CLINICAL TRIAL TRANSPARENCY VS. TRADE SECRECY AND BEYOND: CAN PUBLIC HEALTH POLICIES BE RECONCILED WITH INTERNATIONAL OBLIGATIONS?

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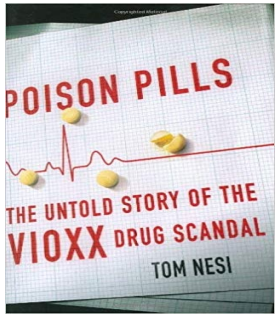
PLAN

- Background
- What and why of Clinical Trial Transparency)?
- TRIPS issue
- Seeking your input

BACKGROUND – TERMS & CONCEPTS

- Clinical trial data
  - Relevance to approval of new drug
  - Relevance to abbreviated approval of subsequent (generic) drug
    - If no Data exclusivity (or after expiration)
- Clinical Trial Transparency

WHY?



- Publication problems
- Advertising
- Independent researchers

TYPES OF TRANSPARENCY

- Prospective clinical trial registration in online database
- Publication of summary results in online database promptly after clinical trials conclude

- Disclosure of underlying documents submitted to regulatory agencies, including trial methods, meta-data, and individual patient data

- Avoids outcome switching

- Avoid publication delay and publication paywall

- Permits independent assessment and maximum information about safety and efficacy

POTENTIAL FOR CONFLICT?

- Movement for publication of individual clinical data

- Domestic Actions

INTERPRETATION OF TRIPS

Basic Rules

- Final text to be interpreted in good faith based on "ordinary meaning" of words, and in light of broader context
- Secondary material s.a. negotiating history or subsequent agreements only to confirm interpretation

TRIPS specifically

- Flexibility exists for nations for undefined terms

TRIPS ART. 39

1. In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3

2.Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices[10] so long as such information [constitutes a trade secret]:

- 3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use.

- In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use

TRIPS ART 39(3)

- 3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use.
- In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use

- "unfair commercial use"
  - Prior draft:
    - "data may not be relied upon for the approval of competing products for a reasonable time"

TRIPS ART. 39(3) – SENT 2

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- General duty to "protect" data from disclosure, with 2 exceptions

- "Necessary to protect the public" exception
  - Context
    - Negotiating history
      - Prior draft only permitted disclosure if "indispensable to inform the general public about the actual or potential danger of a product"
    - TRIPS pmbl, articles 7-8
    - GATT/WTO
    - Doha Public Health Declaration

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- Protection against "unfair commercial use" exception = ?
  - Data exclusivity?
  - Use of data to approve another drug

- What country?

TRIPS VS.CANADA'S LAWS

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- Law permits Health Minister to disclose data if he/she subjectively "believes that the product may produce serious risk of injury to mental health"

- Law permits Health minister to disclose data to anyone who "carries out functions relating to the protection or promotion of health or safety of the public"

- Law does not require confidential agreement

- Any need to address general industry objections (that have evolved) and/or evolution in EMA position?

- Should other int'l issues beyond TRIPS be addressed?
  - i.e. investor-state dispute such as PMI v Australia or Eli Lilly v. Canada?

KEY INVESTMENT CLAIMS

- Expropriation
  - Roughly analogous to domestic taking, although can be broader
- FET
  - Since 2003:
    - "legitimate expectation" focus

CURRENT PAPER ORGANIZATION

I. Background
   A. Drug Approval and the Role of Clinical Data
   B. Drug Commercialization
II. Emerging Need for Transparency
   A. Evidence of the need for transparency
   B. Towards Broader Transparency
III. International Issues
   A. TRIPS interpretation
   B. Investor State possibility?
IV. Conclusion

THANKS!