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Roche's Clinical Trials with Organs from Prisoners: Does Profit Trump Morals?

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Abstract This case study discusses the economic, legal, and ethical considerations for conducting clinical trials in a controversial context. In 2010, pharmaceutical giant Roche received a shame award by the Swiss non-governmental organization Berne Declaration and Greenpeace for conducting clinical trials with organs taken from executed prisoners in China. The company respected local regulations and industry ethical standards. However, medical associations condemned organs from executed prisoners on moral grounds. Human rights organizations demanded that Roche ended its clinical trials in China immediately. Students are expected to review the economic and ethical issues regarding the outsourcing of clinical trials to controversial human rights contexts, and discuss how to make business decisions when there are conflicts between making profit and ethical considerations. Was Roche complicit in the human rights violations that were related to its clinical trials? Future patients might benefit from these clinical trials. Do profit and the greater good, in general, trump morals?

Keywords Human rights · Roche · China · Clinical trials · Organ transplantation

Introduction

In 2010, Swiss pharmaceutical giant Roche received the Public Eye Award. Unfortunately, receiving this shame award was nothing to be proud of: The Public Eye Award was given to corporations for their irresponsible behavior that had negative social, ethical, and/or environmental side effects on stakeholders such as workers, local communities, consumers, the environment, or society at large. Previously awarded corporate actions included exploitative working conditions, environmental disasters, human rights violations, or corporate greed. The Swiss non-governmental organization (NGO), Berne Declaration and Greenpeace justified Roche's nomination for the 2010 Public Eye Award as follows:

> China proudly proclaims that roughly 10,000 organ transplants take place annually in its clinics. However because of Chinese culture, there are few voluntary organ donations from the population. Where do all the transplanted organs come from? At the end of 2008, the Chinese vice health minister admitted in a medical journal that more than 90 percent of all transplanted organs come from executed prisoners. The World Medical Association and other international organizations unanimously oppose the transplantation of prisoner organs on ethical grounds. Even when a prisoner supposedly consents to an organ donation, such consent while imprisoned cannot be considered of one's own free will. The drug CellCept, from the Roche pharmaceutical firm, prevents the rejection of transplanted organs. Roche markets the drug in China despite the country's unethical transplantation practices. The company has even been producing CellCept in China for several years. Furthermore, Roche is currently studying the drug's effects in two studies with some 300 transplanted organs in Chinese clinics. Roche claims to have no information regarding the origins of the transplanted organs. The firm must therefore

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immediately halt these studies since it cannot ensure that none of the organs come from prisoners (The Public Eye Awards 2010).

Despite an invitation, none of Roche's representatives attended the award ceremony. Roche, however, anticipated information requests from its stakeholders (e.g., shareholders, employees, and patients). The key question was how to respond to this negative publicity.

It was true that Roche was conducting clinical trials in China involving organ transplantations. However, the company was only responsible for the conduct of the trials. It did not provide the organs. The organ provision was the responsibility of the collaborating hospitals, doctors, and the Chinese regulators. Were the claims by the Berne Declaration and Greenpeace justified? Did the organs come from executed prisoners? If yes, would that make Roche complicit and responsible as the NGOs claim? Would Roche have to terminate the ongoing trials immediately? If yes, on which legal or ethical grounds?

Roche: A Company Overview

Roche is one of the largest pharmaceutical corporations in the world. The Swiss-based company employs over 80,000 people, and sells its products in more than 150 countries in the world. In 2010, the corporation achieved revenue of $51b, an operating profit of almost $17b, and net income of $12b (Roche 2011a).

Roche describes itself as a research-focused and innovative healthcare provider. Its business is divided in two main divisions: diagnostics and pharmaceuticals. Roche's diagnostic products range from tools for disease detection, screening, and evaluation to disease monitoring. Examples of Roche's diagnostic products are testing devices and analyzers for hospitals and other laboratories. The diagnostics division accounts to roughly 22 % of the company's sales (Roche 2011a).

The majority of Roche's profit, however, comes from pharmaceuticals (78 %). The company manufactures and markets drugs in five therapeutic areas: oncology, virology, inflammation, metabolic disorders, and central nervous system. Roche is the world's leading cancer drug manufacturer. Its cancer drugs (e.g., Avastin, MabThera/Rituxin, or Herceptin) alone account for over 50 % of company sales (Roche 2011c).

