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| Institution: University of Central Lancashire |
| Unit of Assessment: UOA3 Allied Health Professions, Dentistry, Nursing and Pharmacy |
| Title of case study: Health Impact Fund |
| <p>1. Summary of the impact (indicative maximum 100 words) Ten million people die each year because they lack access to medicines. The Health Impact Fund (HIF) is a reform plan to improve access to new medicines. Our research on the HIF has influenced policy and public debate and engendered worldwide media coverage and a wide range of global policy endorsements. The HIF proposal was selected by the World Health Organisation (WHO), endorsed by the Organisation for Economic Cooperation and Development (OECD) project, and recently again included in the electoral platform of the German Social Democratic Party's parliamentary delegation.</p> |
| <p>2. Underpinning research (indicative maximum 500 words) Access to life-saving medicines has been recognised as a determinant and consequence of inequalities in health, income, and development. The international intellectual property rights (IPR) system hampers access to medicines for the poor. UCLan-based research contributing to the Health Impact Fund (HIF) is designed to mitigate these problems.</p> <p>The following staff were involved in the research for the HIF: Prof. Thomas Pogge, Professor of Political Philosophy, since 2007. Prof. Doris Schroeder, Director of Centre for Professional Ethics, since 2004.</p> <p>From 2006 to 2009, Pogge, in collaboration with Hollis (see below) analysed problems within the current IPR system, which are: exclusion of the poor from life-saving medicines, neglect of diseases concentrated in low-income countries, bias towards maintenance drugs, wastefulness through excessive litigation, counterfeiting (which in turn can lead to drug-resistant strains for some medicines), excessive marketing and last mile problems (promoting optimal use of their drugs is insufficiently lucrative for pharmaceutical companies) (Publication No 1 below).</p> <p>Based on the above, from 2006 to date, Pogge developed and refined a reform plan, which addresses the major drawbacks of the current IPR system by giving innovators the option to register any new medicine for rewards according to their health impact provided they agree to sell it at cost (ibid.). The work in economics required to develop metrics for measuring health impact was undertaken at Yale and Calgary University.</p> <p>From 2008 to 2010, Pogge completed a human rights justification for the HIF (Publication 2 below) and the underpinning philosophical framework, for which he won the American Philosophical Association's 2013 Gregory Kavka prize in political philosophy (Publication 6 below).</p> <p>Adding to this, from 2008 to 2010, Schroeder, in collaboration with Singer (see below) identified and analysed prudential and moral reasons for IPR reform (Publication 4 below).</p> <p>From 2008 to 2010, Pogge collaborated with Frewer (see below) to develop a Delphi analysis to identify major barriers to the implementation of the HIF (Frewer L J, Ruto E, Coles D, Stakeholder views regarding the objectives and implementation of a Health Impact Fund (HIF) to incentivise pharmaceutical innovation relevant to diseases of poverty (accepted for publication in <i>Global Health Governance</i>)).</p> <p>Details of external colleagues involved in Professor Pogge's work (a selection): Aidan Hollis, Professor of Economics, Calgary University, Canada; Peter Singer, Professor of Philosophy, Princeton University, US; Lynn Frewer, Professor of Food and Society, Newcastle University, UK; Harvey Rubin, Professor of Medicine and Director of the Institute for Strategic Threat Analysis and</p> |

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Response (with Consultative Status at the UN), University of Pennsylvania, US.

HIF Advisory Board members (a small selection): Sir Michael Rawlins (former Chairman of NICE, UK); Baroness Onora O'Neill (President of the British Academy); Prof. Amartya Sen (Nobel Laureate); Prof. Kenneth Arrow (Nobel Laureate); Paul Martin (former Canadian PM).

