EMF: Evaluating Evidence and Use of the Precautionary Principle. David Gee, Science, Policy,

Innovation, EEA, Copenhagen.

Two Questions to help structure the debate:

- 1. Why did the EEA in 2007, and Professor Herberman in 2008 in the Congressional hearing on RF conclude that there was a sufficiency of scientific evidence to justify reducing the head exposures to RF energy from mobile phones?
- 2. To whom or to what shall we give the benefit of the scientific doubt about head tumours and mobile phones: to the phones or the phone users?

What is the EEA and what does it do?

- An EU institution that is "independent" of its main clients: the Council of Ministers, the Member States, the EU Parliament, and the EU Commission.
- We provide data ,information, and knowledge about the environment and its health impacts; no policy making or policing, or basic research.

Who is Prof Herberman?

- Founding Director, University of Pittsburgh Cancer Institute, 1985-; Hillman Professor of Oncology; Prof of Medicine; Associate Vice Chancellor for Cancer Research: responsible for c3000 cancer experts and other staff; ex-President of the Association of American Cancer Institutes; author of 700+ peer reviewed articles; associate editor of 10 peer major cancer scientific journals; etc.
- Has knowledge of cancer but no expertise on EMF.

EEA "Early Warning" on EMF, Sept 2007

"Appropriate, precautionary and proportionate actions taken now to avoid plausible and potentially serious threats to health from EMF are likely to be seen as prudent and wise from future perspectives"

(Prof. Jacquie McGlade, Executive Director, EEA, September 2007).

Conclusion of Prof Herberman on head tumours and mobile phones

• Afrer critical evaluation of the evidence, and consultation with cancer experts in the US and Europe I "recognised that there was sufficient evidence to justify the precautionary advisories that had been issued in other countries, to alert people about the possibility of harm from long term frequent cell phone use, especially by young children....cell phones may be a substantial risk to public health".

(Evidence to US Congress, Sept 25th 2008)

Some relevant Knowledge and Judgements that underpin the EEA and Herberman views

- 1. The Disease process
- 2. The Tissue Heating paradigm and Cell Signalling
- 3. The power and perils of prevailing paradigms
- 4. Mechanisms of Action
- 5. The Latency Traps
- 6. Arbitrary "safety factors"
- 7. Weights for Human, Animal, Cell evidence?
- 8. Weights on consistency and biological plausibility?
- 9. A sufficiency of evidence for whom and for what?
- 10. The relevance and utility of the precautionary principle



JSERSE" PMOCRSS PREPARATION INITIATION PROMOTION RETARDATION PROGRESSION DISEASE SEVERITY PREVALENCE

WITH **MULTIPLE CAUSES**; SEVERAL PATHWAYS;

AND IMPORTANCE of TIMING

2. The Tissue Heating paradigm...?

The ICNIRP guidelines for limiting unacceptable RF exposures are :

" based on short term, immediate health effects, such as stimulation of peripheral nerves.....and elevated tissue temperatures". (ICNIRP Guidelines for limiting exposures to time-varying electric, magnetic and electromagnetic fields(up to 300GHz)", Health Physics, 1998, Vol 74, No. 494-522, p496.)

...Or the disruption of cell signalling?

The Biological Cell Communications systems of people, which works via exquisitely tiny and timed chemical and electrical impulses, is more likely than not to be harmfully disrupted by non-ionising radiations at energy levels below that needed for tissue heating.

3.Scientific Paradigms prevail: then often perish.