Roche has been constantly working on the improvement of its existing drugs and on the development of new drugs. Research and development is crucial in the healthcare industry, and Roche invests over $9b per year in research and development. In 2010, Roche had more than 100 projects that were in the pipeline, and already tested on humans (Roche 2011a, d).

Roche's CSR Activities

As a pharmaceutical company, Roche's business is crucial for society. The company develops products to save and prolong life, and addresses unmet medical needs. Operating in such an industry calls for special responsibilities. Roche is aware of its responsibilities and takes them seriously. The company is committed to "running our business in a way that is ethical, responsible and creates long-term value for stakeholders" (Roche 2011a, p. 102).

Roche reports regularly on its approach to corporate social responsibility (CSR) in its annual report. The company specifically addresses the expectations, needs, and demands of its core stakeholders: patients, employees, society, and investors. Its CSR activities range from training employees, respecting worker and human rights, supporting humanitarian and social projects, risk and crisis management, to sustainable supply chain initiatives, responsible marketing, and animal welfare (Roche 2011a).

As Roche's main activities involve the development and testing of drugs, the company puts a special focus on providing value to patients. The company advances, amongst others, the following principles in regards to patients as stakeholders (Roche 2011b):

- Demonstrating the medical and economic value of their products
- Ensuring patient safety
- Listening and responding to customers' views
- Building relationships with patients groups
- Helping to improve global access to healthcare
- Running safe and ethical clinical trials

The last two principles are especially important in the healthcare industry: Providing access to healthcare, and providing safe and ethical clinical trials. To provide global access to healthcare, Roche follows sustainable patent and pricing policies (Roche 2011a). Roche knows that some of its products are desperately needed in developing countries. Therefore, the company does not enforce any patents for products in the least developed or low-income countries. Also, Roche supports international initiatives to improve cancer care in Africa. To secure medicine access in developing countries Roche introduced a specific pricing program to ensure that patients in those countries can get access to drugs for cancer, hepatitis C, or rheumatoid arthritis. For example, Roche "negotiated commercial access programs in middle-income countries for our hepatitis drug Pegasys, as well as for our cancer drugs Avastin, Herceptin, MabThera and Tarceva" (Roche 2011a, p. 108).

Roche's Clinical Trial Policies

Besides its patent and pricing policies, Roche also ensures that its clinical trials adhered to existing safety and ethics

standards (Roche 2011a). Clinical trials are extremely important to test the safety and effectiveness of a drug—eventually benefiting patients on a large scale. Clinical trials also offer advantages to participating hospitals through educational, financial, and medical support. Roche has clear and strict policies in place to ensure patient safety. The company adheres to the Good Clinical Practice guidelines issued by the International Conference on Harmonization (2002). The Good Clinical Practice guidelines include the protection of human rights (patients), standards on how trials are to be conducted, and responsibilities of trial sponsors, investigators, doctors, and clinical research associates. Detailed principles include for example that each person involved in the conduct of the trial is qualified by education, training, and experience, or that each subject (patient) voluntarily agrees to participate in the trial, and is informed about the procedure, process, and potential consequences (European Medicines Agency 2002).[1]

As many of Roche's clinical trials occur in developing countries the company outlines specific guidelines regarding its clinical trials in low and middle-income developing countries (Roche 2008a). In its policy papers on clinical trials in developing countries Roche stresses that patient safety has absolute priority (Roche 2008a, 2012). Therefore, the company ensures that patients participating in its trial are fully informed about the drug and any related risks, voluntarily consent to the participation in the trial, and have access to the necessary drugs during but also after the trial to ensure their continuous wellbeing (Roche 2012). Also, Roche conducts only clinical trials in countries where it aims to market the drug later (Roche 2008a). This avoids the notion that patients in poorer countries are exploited for the benefits of the developed world.

Roche guarantees full transparency and the adherence to highest ethical standards during their clinical trials (Roche 2012). "Roche respects human rights and believes that one of its most important aspects is the freedom to choose. Roche is focused on protecting human dignity, patient safety, and ethical principles in the conduct of clinical trials" (Roche 2012, p. 1/2). The company stresses that its clinical trial policies are universal applying to any country—developed or developing—where the company conducts clinical trials.

Other pharmaceutical corporations have similar policies in place in regards to clinical trials in developing countries. The Swiss pharmaceutical corporation Novartis, for instance, refers to the same international guidelines as Roche: Good Clinical Practice guidelines, the Declaration of Istanbul on Organ Trafficking and Transplant Tourism, and the WHO guiding principles on Human Cell, Tissue, and Organ Transplantation (Novartis 2011; Roche 2012).

