumer good products…..
  - The victim has to prove the **defect of the product** (no mention of the risk of side-effect in the package leaflet)….
  - …but producers can be exonerated for **risk of development** when an unexpected risk, ie non-scientifically known, occurs…
  - The victime must prove the causal relationship and the imputability between the drug and its damage.
  - The limitation period is **3 years after the occurence of the damage** AND the right is extinct **10 years** after the product has been placed on the market.

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Clinical trials and liability regimes in Europe and in France

- When participating to clinical trials, EU regulation protects unexpected ADR victimes via diverse insurance-like mechanisms (depending on the MS).
  - In Europe: member states have to insure compensation for damages occuring during a clinical trial (*art.76 of EU regulation 536/2014)*
- In France:
  - If the promoter is faulty: his insurance should compensate for the victim's damages
  - If the promoter is not faulty; ONIAM (Office National d'Indemnisation des Accident Médicaux), a public fund is in charge of compensating the victim's damages
  - The limitation period is 10 years after the consolidation of damages

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What is at stake and how to solve the issue?

- Protection of unexpected ADR victims : clinical trials liability regimes should be extended to all unexpected ADR victims after the drug authorization.
  - Unexpected ADR victims are unaware guinea pigs
- Development risk exemption should be suppressed for drugs
- Risks taken by new marketed drugs consumers should be better advertised

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