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Is this input submitted as an organisational or individual response? Individual

Are you happy for your response to be published by the Academy? Yes

Email from John Urquhart to Claire Cope

27 July 2015 19:37

RE: Call for evidence- How does society use evidence to judge the risks and benefits of medicines

Dear Claire,

Thank you for the note. My response to your 'call for evidence' is the following.

The British Medical Society published a monograph called Living with Risk in 1987. See this URL: <http://www.worldcat.org/title/living-with-risk-the-british-medical-associationguide/oclc/15628884>. That monograph addresses the question you are asking.

About 3 years before the aforesaid monograph was published, Prof. Klaus Heilmann, MD (U. of Munich) and I wrote a book called RISK WATCH, published by Facts on File in both the US and the UK. Our aim in that book was to describe an approach to the measurement and public communication of risk that avoids the often-major difficulties one faces in the effort to quantify risk. Our aim was to put the measurement of risk in terms comprehensible to educated people, but not requiring advance education in actuarial science. RISK WATCH described a then-novel means for quantifying risk, which we call the 'safety-degree scale'.

Together with a Dutch colleague, Prof. H.A.J. Struijker-Boudier, professor of pharmacology at Maastricht University, we also wrote a Dutch version of the RISK WATCH, which was published in the Netherlands in 1984 under the title "Risico's Meten", which means 'the measurement of risk'. The title of the Dutch version is related to a centuries-old Dutch proverb: "meten is weten", loosely translated as 'measurement brings wisdom'. Because of their centuries-long efforts to exclude the ocean, driven by its winds and tides, from over-running their land, the Dutch have unique perspectives on the maintenance of an apt balance between costs and results of actions intended to reduce the risk of inundation.

The publication of 'Risico's Meten' preceded by 2 years my appointment as Extraordinary Professor of Pharmacoepidemiology at Maastricht University. Pharmaco-epidemiology is the relatively new discipline that concentrates on the population-based measurements of benefits and risks of medicines. Its name was coined by W.H.W. Inman, MD, who was the first-ever professor of pharmaco-epidemiology and who had been a protégé of Prof. Sir Derek Dunlop, who organized the Committee on the Safety of Medicines in the UK. Dunlop encouraged Inman to initiate what became the Yellow Card system for the reporting of seemingly adverse reactions to prescription drugs. Prof. Inman, who was long-confined to a wheelchair, died about a decade ago. Inman's professorship of pharmaco-epidemiology was at the University of Southampton. I am the 2nd-ever professor of pharmaco-epidemiology, though I had to retire from my professorship at Maastricht University when I turned 70, back in 2004. (Mandatory retirement ages are called 'age-discrimination' in the US, and, as such, are illegal, but the US has 180+ medical schools, and

thus ~180 professorial chairs in each medical area; the Dutch have only 8 medical schools, and justify mandatory retirement ages as a means of facilitating career development for young faculty.)

The British Medical Society monograph had this to say of RISK WATCH: "Several books offer an overview of risk related matters. The easiest for the non-technical reader is *Risk Watch*, a first-class introduction to the topic and, as we have already noted in this book, a major contribution to discussion on how degrees of risk should be publicly represented." It was also favorably reviewed in JAMA, the N. Engl. J. of Medicine, and Nature.

RISK WATCH is out of print, but used copies are readily available at Amazon.

A fundamental complication in risk analysis is the role played by time, i.e., the duration of exposure to the hazardous activity in question required to elicit and/or reveal measurable adverse consequences. It can vary from minutes to decades, as illustrated by the contrast between the risk of early death from inhalational smoking of cigarettes versus the risk of early death from air travel: death from inhalational cigarette smoking usually takes several decades, or more, of exposure to inhaled cigarette smoke before it occurs, whereas death from an air crash can occur within minutes of one's first exposure to flight.

Both RISK WATCH and LIVING WITH RISK were written about 30 years ago, and are thus not 'new', but newness is not an automatic virtue in an intellectually complicated field, which is an apt description of the field of evaluating and communicating medical risks. Also 'not new' is the need for sound quantification of risk arising from use and mis-use of potentially hazardous medicines. In today's world, pharmaco-epidemiology is, or ought to be, the discipline most relevant to your question. The person who has been in the forefront of intellectual leadership is Professor Samy Suissa at McGill University School of Medicine, in Montreal, Canada. Here are his particulars:

Suissa, S

Professor, Department of Epidemiology, Biostatistics, and Occupational Health Biostatistics; pharmacoepidemiology; methods for the design and analysis of epidemiologic studies.

I hope that this is helpful. If I can be of any further help in this matter, I would be pleased to do what I can.

Best wishes,

John

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Attached Documents:

- Companies Stall on Reporting Drug Deaths, *Medscape*, July 27, 2015.