Roche's CSR approach received external recognition: The company was named "Supersector Leader" in healthcare for two consecutive years (2009 and 2010) (Roche 2011a). Despite this recognition of being a leader in CSR in its industry, Roche received severe criticism involving its product CellCept in 2008 and the following years.

The CellCept Controversy

CellCept was a drug that prevented organ rejection. It was used on patients that had received kidney, heart, or liver transplantations. The drug weakened the immune system and thereby increased the chances that the human body accepted the new organ.

Syntex had developed CellCept. In 1994, Roche had acquired the in Palo Alto headquartered corporation, and introduced CellCept shortly afterwards to the U.S. and European markets (Roche Historical Archive 2008). Later, CellCept was also available in Russia and China. Roche enjoyed a privileged position in the market with CellCept. However, during the last years the competition had intensified, and competitors offered good alternative drugs to CellCept. Also, patents of CellCept had expired in 2009 (Roche 2011a). Since then, the competition in drugs facilitating transplantation acceptance had increased. Sales of CellCept declined in 2010 due to this increased competition (Roche 2011a). Roche aimed at offsetting these losses from the expired patent by increasing its market share in markets such as Latin America and China (Keller 2010).

Even though CellCept had been marketed for over 15 years, the drug was still tested in trials in several countries. In 2008, Roche started clinical trials in China in which Roche combined CellCept with two regiments of reduced calcineurin inhibitors. The aim of the study was to examine the efficacy and safety of CellCept. The clinical trial included patients having liver transplantations (Roche 2011e). In another clinical trial in China, Roche combined CellCept with cyclosporine A and steroids, and examined the effect on renal function and the prevention of rejection in heart-transplant patients (Roche 2010a). Between 2008 and 2010 more than 300 Chinese patients participated in Roche's clinical trials (The Public Eye Awards 2010). Roche has been conducting clinical trials in Shanghai, Zhejiang, Nanjing, Fuzhou, Peking, Guangzhou, Chengdu, Changsha, Chongquing, Jiangsu, and Xian City (Keller 2010). While most of Roche's CellCept clinical trials in China aimed at investigating further long-term effects of CellCept and any interactions with other drugs, such trials

[1] The complete guidelines are available online (http://www.emea.europa.eu/pdfs/human/ich/013595en.pdf).

also functioned as a marketing tool to get access to hospitals (Keller 2010). China was one of the most lucrative markets for its clinical trials on CellCept.

China: An Attractive Location for Clinical Trials

Roche was not the only pharmaceutical company conducting its clinical trials in China. During the last decades pharmaceutical corporations had followed the outsourcing trend towards China (Einhorn and Arndt 2008), which was observable in many other industries such as the garment, toy, or electronics industries (Harney 2009; Santoro 2009). China had developed into a lucrative outsourcing location for clinical trials. A 2008 study by consultancy firm A.T. Kearney revealed that China was the number 1 location for clinical trials—before India and Russia (Einhorn and Arndt 2008).

The reasons why China belonged to the top locations for clinical trials were manifold: First, it was not difficult to find participants for clinical trials in China. Vital Therapies Inc., for example, struggled finding enough patients suffering from hepatitis B in the United States. In China, however, authorities estimated that there were over 130 million hepatitis B patients willing to participate in clinical trials (Einhorn and Arndt 2008). Second, poor Chinese citizens were highly interested in participating in clinical trials. For them, clinical trials were often the only option to get medical care. Third, the costs of clinical trials in China for pharmaceutical corporations were relatively low compared to costs of trials in Western countries, such as the United States or Europe. Finally, Chinese regulations were more welcoming. Chinese medical authorities were less risk-averse than their Western counterparts. During the last years China allowed risky experiments such as stem cell injections or treatments involving the manipulation of human genes. Also, Chinese authorities allowed the sale of drugs only after they were tested locally (Einhorn and Arndt 2008). This meant that if pharmaceutical corporations wanted to sell their drugs in China, they had to conduct tests and clinical trials beforehand anyway.

Hence, it came as no surprise that pharmaceutical corporations like Roche or Novartis did business and invested in China (Roberts 2009). Novartis, for example, invested over $1 billion dollars in China to setup a large R&D center. Also, most pharmaceutical corporations conducted clinical trials in China given its business attractiveness.