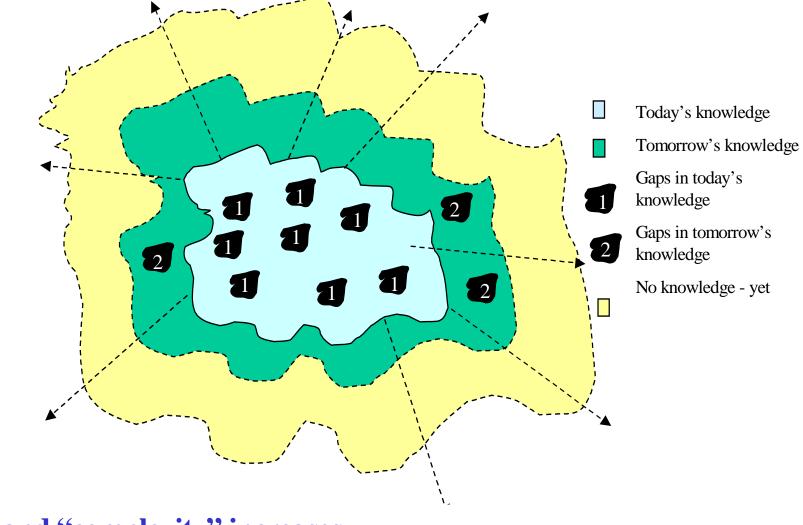
"A new scientific truth does not triumph by convincing its opponents and making them see the light but rather because its opponents eventually die, and a new generation grows up that is familiar with it" *(Max Planck, Nobel physicist, 1949)* IPPC advice to its scientific authors about the perils of prevailing paradigms

Be aware of:

"the tendency for a group to converge on an expressed view and become over confident in it. Views and estimates can also become anchored on previous versions, or values, to a greater extent than is justified".

(Guidance Note on Uncertainty to its 4th Assessment authors, Intergovernmental Panel on Climate Change, 2005)

'Knowing' and not knowing: A dynamic expansion.....



....and "complexity" increases.

4.The Importance of "Mechanisms of Action"

- MoA takes a long time to appear eg cholera, smoking, DES pill, BSE
- If present ,great: if absent, put little weight on it as evidence *against* causality.
- If absent, as is the case with EMF, then expect both negative animal evidence and uncertainty about which exposure metrics are relevant.

SCENIHR 07 on animal evidence..

- *Animal cancer studies have not provided evidence that RF radiation could induce cancerThe open questions include adequacy of the experimental models used...."* (p 28).
- "While it seems appropriate to perform experimental studies using pure experimental RF fields ,it may be appropriate to emulate the complex modulation patterns and intensity variations typical to real mobile phone use in future studies". (P 23).

5. The Latency Traps

- 1. Epidemiological Observation must be for at least as long as the average latent/induction period for the cancer of concern eg little evidence for lung cancer in asbestos workers found till 25 years from first exposures.
- 2. Technological change means that "safety today" can be asserted in face of strong evidence of harm from yesterday's exposures (but "no threshold" for carcinogens can undermine that assertion).

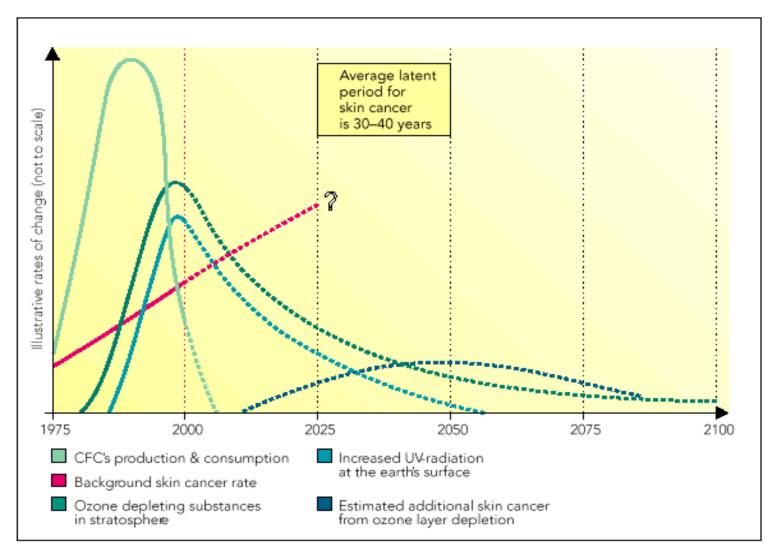
Example of the "Latency Trap 2"

 "One hears, generally speaking, that considerable trouble is now taken to prevent the inhalation of the asbestos dust so that the disease is not so likely to occur as heretofore".