3. References to the research (indicative maximum of six references)

1. Banerjee, A., Hollis, A., **Pogge, T.** 2010. The Health Impact Fund: incentives for improving access to medicines, *Lancet* 375:166–169
2. **Pogge, T.** 2009. The Health Impact Fund and Its Justification by Appeal to Human Rights” in Human Rights: Normative Requirements and Institutional Constraints, *Journal of Social Philosophy*, 40(4)542–569
3. **Pogge, T.** 2010. Politics as Usual: What Lies behind the Pro-Poor Rhetoric. Cambridge: Polity Press
4. **Schroeder, D.**, Singer, P. 2011. Access to Life-Saving Medicines and Intellectual Property Rights – An Ethical Assessment, *Cambridge Quarterly of Healthcare Ethics*, 20:2, 279-289
5. **Schroeder, D.** 2011 Does the Pharmaceutical Sector have a Co-Responsibility to Secure the Human Right to Health? *Cambridge Quarterly of Healthcare Ethics*, in 20:2, 298-308
6. **Pogge, T.** 2011. Are We Violating the Human Rights of the World’s Poor? *Yale Human Rights & Development L.J.* 14(2) 1-33.

Grants and fellowships that supported this work:

The work has been supported at UCLan, Yale University and the Australian National University. UCLan holds the largest single grant supporting the co-development of the HIF. The consortium, led by Pogge, included the Chinese Ministry of Science and Technology and the main New Delhi think-tank of the Indian Ministry of External Affairs (RIS).

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| Who the grant was awarded to: Thomas Pogge, UCLan | The grant title: Pharma-Innovation – Patent-2 |
| Sponsor European Commission | Period of the grant (with dates): 1 June 2008 – 31 May 2011 |
| Value of the grant: 728,640 Euros | |

The funding was provided to: advance knowledge and ethical insight into reform plans for the current IPR system; finalise an existing plan to amend the current IPR system in the area of pharmaceutical innovation; provide a reality check for the new system from the world’s two most powerful developing countries (India and China); promote urgent policy developments on IPR by forging a consensus for the new system and providing a policy action plan.

4. Details of the impact (indicative maximum 750 words)

During the REF period 2008-2013, our research has stimulated and informed policy and public debates, influenced international agencies and organisations and made a significant contribution to research-informed policy at the global level.

In 2008, Pogge made a submission to the WHO’s Expert Working Group on Research and Development Financing (EWG, WHA61.21), which summarised research on the HIF, especially evidence of problems with the current patent system and ways of overcoming them. In December 2009 the EWG delivered its report, recommending that "efforts should be made to examine other promising proposals in their local contexts, such as open source products; patent pools; Health Impact Fund; priority review voucher scheme; and orphan drug legislation." Given that all other

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named mechanisms were already being tried, it is most encouraging that the HIF was included in this policy advice to the WHO Director General. [A]

A later WHO working group "considered that the ideas underpinning the HIF were of interest and that, if successfully implemented, it would address many of our criteria." However, currently "a sufficiently reliable measurement of health impact" is not available in developing countries and pilot studies are needed (2012 Report, and see below for planning). [B]

The HIF reform plan directly addresses intellectual property management issues by seeking to incentivize R&D relevant to the disease burden in developing countries, while also facilitating access by de-linking the price of relevant products from the cost of R&D. As a result, the HIF would have a favourable distributive effect and boost the availability and affordability of important medicines in developing countries while also incentivizing firms to promote wide and optimal use. The proposal was considered a useful complement to the existing set of intellectual property incentives in that firms can choose whether to register their product with the HIF or use the patent system as they do now.

Following the publication of Nathan, Carl (2007) 'Aligning pharmaceutical innovation with medical need', *Nature Medicine*, 13:301-308, which compared IPR reform plans and selected the HIF as the only one without detrimental medium- or long-term consequences, Prof. Harvey Rubin contacted Pogge. After briefing him on the details of the HIF, an OECD project report written by Rubin endorsed the reform plan. [C]

From 2007, Pogge gave various prominent lectures for the German Social Democrats (SPD), in the Willy Brandt Haus, at the Hannah Arendt Days and three times with Heidemarie Wieczorek Zeul [former German Minister for Economic Cooperation and Development] as partner. As a result, Karin Roth, a member of the German Parliament, invited him to a conversation. After deliberations with a range of German SPD politicians, the HIF was included – in 2011 - in the platform of the German Social Democratic Party's (SPD) parliamentary delegation (the SPD is one of two main parties in Germany, comparable to the British Labour Party).

