

WHO/SDE/ETH

**Monash/WHO Fellowship**

Report for Monash University

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Internship: April-June 2007

My internship represented the first time a Monash intern had been placed within the Ethics and Health Unit, which forms part of the Department of Ethics, Trade, Human Rights and Health Law (ETH) at the World Health Organisation. During my time within this unit both Dr Andreas Reis, and Dr Marie-Charlotte Bouèsseau, the two technical officers of the unit, supervised me.

The Ethics unit engages with a broad range of issues. Current concerns are the building of infrastructure in the ethical review of clinical trials in developing countries; an analysis of the ethical issues that an influenza pandemic would raise; and the ethical issues raised by a lack of access to critical HIV medication.

I felt very lucky to work within this unit, for many reasons. Not only is there a broad range of possible projects to involve yourself in, there is a lively intern community in the ETH department, and added to this, Doctors Reis and Bouèsseau are extremely supportive of, and value the contributions of the interns. They were conscientious about engaging us in practical, worthwhile projects, actively seeking to match an intern's interests and skills with appropriate projects, even if it meant placing us outside of the department.

My work at WHO fell into two major components. One project concerned work related closely to my thesis area – the ethics of the pharmaceutical industry, while the other project was a secondment to the Global Forum on Bioethics in Research, housed in the offices of COHRED, a ten minute walk from WHO HQ. In addition to these areas, I also had the privilege to be involved in the World Health Assembly in May, and a meeting of the bioethics unit of the Council of Europe in Strasbourg in June.

On my arrival at WHO, Dr Bouèsseau was keen to find out my areas of interest and skill. Once she identified that my thesis area concerned ethics and the pharmaceutical industry, she put me in touch with Dr. Guitelle Baghdadi-Sabeti in the Medicines Policy and Standards department. Dr. Baghdadi-Sabeti required assistance in the development of two outcomes: An annotated bibliography of key articles concerned with corruption in the public administration of pharmaceuticals, and the creation of an Endnote database/library along similar lines, but with a broader scope. Both items are intended to be used as research material for both WHO member countries and staff, and more particularly as tools for developing countries, highlighting for the governments of those countries key areas susceptible to corruption in pharmaceutical administration.

Over the 3 months I was at WHO, in the latter half supported by a second intern, Stacy Yeh from the University of Toronto, I researched and compiled articles concerned with

corruption in all areas of the pharmaceutical supply chain – from research and development, to manufacture, through to licencing, prescription and dispensing. Areas of corruption identified were the production of counterfeit pharmaceuticals, the bribing of border officials, concealment of negative trial results, theft, and public officials being bribed to drafting laws favourable to the pharmaceutical industry. Stacey and I located almost 200 published articles, magazine investigations, white papers and books.

The second stage involved paring down the articles located, through two screening processes. The first involved deciding which articles were to be kept in an online Endnote database. We drafted a set of criteria for deciding which articles were relevant, trustworthy, and did not duplicate information, and in this way we selected 135 articles. Each article was tagged with its abstract, and key identifying information, and filed into the electronic database.

The final stage involved selecting articles to be included in the annotated bibliography: *Corruption and Ethical Issues in the Pharmaceutical Sector*. This bibliography is currently under first draft review and will hopefully be published sometime in 2008. 47 articles were selected as definitive assessments on general corruption, corruption in the administration of pharmaceuticals, and corruption in each step of the pharmaceutical supply chain. Each article was summarised, catalogued by topic, and placed within the context of a general introduction and conclusion. The bibliography also provides key figures related to pharmaceutical corruption, and provides a list of helpful websites.

The second major engagement during my time at WHO was a secondment to the Secretariat of the Global Forum on Bioethics in Research (GFBR). The Ethics and Health Unit are on the steering committee of the GFBR. While working at the secretariat, I was supervised by Ms. Sandra Realpe, the Ethics Officer for the GFBR. The major task I was assigned was to revive and maintain the ‘memory’ of the GFBR, through updating the website, and developing communications tools.

