

Mad Medicine: Do conflicts of interest drive you crazy?



24 September 2011



EVENT MEMO

This year, HAI Europe's Annual Open Seminar took a closer look at the conflicts of interest that persist in the world of psychiatric medicines research, practice and policy. This event was co-hosted by the Critical Voices Network Ireland (CVNI), a network of citizens who are interested in considering and developing responses to human distress beyond the narrow bio-medical one, responses that are creative, enabling, respectful and firmly grounded in human rights.

The Open Seminar aimed to promote greater public awareness and debate about the Irish and European drug regulation systems, and conflicts of interest in medicines regulation. The seminar was divided into three panels, each addressing potential conflicts of interests in various phases in the pre- and post-marketing life of drugs, including research, publication of research findings, licensing for sale, promotion, reimbursement, prescribing and monitoring of adverse drug reactions.

In her opening remarks, Teresa Alves, Coordinator of HAI Europe, warmly thanked the invited speakers and emphasised that the most important objective of the day was to share experience and expertise.

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Agency for
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This document arises from the HAI Europe's Operating Grant 2011, which has received funding from the European Union, in the framework of the Health programme. The views expressed in this publication are those of the author, who is solely responsible for its content. The Executive Agency for Health & Consumers is not responsible for any use of the information herein.

Dr. Orla O'Donovan (co-organiser, University of Cork) welcomed everyone to the seminar which was organized to “raise awareness and raise public discussion about psychiatric drugs.” She also mentioned the absence of the Irish Medicines Board (IMB), marked by the presence of a symbolic empty chair placed alongside the speakers and expressed her hope that the IMB would take an interest in the day's deliberations.

Panel 1: What are conflicts of interest and where can they arise in the “biography” of a medicine?

The first three speakers, John McCarthy, Richard Patterson and Agnes Higgins presented case studies of potential conflicts of interest issues arising in Irish psychiatric medicine. Barbara Mintzes and Adriane Fugh-Berman then discussed where conflicts of interest can arise in medicines regulation and marketing.

Agnes Higgins (Irish Institute of Mental Health Nursing) described a new reality where nurses have ever increasing power over prescriptions in a world where pharmaceutical companies seek to influence prescribing patterns. She cited examples of how drug companies attempt to influence nurses, such as through industry-sponsored conferences featuring only pre-approved presentations, gifts and free lunches offered at educational seminars, and how the current code of conduct in Ireland inappropriately regulates gifts from patients, not from the pharmaceutical industry. “Are people aware of how much we are influenced?” she asked.

Richard Patterson (Critical Voices Network Ireland) told the audience how conflicts of interest in psychiatry changed the biography of his life. His two-part presentation first dissected a promotional leaflet for patients with bipolar disorder, focusing on the leaflet's unquestioning acceptance of the diagnosis as fact and its excessive reliance on the medical model as the only path to wellness. In the second half, he shared excerpts of correspondence between his doctors to illustrate their belief in his mental illness when his professional and academic achievements suggested otherwise.

John McCarthy (Critical Voices Network Ireland) illustrated the most tragic consequence of irrational use of medication: the death of a four-year old child, Rebecca Riley, as a result of being medicated for ADHD. He questioned the role of drug companies in promoting medicines, the role of physicians and psychiatrists as compliant prescribers and the role of patients as victims. He encouraged greater openness, specifically calling on the media to seek evidence that mental health is a biological condition from scientists.

Barbara Mintzes (University of British Columbia) spoke about conflicts of interest in regulation and the meaning of medicines 'effectiveness' and 'safety'. She explained that decisions about which medicines are sold on the market are a product of science and judgment – and either aspect is susceptible to undue influence by industry financing of regulation, clinical trial design, conflicted expert advisors, widespread secrecy, and the revolving door¹. Full access to information about the decision makers and the public financing of regulation are two recommendations she offered to improve the governance and the science behind regulatory decisions.

¹ The revolving door refers to the case where people who worked for industry then enter public service and regulate industry they used to work for. Or they leave their regulatory role to work for the industry having insider knowledge.

Adriane Fugh-Berman (PharmedOut.org & Georgetown University) addressed the widespread practice of promotion to healthcare providers through industry-sponsored key opinion leaders² and ghostwriting³. Unlike a medicine, she underlined that it is not illegal to market a disease. She further noted that three times more is spent on marketing a drug prior to the release of a drug than in the first year of it being on the market and that anti-psychotics are the biggest selling drug class in the USA and are sold mainly off label⁴. She added that one in ten boys in the USA takes some form of psychiatric drug. With these deceptive marketing strategies targeting healthcare providers, is transparency really enough to ensure doctors make the best decisions for their patients?

In the Q&A session, the audience raised issues of the permanent damages left by psychiatric medicines. John McCarthy explained that the autopsy of a person who took anti-psychotic medicines for schizophrenia shows signs of lesions in the brain while no lesions are detected in the brain of a non-medicated person who was diagnosed with schizophrenia. He further emphasised the role of academia in speaking out as some individuals who wish to do so are bound by legislation and cannot speak in the public domain about what is going wrong. A member of the audience enquired on the number of research studies that need to be carried out in order for a medicine to be approved. Adriane Fugh-Berman explained that the number of clinical trials required depend on the medicine being tested. In some cases, only one trial is required. Also, today it is not necessary to show a new medicine is better than an existing treatment: simply comparing it to a placebo is sufficient.

