To: International Human Rights Program
From: Kelly Tai
Date: September 10, 2012
Re: IHRP Internship Final Report

This summer, I interned with the Open Society Foundations' (OSF) Public Health Program (PHP) in New York City. The PHP advances the health and human rights of marginalized groups through capacity building at a local level and advocating for greater accountability and transparency in health policy and practice. Having developed a strong interest in health law and policy during law school, the internship was a fantastic opportunity for me to develop my knowledge on health and human rights in a not-for-profit setting.

I was involved with one of PHP's twelve project areas, the Access to Essential Medicines Initiative (AEMI). The AEMI's main objective is to increase access to essential medicines in low-resource countries. However, my summer work instead focused on a public health issue that has generated considerable media interest in the United States (US). I was responsible for drafting a background paper on a human rights-based approach to advocating for accountability and transparency in pharmaceutical industry-sponsored research and the regulatory drug approval process.

Over the last 10 years, several highly publicized incidents have occurred where the sale of drugs with questionable benefits has had a large-scale impact on public health. For instance, the painkiller Vioxx caused an estimated 100,000 heart attacks and strokes in the US prior to its withdrawal from the global market in 2004. These drugs were able to enter the market in part because drug companies misrepresented and concealed clinical trial data showing their products cause lethal harm. Regulatory agencies like the US Food and Drug Administration and the European Medicines Agency also rely on industry user fees for a large part of their funding and thus make decisions under a conflict of interest. To combat bias, commentators have called for changes in regulations to improve access to drug safety and efficacy data from clinical trials.

Surprisingly, the issue has received almost no attention in human rights literature although there is a clear link between human rights and access to drug safety and efficacy information. Government and industry violate the right to health and the right to life when drugs are approved with the knowledge that they may expose consumers to harm. A government's failure to implement regulations that force companies to disclose drug safety and efficacy information also affects its citizens' abilities to make

informed health decisions. Access to information has been enforced through various human rights such as the right to freedom of expression and the right to respect for private life.

This issue implicates many areas of law – including drug regulation, access to information, pharmaceutical product liability, and civil and criminal fraud – and made for a fascinating and challenging research project, given the limited amount of time I had to complete the report. I was also able to explore my interest in corporate social responsibility through this project. Because corporations cannot be held legally accountable under existing international human rights instruments, I spent part of my time focusing my research on soft law solutions.

My internship with the PHP gave me an opportunity to learn about the groundbreaking work OSF and its grantees have conducted on health and human rights issues. I also attended internal workshops ranging from lunch and learn sessions on topical human rights issues and strategies for advocacy work, to a seminar on strategic human rights litigation. It was a privilege to learn from the staff at the PHP, several of whom provided me with valuable feedback on my report. I would especially like to thank Els Torreele, Director of the AEMI, and Professor Trudo Lemmens for their guidance and support. I am grateful to the IHRP for facilitating this opportunity to contribute to such an important project.

Additional Information

Organization website: http:///www.soros.org