(Dr Murray, evidence to UK Government Inquiry into Industrial Diseases, 1906).

Asbestosis was not classified as an industrial disease by the Committee...

CFCs Chapter: Skin Cancer and Time Lags



6. "Safety Factors" for exposure limits are arbitrary judgements: and exposure limits can change mainly

via technical feasibility, not scientific evidence

• Conventionally applied "safety factors" such as the 10x for animals to humans are arbitrary and imprecise judgements that are better than nothing but which are very crude aproximations to complex biological realities

Eg thalidomide was negative in rodents but positive in guinea pigs; and betanapthylamine was negative in rodents but positive in dogs

 Swedish Radiation agency decision to lower exposure limits for VDUs by <1k x was based on weak scientific evidence but strong technical feasibility-similar to mobile phones now?

7. Weights for Human, Animal and Cell Evidence?

How reliable is negative animal evidence in face of strong human evidence? Or vice versa?

"I would need a well designed study of 40K people followed for 30+ years, with accurate data on the exposed and not exposed, with a negative result, before I would confidently over rule the positive animal evidence"

(Prof R Peto, epidemiologist, US Congress hearings on occupational cancer, 1978).

8. Consistency and Biological Plausibility

 "Consistency in nature does not require that all, or even a majority of studies, find the same effect. If all studies of lead showed the same relationship between variables, one would be startled, perhaps justifiably suspicious"

(Prof Needlemann (1995) "Making Models of Real World events: the use and abuse of inference, Neurotoxicology and Teratology, vol 17, no. 3.)

WHO and ELF: simplistic models and biological implausibility?

- For example, the WHO review of power line ELF states that:
- "The absence of a clearly elucidated, robust and reproducible mechanism of interaction of low level magnetic fields with biological systems deprives epidemiological studies of focus in their study design and hinders their interpretation. Based on known physical principles and a simplistic biological model, many authors have argued that average magnetic fields of 0.3-0.4 microTesla are orders of magnitude below levels that could interact with cells or tissues and that such interactions are thus biophysically implausible".("Extremely Low Frequency Fields, Environmental Health Criteria, No 238, WHO, 2007, p274).

Bradford Hill on biological plausibility

"this is a feature we cannot demand. What is biologically plausible depends upon the biological knowledge of the day".

(Bradford Hill, The Environment & Disease: Association or Causation?", Proc Roy. Soc Med ,1965, 58, 295-300).

the classical "criteria" for "causation":

Strength of association Consistency Temporality Specificity (of effect) Biological gradient Biological Plausibility Coherence Analogy Experiment (ie prevention worked)

Bradford Hill, The Environment & Disease: Association or Causation?", Proc Roy. Soc Med ,1965, 58, 295-300.

Bradford Hill recognised his "criteria" were asymmetrical

The *presence* of the "criteria" provides good evidence *for* causation; their *absence* may not provide good evidence *against* an real association.

And ,given multi-causality and complexity, *this asymmetry is now larger than in 1965*

9. Sufficient evidence for action?

"The Case for Action"

".... we must surely ask what is involved in our decision... it almost inevitably leads us to introduce *differential standards* before we convict."

Bradford Hill. 1965

Bradford Hill on different levels of evidence

- "relatively slight evidence" for pregnancy pill ban
- "fair evidence" for reduced/eliminated exposure to probable carcinogenic oil at work
- "Very strong evidence" for public restrictions on smoking or diets.

Some Strengths of Scientific Evidence

- Beyond all reasonable doubt (criminal law)
- Reasonable certainty (IPCC, 2007)
- Balance of probabilities/evidence (IPCC,2001)
- Strong possibility (IARC on ELF 2002)
- Scientific suspicion of risk (Swedish Chemicals Law: SCENHIR 2007?)
- "Pertinent information" (WTO SPS justifying MS actions to protect health

Choosing an "appropriate " strength of evidence for action is an Ethical issue

Who benefits and who gains from being wrong in acting, or not acting, early enough to prevent harm?

