Editorial: Looking for Justice from the Health Industry

DORIS SCHROEDER and JULIE COOK

"Dumping" is a predatory activity which increases personal or group gain at the expense of others. For instance, the price dumping of goods into a market at below-cost prices aims at the bankruptcy of competitors and thereby at a future monopoly. Social dumping can refer to using uninsured labor to reduce costs. Environmental dumping involves the transport of waste from one country to another (for instance, nuclear waste) where environmental laws are less strict.

The term "ethics dumping" has been created by the Science with and for Society unit of the European Commission to describe double standards in research.

> Due to the progressive globalization of research activities, the risk is higher that research with sensitive ethical issues is conducted by European organizations outside the E.U. in a way that would not be accepted in Europe from an ethical point of view. This exportation of these noncompliant research practices is called "ethics dumping."[1]

It occurs mainly in three ways. First, when research participants and/or resources in low- and middle-income countries (LMICs) are exploited intentionally, for instance because research can be undertaken in a LMIC that would be prohibited in a high-income country. This aligns with environmental dumping dynamics; locations with less restrictive laws and regulations are actively sought in order to move research from one country to another. Second, exploitation can occur due to insufficient ethics awareness on the part of the researcher or their home institutions: The researcher is unaware of applying double standards. For instance, when undertaking research on highly vulnerable indigenous populations, it is standard practice to obtain group or community consent before approaching individuals.[2] But a researcher/institution from a high-income country (HIC) may not be aware of this requirement due to lack of experience. Third, and relatedly, lack of researcher awareness can intersect with low research governance capacity in the host nation. The ethics committee in the host country should know about the group consent requirements, for example, but due to capacity issues, is not able to intervene in research and request necessary changes to a protocol.

A wide range of ethics dumping cases have been described in a recent book.[3] To give some examples: cultural prohibitions may be ignored in research with vulnerable populations; the standard of care may be misconstrued, putting research participants at unnecessary risk; benefit sharing may not take place; new technologies may be tested in settings with less public resistance due to lack of information; ethics approval may be sought retrospectively; or research participants may not be insured for harm incurred during a study.

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This symposium of four papers focuses on health research undertaken by the private sector. "Working Together to Make the World a Healthier Place: Desiderata for the Pharmaceutical Industry" (Klaus Leisinger and Kate Chatfield) links pharmaceutical research to the United Nations Sustainable Development Agenda and the newly emerging concept of responsible research and innovation[4] (RRI) to build a hierarchy of obligations based on Ralf Dahrendorf's work. They conclude that the adoption of RRI could prove to be an effective way of building trust in the research and innovation activities of pharmaceutical companies with the assurance that such activities are socially acceptable, desirable, and sustainable.

In "Continued Access to Investigational Medicinal Products for Clinical Trial Participants—An Industry Approach," Ariella Kelman, Anna Kang, and Brian Crawford describe an industry approach to a long-standing and complex problem in equitable research relationships. In 2000, at the 52nd World Medical Association General Assembly in Edinburgh, posttrial obligations were added to the Declaration of Helsinki. In its current version, Article 34 of the Declaration of Helsinki requires that

> In advance of a clinical trial, sponsors, researchers and host country governments should make provisions for posttrial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.[5]

To realize posttrial access to successfully tested drugs is fraught with difficulties.[6] The Roche approach, developed in conjunction with bioethicists and patient advocates, is described theoretically and practically using an example of the investigational medicine *Etrolizumab*. It is clear that the close collaboration of all stakeholders is vital to agreeing on a feasible policy and implementation. Societal and stakeholder engagement is one of the key action points of RRI, the importance of which is confirmed by the "Roche Global Policy on Continued Access to Investigational Medicinal Products."

"Healthy Volunteers For Clinical Trials in Resource-Poor Settings: National Registries Can Address Ethical and Safety Concerns" (Francois Bompart) is a new initiative by the Sanofi Bioethics Committee in collaboration with the TRUST project.[7] The paper outlines why healthy volunteers are a particularly vulnerable group in medical research, especially in LMICs. One of the most worrying concerns is concealed participation in multiple trials. Highly interesting data are provided about the number of healthy volunteers involved in trials worldwide; most are involved in pharmacokinetic rather than "first-in-human" studies. To protect healthy volunteers from harm, the author advocates for the setting up of national healthy volunteer registries as already established in France and the U.K.

The final paper in the symposium, "Involving Patients in Research? Responsible Research and Innovation in Small- and Medium-Sized European Health Care Enterprises" provides insights into contrasting perspectives. Kalypso Iordanou analyzes the reluctance of small enterprises involved in health research to undertake research involving patients. According to interviews and literature research, some small enterprises avoid involving stakeholders, especially patients, in their research due to the high expected costs and the difficulty to satisfy patient expectations.

The United Nations Sustainable Development Agenda is likely to be the most ambitious activity of our generation towards worldwide justice and equality. Goal No. 3, "Ensure healthy lives and promote well-being for all at all ages," requires collaboration of all stakeholders, private and public. The pharmaceutical industry and its contribution towards the health and well-being of people around the world can and should play an active role in this process.

Notes

1. CORDIS Community Research and Development Information Service. *GARRI-6-2014 - Reducing the Risk of Exporting Non Ethical Practices to Third Countries* [cited 2017 Oct 24]; available at http://cordis.europa.eu/programme/rcn/665155_en.html (last accessed 15 Sept 2018).
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