FUEHRING Stefan (ENTR)

From: raymond bell [raymondb48@googlemail.com]
Sent: jeudi 17 décembre 2009 13:33
To: FUEHRING Stefan (ENTR)
Subject: PROTECTING HUMAN RESEARCH SUBJECTS IN THE EU

Dear Mr Fuehring,

I wish to raise a new issue in response to Consultation item 18: What other item would you like to highlight in view of ensuring the better regulation principles ?

PROTECTING HUMAN RESEARCH SUBJECTS. THE NEED FOR HARMONISATION OF LAWS IN THE EU MEMBER STATES FOR THE PUNISHMENT OF VIOLATORS OF THE EC CLINICAL TRIALS DIRECTIVE

PRIVIREAL was a European Commission Framework 5 funded project.
The project examined the implementation of 95/46/EC in relation to medical research and the role of ethics committees.

One of the most striking facts to emerge from the Privireal report was the great disparity between the Member States on
how medical professionals, and others, are penalised for violating medical research ethical guidelines.
Violations could be carrying out clinical trials without the consent of the patient, or not reporting the clinical trial to a research ethics committee.

Privireal makes a country by country survey of how complaints of unethical research are handled, and what legal
provisions are made for the punishment of offenders, ref:
www.privireal.org/content/rec/countries.php

I will give one example of two neighbouring countries: In Sweden violators can face a term of imprisonment of up to six
months imprisonment. In Finland violators may only be punished by a fine. No reference is made to detention.
Clearly, it would be better to carry out unethical medical research in Finland than in Sweden.

WHAT ACTION WOULD I LIKE THE EUROPEAN COMMISSION TO TAKE ?

To work towards harmonisation of national laws in the Member States, for the punishment of violators of the Clinical Trials Directive 2001/20/EC
In particular, the aim should be to have similar penalties for the carrying out of clinical trials, without the consent of the
patient. Today, we have a situation which encourages clinical trial "location shopping." This is where international drug
or manufacturers of medical devices may choose locations not because of the best services, but where national laws
are the most lax and punishments the least.

I will be glad to answer any questions or give further evidence on this important issue.

Yours sincerely,

Raymond Bell