Pogge and his global team have been working with leading health care assessment organizations such as the George Institute for International Health, PolicyCures, NICE International, PATH and the Institute for Health Metrics and Evaluation, to conduct a pilot, evaluating the health impact of products in various countries. A UCLan-based proposal (€1,924,989) has been submitted to the European Research Council (ERC) to provide further funding for the research preceding the pilot. (At the time of writing, Pogge has been invited to grant negotiations for the full amount with the new project to commence in 2014).

Influence on Public Debates

Our high-level programme of knowledge exchange has enabled our new theoretical insights to enter the public domain and to shape public opinion. Significant media coverage of the HIF has been achieved on all continents. The following are selections from almost 100 items between 2005 and 2013, all attesting to contributions to and influence on public debates.

- Suhrith Parthasarathy, "Adverse reaction: India's radical challenge to the global patent regime," *The Caravan*, June 1, 2013.
- Carl Nathan, Let's gang up on killer bugs, *New York Times*, December 9, 2012
www.nytimes.com/2012/12/10/opinion/teaming-up-to-make-new-antibiotics.html?_r=1&.
- TED is a non-profit company "devoted to Ideas Worth Spreading", T Pogge, Ted Talk, September 2011,

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www.ted.com/talks/lang/en/thomas_pogge_medicine_for_the_99_percent.html (watched over 200,000 times).

- Pogge interviewed on Austrian television (political talk show: Talk im Hangar-7, June 10, 2010), www.servustv.com/cs/Satellite/Article/Talk-im-Hangar-7-011259276607980.
- Thomas Pogge, "Rettferdig medisin." *Morgenbladet*, May 7-13, 2010. [In Norwegian, Norway's first daily newspaper, since 1819], online copy in addition to print copy: http://morgenbladet.no/ideer/2010/rettferdig_medisin
- Thomas Assheuer, "Der Weltverändererdenker." T Pogge featured by German newspaper *Die Zeit* [national weekly with a readership of 2 million]. April 23, 2009 www.zeit.de/2009/18/PD-Thomas-Pogge
- Peter Singer, "Tuberculosis or Hairloss". *Guardian*. September 16, 2008, <http://www.guardian.co.uk/commentisfree/2008/sep/16/health.pharmaceuticals>

5. Sources to corroborate the impact (indicative maximum of 10 references)

- A. Expert Working Group on Research and Development Financing. *Public Health, Innovation and Intellectual Property: Report of the Expert Working Group on Research and Development Financing*. Geneva: World Health Organization; 2009, at p. 19. This WHO report recommends the HIF, which attests to the influence on policy claimed in this case study.
- B. Expert Working Group. *Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination* Geneva: World Health Organization; 2012, at p. 55f. This WHO report recommends further action needed to refine the plan for tailored use in developing countries.
- C. Rubin, Harvey (2011) *Future Global Shocks: Pandemics*, OECD IFP/WKP/FGS(2011)2, available at: www.oecd.org/dataoecd/58/1/46889985.pdf, page 62. OECD report endorsement: 'In this regard, we strongly support the work on the Health Impact Fund as one of the creative and practical solutions to the problem of incentivizing the discovery and distribution of new drugs and vaccines'.
- D. Deutscher Bundestag. Drucksache 17/2135, 16.6.2010, SPD motion to German parliament on 16.6.2010 endorses HIF. <http://dip21.bundestag.de/dip21/btd/17/021/1702135.pdf>
An equally promising plan is the Health Impact Fund (HIF), which links financial incentives with impact. The HIF is also included in the WHO's Global Strategy and Plan of Action. Our translation from: Ein ebenfalls vielversprechender Ansatz ist der Health Impact Fund (HIF), der finanzielle Anreize mit dem Nachweis der Wirksamkeit verbindet. Auch der HIF wird im GSPA der WHO aufgeführt.
- E. Working Group on Economic Cooperation and Development of the SPD parliamentary group in the Bundestag, *One world, one future – for a sustainable and progressive social democratic development policy*, p. 12: "One solution that promises to benefit people in developing countries and serve the interests of pharmaceutical companies is the Health Impact Fund, which would encourage research into neglected diseases and substantially improve access to effective drugs worldwide."

Contact 1: Baroness O'Neill of Bengarve, Former President of the British Academy.