Short term, specific, economic interests? Or long term health/ecosystem/general welfare interests?

10 The Precautionary Principle-EEA working definition

"The PP provides justification for public policy actions in situations of *scientific complexity, uncertainty and ignorance,* where there may be a need to act in order to avoid, or reduce, potentially serious or irreversible *threats* to health or the environment, using an *appropriate level of scientific evidence,* and taking into account the likely *pros and cons* of action and inaction".

Some myths about the PP

- It does not mean a ban-no action can also be fine-it depends on specific case.
- Strong evidence of harm may not mean strong action to remove exposure eg cars.
- It needs some scientific evidence, not just emotion
- The evidence need not be quantitative, or from a majority of scientists-qualified minority views can be sufficient

BioInitiative 2007

"The BioInitiative report compiles individual contributions from different EMF experts, each of whom summarises the relevant and largely peer reviewed science in their own areas of expertise. It is not a review of the overall evidence on EMF but a collection of separate contributions from experts who feel that aspects of the relevant science are not recieving the attention that they merit"

(Jacquie McGlade, Executive Director, EEA, September 2007).

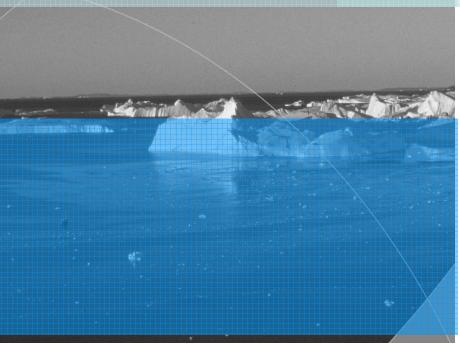
"Disagreements are at the heart of good science"

"Other scientists disagree with the Bioinitiative points of view: but disagreements are at the the heart of good science,particularly when ,as is currently the case for EMF, the science is at a rather immature stage of development" (JMG).

EEA contribution to BioInitiative Report

"The EEA's contribution to the BioInitiative report was a chapter on the history and general application of the precautionary principle to a number of well known hazards for which there had been, and in some cases still is, much scientific uncertainty. The chapter summarised the main messages from our report, "Late Lessons from Early Warnings: the Precautinary Principle 1896-2000", (EEA 2001).

⁴ Late lessons from early warnings the precautionary principle 1896-2000'







Applying lessons from history..

The point of the chapter was to illustrate how past uncertainties had been dealt with so as to provide lessons that may be helpful in dealing with current hazards for which there is much scientific uncertainty as well as high stakes, both health and economic.

EEA: "Early Warning" about Possible Cancer Hazards of RF

"Over the last two years the epidemiological evidence of possible cancer risk amongst the 10 year plus mobile phone user group, has got stronger. It is now also supported by preliminary scientific reports on the damaging effect to cells of RF and ELF exposures. This is a cause for concern, given the widespread and generally rising exposure of the public, especially children, to RF from mobile phone technology".

(Jacquie McGlade, Executive Director, EEA, September 2007).

EEA: Advice to Mobile Phone Industry: "A Prudent Response to the Evidence is Needed".

"The evidence, though necessarily limited at this point in time, *is sufficient* for health authorities to consider advising the reduction of RF exposures, where feasible. I note that such advice was issued by the German Federal Office for Radiation Protection in July 2007, and the French Ministry of Health , January 2008. It would also be prudent to reconsider the adequacy of the ICNIRP Guidelines on **Exposure limits of 1998 to protect public** health, especially of vulnerable groups". (JMG, Jan 2008)

SCENHIR 2007 on RF: "The perils of the Precis"?

- "Since 2001 extensive research has been conducted.. no health effect has been consistently demonstrated at exposure limits below the limits of ICNIRP".
 Abstract..p4
- .for "less than 10 years" exposure Conclusions p 28
- "For longer term use, data are sparse, since only some recent studies have reasonably large numbers of long term users. Any conclusion therefore is uncertain and tentative".

Conclusions p28

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