Patients Involvement in Clinical Studies

Šarūnas Narbutas
Board member, ECPC

EUROPEAN CANCER PATIENT COALITION

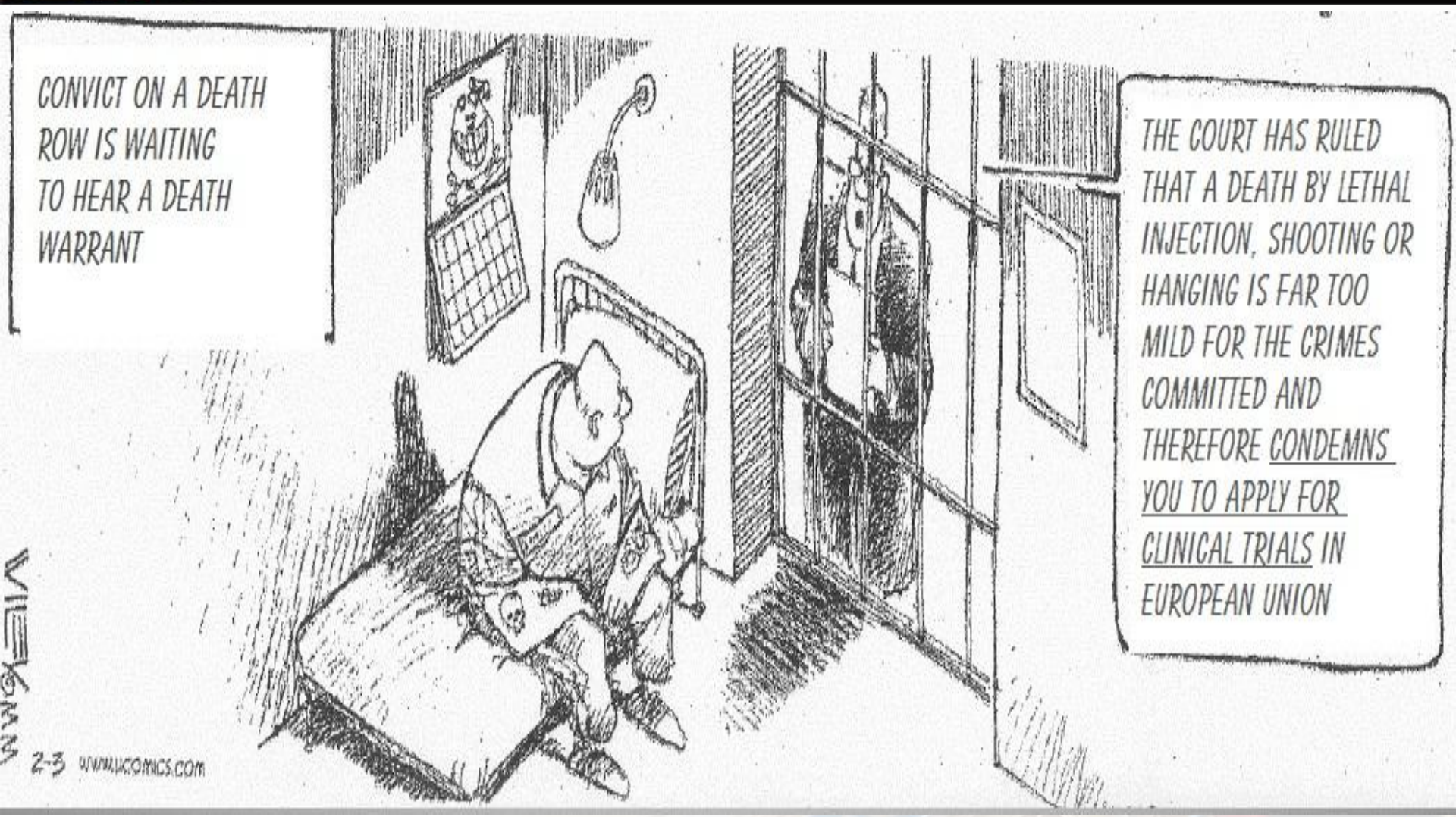
Clinical Studies from Patient Perspective

- Individual patient is **not aware** about EU health policy, nor EC initiatives: *(1)* Patient-Partner; *(2)* Value+; *(3)* Predict; *(4)* Respect
- Websites of clinical trials are **not patient - friendly**
- Enrolment procedures are **complex** and often not explained
- Proposal for revised CT directive **lacks vision** and does not assess needs of patient as a priority

Regulatory Perspective: USA

- Dr. Richard Pazdur, **director of the cancer drug office** at the Food and Drug Administration, said in a recent interview that the new wave of drugs in development — especially for intractable cancers like melanoma — might require individual evaluation.
- “This is an unprecedented situation that will, hopefully, be increasingly common, and it may require a **regulatory flexibility** and **an open public discussion**,” he said.

Regulatory Perspective: EU



Types of Patient Involvement

Source: Patient-Partner FP7 Project (2010)

Involving Patients in Decision Making Contributes to:

- Managing stakeholder **expectations**
  - → hope vs hype
- Enhanced **accuracy** of measuring outcomes that will be used for economic evaluation
  - → quality of life
  - → return to normal life
  - → impact on carers
  - → well-being rather than health
- Increased accuracy of economic modelling done by industry
  - → assuring that direct and **indirect costs** are included
  - → involving patients at the stage the issue is converted into economic model
- Enhanced quality of patient involvement during EMA / HTA review
  - → **patient reported outcomes**
  - → additional value for patients
  - → revealing additional evidence

Patients Vision for Revised CT Directive

- Randomized trials to be **accessible** to all patients concerned, without introducing multi-layer limitations
- Temporary registration to become **available** in late stage clinical trials for rare cancer treatments
- Complementary or alternative methods to be **monitored** besides the existing clinical trials
- Registries to be **linked** with tissue banks
- Facilitated **access** to off-label and early use of drugs

On the Bright Side

- Rituximab trial for Chronic Fatigue Syndrome succeeded with **3 patients** in a study
- patientslikeme™ will be adopted for Europe
- Patients number in Ethical Review Committees is **doubling** on a yearly basis

Help us

to

Help you

to

Help ourselves

Thank You

EUROPEAN CANCER PATIENT COALITION

Šarūnas Narbutas

sarunas@ecpc-online.org

www.ecpc-online.org

Nothing about us – without us!