Panel 2: Conflicts of Interest and Psychiatric Medicine

David Healy (Department of Psychological Medicine, Cardiff University) noted that “cardinals of psychiatry and medicines” accepting sums of money from pharmaceutical companies can have a well-known impact on their views and practices. But, this conflict of interest is not the only problem in psychiatric medicine. There is also a case for academics to demand that clinical trial data be made public. Using Prozac as a main example, he highlighted how raw clinical data can be manipulated while divergent conclusions are subsequently published in scholarly journals. Consequently, the harmful effects of antidepressants can be bypassed by regulators and prescribers. The cases of Shane Clancy and Yvonne Woodley, two individuals who committed suicide while/after taking antidepressants, illustrate the drastic and very real consequences of data secrecy.

Lisa Cosgrove (University of Massachusetts- Boston) spoke about conflicts of interest and the Diagnostic and Statistical Manual of Mental Disorders (DSM). She warned of a pattern of institutional corruption at the level of the American Psychiatric Association. Psychiatrists who work on the DSM Task Force to establish and review the definitions and the symptoms of mental illnesses also have privileged relationships with pharmaceutical companies who sell medicines to treat mental illness. This leads to a conflict of interest that transparency alone cannot mitigate. In her view, it is absolutely essential to side-step the source of the bias.

² Key opinion leaders are highly regarded researchers or physicians who are selected to be *thought leaders* by drug makers because their message supports the company's marketing strategy.

³ Ghostwriting is the publication of key marketing messages by influential academics who are paid by the pharmaceutical industry, which can downplay adverse effects and/or attack competitors.

⁴ Off label refers to the practice of using a medicine for a condition other than the one it was approved to treat. In the example above, anti-psychotic medication was promoted to treat insomnia.

Ivor Browne (Critical Voices Network Ireland & former psychiatrist) emphasized the importance of a holistic approach to wellbeing and mental health. He reminded the group that no drug or procedure can teach you how to run your life. Rather than following only the medical model, we need to move in the direction of supporting people to manage their health. “Foster wellness rather than focus on sickness,” he advocated.

Panel 3: How can conflicts of interest be solved in medicines regulation?

Nessa Childers (Labour Party of Ireland, Member of the European Parliament for Ireland, Socialists & Democrats) a former psychotherapist, discussed the ethical issues that arise from dealing with lobbyists and how conflicts of interest can be solved in medicines regulation. She noted the importance of listening to the views of both profit-driven companies and public interest groups as they offer expertise politicians do not have and pointed to the need for Members of the European Parliament (MEPs) to disclose who they are meeting with, information that she already shares on her website.

Furthermore, while it is now mandatory for all interest representatives to register in a public database in order to enter the European Parliament, this does not prevent un-registered lobbyists from simply meeting MEPs outside the Parliament. In addition, transparency of interest groups must also extend to patient organisations that should disclose their sources of funding. As has been mentioned throughout the Open Seminar, she cautioned that these groups may unconsciously be adopting the line of thought of their funders.

Noël Wathion (European Medicines Agency) introduced the EMA’s new policy to handle conflicts of interest⁵ aimed at minimizing the risk of undue influence on the medicines regulation while still securing the best scientific expertise. While the EMA now intends to publish all declarations of interest provided by experts, it was up to the general public to examine these and check the veracity of the information provided. He highlighted that the issue of conflicts of interest is not a “black and white business” and that while transparency does not (re-)solve competing interests, it is an important step in the right direction.

Question & Answer with Noël Wathion (EMA)

Does the EMA sanction experts who are dishonest in their declaration of interests?

Mr. Wathion explained that no individual can become involved with the EMA unless they go through a screening process. The EMA is currently working with the European Commission on addressing the problem of fraud. While there are no financial sanctions, the expert guilty of dishonesty can never again be involved with the EMA.

What criteria are considered when selecting a ‘good’ expert?

Mr. Wathion explained that evaluating the quality of an expert is not an exact science. While the EMA’s Management Board is the body that examines the experts’ CV, it cannot limit those experts proposed by Member States, unless more experts are needed in a particular situation, in which

⁵ Policy effective: 29 September 2010 URL:

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/10/WC500097905.pdf

case the EMA then appoints additional experts. It is therefore important for the public and European associations to verify the declarations of interest that are now published online by the EMA.

Adriane Fugh-Bermann acknowledged that as experts are put forward by member states this limits the EMA. However, she emphasised the fact that experts are manufactured, not born as such. In the USA, journalists started a list of experts with absolutely no conflicts of interests with the pharmaceutical industry. With almost 100 names, this list refuted the common myth that “unconflicted” experts do not exist. “This is a lie made up by industry” she added and suggested that such a list be started in the EU.

Has the EMA met any resistance regarding its revised policy on handling conflicts of interest?

Mr. Wathion explained that the EMA did not consult the pharmaceutical industry in the revision process, which ran from 2008 to 2010. During the last Management Board meeting some members still believed the policy was not going far enough, while others thought it demanded too much.

Public access to clinical trials reports is a big step in the right direction. However, there are still concerns that this information would only be made public once the medicine had already been approved and was available on the market. Isn't that too late?

Mr. Wathion pointed out that unlike the US Food and Drug Administration (FDA) which is the sole regulatory body overseeing medicines approval in one country, the EMA has to work with 27 different governments and communication in multiple languages. He also mentioned that in 2012 the EMA may introduce a new concept of public hearings in a similar way as they are used by the US FDA in order to fulfill its role as regulator and protector of public health.

Closing comments by Doug Ross, Critical Voices Network Ireland (CVNI)

Doug Ross stressed the extreme power of the pharmaceutical industry which was using its expertise for marketing. He further noted that it was “disturbing that we had an empty chair,” referring to the absence of the Irish Medicines Board at this event.

Acknowledgements

We would like to thank CVNI and the College of Cork for hosting this event within their network and their campus. Dr. Orla O'Donovan, Ms. Lorraine Schwanberg and Ms. Rose de Groot, all from the HAI Europe network, were invaluable in organising this Open Seminar.

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