For Roche's CellCept, China was especially important, as the country was the second largest market for organ transplantation (Keller 2010). CellCept, for example was the third most important drug for the company in China (The Public Eye Award 2010). Since 2005 Roche even produced CellCept in China. When Roche opened its manufacturing site in Shanghai, Roche CEO Franz Humer said that he and Roche welcomed the country's openness to organ transplantation compared to other countries such as Japan where organ donation was controversial as it contradicted Japanese culture and religion (Keller 2010). However, human rights activists and NGOs did not agree with Humer's observation and raised ethical concerns related to the human rights context in general and organ transplantation in particular in China.

China: A Controversial Human Rights Context

NGOs, and governments described the Chinese political system as authoritarian and oppressive (Amnesty International 2010a). China had a continuous record of human rights violations. Human rights activists and human rights organizations reported regular violations concerning the right of expression, religion, women's rights, labor rights, and unfair trial conditions (Amnesty International 2010a; Egels-Zandén 2007; Santoro 2009; Yu 2008). Also, NGOs complained about the corruption within the judicial system and police abuses. Given this challenging human rights situation, multinational corporations operating in China were continuously confronted with ethical challenges (Krueger 2009; Tan and Tan 2009), but also received some guidance on how to do business in such an extreme context (Hamilton et al. 2009).

For instance, Chinese authorities oppressed and discriminated against ethnic minorities such as Tibetan or Mongolian (Amnesty International 2010a). Also, followers of unregistered or banned religious groups were harassed, persecuted, and imprisoned (Amnesty International 2010a). The spiritual group Falun Gong,[2] for example, was prohibited, and Chinese authorities continuously discriminated against this spiritual formation (Amnesty International 2010a). Falun Gong members were sent to labor camps for re-education purposes or to prison (Amnesty International 2010a).

Prisoners and Human Rights Violations

In prison, inmates experienced a variety of human rights violations such as torture and harassment, or a denial to see their family and lawyers or denial to medical treatment

[2] Falun Gong is a spiritual discipline that combines mediation, slow-moving spiritual exercises with moral philosophy. It is estimated that over 100 million people worldwide practice Falun Gong. Central to Falun Gong's philosophy are truthfulness, compassion and forbearance. Through meditation, and movement practices, followers of Falun Gong aim at achieving a better life, better health, and spiritual enlightenment. Falun Gong was first introduced in China in 1992. Since 1999, China has officially banned the movement, and persecuted its practitioners. The Chinese communist party considers Falun Gong and its practitioners as a threat to communism. The persecution of Falun Gong includes propaganda campaigns, enforced ideological conversion, re-education, violence, torture, forced labor, and executions (Amnesty International 2010a).

(Amnesty International 2011). Also, NGOs criticized other human rights violations related to prisoners such as unfair trial procedures. Reports suggested that suspects were unfairly treated: confessions were extracted under torture, access to legal representatives was often denied, police abuses were reported, and corruption occurred within the judicial system (Amnesty International 2010a, b). Finally, NGOs criticized the severity of punishment that prisoners faced. China belonged to the 56 countries in the world with death penalty and executions. The death penalty was applied to almost 70 offences, including non-violent ones. In 2009 for example, a Chinese businesswoman was executed for fraudulently raising funds (Amnesty International 2010b). Her lawyer later confirmed that the regular sentence for such an offence should have been 10 years imprisonment and a fine of up to $73,000 (Amnesty International 2010b).

Given all these human rights violations related to prisoners, it is not surprising that human rights activists, NGOs, and the international community criticized the high rate of state-issued executions in China. China had one of the largest records of executions in the world (Amnesty International 2011). While death sentences were declining worldwide, international NGOs such as Amnesty International doubted that death sentences were declining in China (Amnesty International 2010b). NGOs estimated the amount of executions in China to be in the thousands (Amnesty International 2010b). In 2009, "China executed more people than the rest of the world put together" (Amnesty International 2010b, p. 17).

While regime opponents and inmates experienced a variety of human rights violations during their imprisonment, critics pointed out that human rights violations continued even after the prisoners' executions as their organs were taken without the prisoners' or their families' consent.