The GFBR is a global forum that seeks to build capacity in the ethical review of research in developing countries. To this end, they have met 8 times, semi-annually over the 7 years, building relationships with the ethics review communities in developing countries, raising issues to debate, and by supporting and mentoring those involved in the ethical review of clinical trials. During the course of my work reviving the GFBR website ([www.gfbronline.com](http://www.gfbronline.com)) I conducted a historical survey of each of the previous fora: identifying when and where each forum was held, which participants were present, who the partners were, which case studies were discussed, which topics were raised, any salient points raised during the discussions, and seeking out meeting reports for each forum. This work allowed me to network with many key players in the area of bioethics in research, from South America to Eastern Europe, Thailand to South Africa. Once I had a complete set of information for each forum, it was added to the website.

A secondary piece of work I was engaged in was developing a tool for communicating with all the stakeholders of the GFBR. To this end I designed and developed a quarterly newsletter, and was in charge of publishing the Spring edition. The newsletter contained

updates on upcoming forums, provided introductions to the members of the Secretariat, and detailed some of the history of the GFBR.

Finally, I was privileged enough to be invited to attend the 8<sup>th</sup> Global Forum on Bioethics in Research, held in Vilnius, Lithuania at the end of June. The topics discussed were the building of infrastructure in ethics and research (how to train ethics committees, what courses were most suitable, specific training issues faced by developing countries) and ethical issues raised by researching mental health patients. During the course of the forum I was able to meet people from a variety of countries, and with a variety of experiences, all with an interest in and concern for the treatment of patients on clinical trial situations. Finally, the host, Dr. Eujenijus Gefenas from the University of Vilnius, ensured that the participants were able to experience Lithuanian culture, with a tour of the Vilnius Old Town (a UNESCO world heritage listed site) a Lithuanian banquet, and a concerto performance in one of the churches in the University.

Aside from these two central projects, I also had the luck and the pleasure to be involved in representing the Ethics and Health Unit at the 60<sup>th</sup> World Health Assembly, held at the Palais des Nations. Highlights were watching Dr. Margaret Chan give her opening address, and also disseminating information about the work of the Ethics and Health unit to visiting Ministers of Health from member countries. Dr Bouésseau also ensured that I travelled to Strasbourg in early June to attend a meeting of the Council of Europe Steering Committee on Bioethics. The WHO has observer status on this committee, and thus does not have any voting power, but is invited to comment on issues being discussed. During this particular meeting I was able to see the process of drafting legislation regarding the sale and use of genetic tests in member countries of the Council of Europe. In addition to these activities, my time at WHO was kept full through attending various seminars, commenting on documents that the unit was producing, and helping to maintain databases and websites related to the work of the department.

I cannot overstate how incredible the experience I had at WHO this last spring was. I have had the opportunity to witness a World Health Assembly, to watch European legislation being drafted, to contribute to a bibliography that will be published as a WHO document, and to contribute to the valuable work of the GFBR and attend one of their forums. I would strongly recommend the Monash-WHO fellowship to anyone with an interest in bioethics who wishes to see how it is applied at the global policy level. The value of this experience, in terms of developing professional skills, general education, developing a global perspective and making valuable contacts in the industry, cannot be exaggerated.

If I had the opportunity to do it all over again, I wouldn't hesitate. The best advice I can give to the next Monash fellow at WHO is simply to get involved. Join the intern community, go to happy hour on Wednesday nights, go to the lunchtime seminars, and visit other departments at the WHO, to see if their work interests you. Take hold of as many opportunities as you possibly can. And on a practical note, book accommodation sooner, rather than later.

I am extremely grateful to Monash University, and in particular Dr. Justin Oakley for facilitating my time at WHO through the Monash-WHO fellowship. I am also grateful to my supervisors Doctors Reis and Bouésseau for keeping me involved in areas of interest to me, allowing me to travel to places such as Strasbourg and Vilnius, and including me in all areas of the unit's operations - making me feel like a full member of staff. I also owe a vote of thanks to Dr. Baghdadi-Sabeti for welcoming me into her department, and providing me with an opportunity to work in an area I am passionate about. Finally, thanks to Sandra Realpe at the GFBR-Secretariat, for all her assistance during my work there, and for her advice, support and the opportunities she provided.

Danny Edwards  
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