May 12 th 2011 Copenhagen.

To :

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL
Public Health and Risk Assessment
Pharmaceuticals
Brussels, 09/02/2011
SANCO/C/8/PB/SF D(2011) 143488

REVISION OF THE 'CLINICAL TRIALS DIRECTIVE' 2001/20/EC CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION

Dear Sir,

I thank you for the opportunity to let my voice be heard as an individual Danish citizen, being an individual consumer stakeholder. If by any chance you think I am not entitled to that ,please, let me know.

For many years I have been trying to work for the protection of individual civil rights in The Danish Health Care System.

www.bioetikkonvention.dk and
www.bioetikkonvention.dk/ak

Some initial comments:

Possible grey areas should be carefully avoided: emergency research – transplants, brain deaths etc- !! where does the one start and where does it end!

I think an EU referendum is necessary if you want to make a Directive with the below content legal.

I elaborate further below after qoute of "consultation item no. 15 "

emergency clinical trials,

"Consultation item no. 15: Do you agree with this appraisal? Please comment.
2.6. Emergency clinical trials
This issue has been extensively explored in the 2009/10 public consultation (section 6) and discussed by stakeholders in their responses.
In order to address the situation, the Clinical Trials Directive should take into account internationally agreed texts (Declaration of Helsinki of the World Medical Association, the Convention on Human rights and Biomedicine of the Council of Europe, and the Guidelines on Good Clinical Practice of the

International Conference on Harmonisation, 'ICH'). All these texts explicitly address the issue of emergency clinical trials.
In view of these texts, the Clinical Trials Directive could be amended to the effect that the informed consent and the information from the investigator may take place during or after the clinical trial under the following conditions:

The trial subject is not in a state to give informed consent;

The physical or mental conditions that prevents giving informed consent is a necessary characteristic of the research population;

Because of the urgency of the situation, it is impossible to obtain informed consent from the parents/legal representative (in case of adults) in accordance with the Clinical Trials Directive, and it is impossible to give the information, as provided in the Clinical Trials Directive;

The trial subject has not previously expressed objections known to the investigator.

In this case, the informed consent would have to be obtained as soon as possible from the parents/legal representative (in case of adults) or the trial subject, whichever is sooner. The same holds for the supply of information to the trial subject.
All other rules for clinical trials (approval, safety reporting, etc.) would remain applicable. "

Some comments:
The specific Danish situation is characterized by self-rule by physicians. They are almost one hundred per cent organized under The Danish Medical Association (DADL) . Medical self-rule in Denmark is a fact. A new Bill L 169 which deals with among other things emergency research is a 72 page Bill made by a representative of trust from DADL and civil servants in The Ministry of The Interior and Health. The Bill has not been subjected to a genuine public hearing in the media etc. The fact that emergency research without consent has been going on for years in Denmark is unknown to the general public.

The absolute minimum shield for humanity and individuals against research in :

the Convention on Human rights and Biomedicine of the Council of Europe is:

openness, publicity, debate. (guidelines and article 28)

In Denmark there´s no such openness,publicity and debate seen from the point of view of ordinary citizens.
<u>The Danish Parliament is a one chamber Parliament.</u>
In the 1953 revision of The Danish Constitution ,Article 42 , was supposed to to function as a second chamber, upper house, if you like, by opening up for the possibility of referendums about certain bills if a certain amount of Parliament members demands it .
To my knowledge Article 42 has never been used- Our one chamber Parliament´s argument for not putting it into use is that issues are too complicated for a referendum. Important health care decisions are put forward by DADL to the government and DADL stands firm when it comes to having a monopoly on medical issues even when they are being very broadly interpreted as such.

The Danish health Care system is public. The right to a second opinion is not popular with DADL and its collegial rules of loyalty. Danish citizens are in more than one respect

subjects- subjects and trial subjects. Research and general treatment now walk hand in hand. Difficult to escape research in a public health care system, since research is the first priority of DADL and the first priority when it comes to advancements.
The result is far too many superfluous research projects far less individual treatment, far less service and attention given to individual citizens.

So a new Directive with EU quota for research protocols and non-interventional projects etc. for EU countries according to number of inhabitants. Thank you. Danes are in special need protection.

Convention on Human Rights and Biomedicine of the Council of Europe :

Article 2 : Primacy of the human being.
The interests and welfare of the human being shall prevail over the sole interest of society or science.

I fail to see how research without consent from the subject himself, family or friends can be in accordance with article 2.

In Denmark where subjects are not provided with a" contact point where he may obtain further information" (Directive 2001/20/EC article 3,4) and where information in general and to individuals is not prioritized we need you in EU to give us better protection. Is it not possible to make article 3,4 more precise ??

If emergency research as proposed will be legalized in a new EU Directive the individual European must be better protected. It is important to emphasize that emergency research is to be a rare exception . (quota)

Information during and at any rate after "treatment" must be in written form and must be given to the subject and to an independant authority too within say three days . There must be an obligation to make the number of subjects , casualties, deaths, and results of such emergency projects public in quarterly/annual reports (without delay and protraction) from that independant authority.

Independant means governed by a non-medical person preferably a high-ranking and very competent and reliable jurist assisted by non-medical civil servants. Written information is a "must" for a number of reasons ,e.g. for security reasons- as a brake to stop superfluous projects – and in order to create an incentive for researchers to communicate better to the population (to their subjects) which they are supposed to serve.

Yours sincerely

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(retired lecturer working at home).

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