Organs from Executed Prisoners and Practitioners of Falun Gong

Prisoners had been traditionally executed through shooting. In 2009, Chinese authorities announced that firing squads would be increasingly replaced with lethal injections, as this execution method was "cleaner, safer and more convenient" (Amnesty International 2010b, p. 13). The outside media, however, reported that the main reason for changing the execution method was so that transplant organs could be taken from the bodies of executed prisoners (Amnesty International 2010b). Chinese authorities proudly stated that there were roughly 10,000 organ transplantations per year in Chinese hospitals. However, according to state officials and NGOs between 65 and 90 % of those organs came from executed prisoners (Amnesty International 2010b; The Public Eye Awards 2010).

NGOs, international organizations such as the United Nations, and medical associations such as The Transplantation Society (2011) criticized Chinese authorities for retrieving transplant organs from executed prisoners. The World Health Organization (2004) called for transparency and traceability in its Guiding Principles on Human Cell, Tissue, and Organ Transplantation. An excerpt of those principles is provided in Appendix 1. The Transplantation Society (2011) doubted that prisoners or their relatives voluntarily agreed to donate organs. According to human rights organizations prisoners might sign organ donor agreements under torture. This was in contradiction to all accepted ethical standards in organ transplantation (World Health Organization 2004).

Several activists, NGOs, and human rights lawyers have raised specific concerns regarding the treatment of practitioners of the religious group Falun Gong. In a 2007 report[3] David Matas (U.S.-based human rights lawyer) and David Kilgour (former Canadian Minister of State) stated that organs were taken from specifically practitioners of the religious group Falun Gong (Matas and Kilgour 2009). Matas and Kilgour (2009) had proof that, for instance, organs from Falun Gong practitioners were sold to foreign transplant tourists between 2001 and 2006. In an updated report, Matas (2008) provided further information on the use of organs from Falun Gong practitioners. Chinese officials took organs explicitly from arrested and executed Falun Gong practitioners (Matas 2008). According to Matas (2008) evidence existed that blood from arrested Falun Gong practitioners was systematically tested while blood from other (non-Falun Gong) prisoners was not. As a matter of fact, the amount of organ transplantation in China had significantly increased with the rising persecution of Falun Gong since the beginning of the 2000s. Matas's (2008) report to the United Nations, as well as Matas and Kilgour's (2009) book have been independently reviewed and confirmed by representatives of universities and transplant surgeons. Even within China, the usage of organs from executed prisoners was criticized: The Chinese vice-health minister admitted that prisoners were "definitely not a proper source for organ transplants" (Amnesty International 2010b, p. 13).

Clinical Trials and Violations

NGOs did not only criticize the dubious organ sourcing practices from executed prisoners and followers of Falun Gong. NGOs also criticized the general terms and conditions of clinical trials in China: Chinese authorities tended to allow risky experiments that were considered unethical or too risky in other countries such as stem cell injections

[3] The report is available online (http://organharvestinvestigation.net/report0701/report20070131.htm), but an updated version has been published as a book in 2009 (Matas and Kilgour 2009).

or treatments involving the manipulation of human genes (Einhorn and Arndt 2008). Also, it seemed that patients were not always fully informed about the trial conditions. Some patients were not even informed that they were actually participating in trials, and receiving non-approved treatments. For some sick people the participation in clinical trials was the only option to receive treatment, as they could not afford any medical treatment.

Human rights organizations and other activists were afraid that poor and uneducated citizens in China were exploited and even coerced in participating in clinical trials (Simons 2005). The medical system in China was underfunded and regulations were poorly enforced. This opened the door for rather dubious clinical practices: Review boards of clinical trials in China, for example, did often not include ethicists and focused rather on the interest of hospitals and their doctors (Simons 2005). Given the underfunded medical system, money from foreign pharmaceutical corporations for clinical trials was often the main source of income for Chinese hospitals. Given the favorable conditions for clinical trials in China as discussed in previous sections, it came as no surprise that many pharmaceutical corporations had entered the Chinese market. However, this rapid growth posed challenges for Chinese regulators, as they might not be able to follow up on ethical standards at such an accelerating rate (Simons 2005). According to Simons (2005) many of the international guidelines for clinical trials such as informed patient consent, trial inspection by an independent ethics committee, and on-site monitoring, were hardly met. While such standards sounded great in theory, they were hardly found in practice—at least not in China (Simons 2005).

Organ Transplantation in China

In addition to the ethical challenges involving clinical trials in China, there were also ethical challenges involving organ transplantation. Like in most other countries, China had a shortage of organs. The list of people needing organs vastly exceeded the number of available donors (Phillips 2012).

For a long time China did not have any organized, defined organ donation program or specific laws outlining the donation process (Budiani-Saberi and Delmonico 2008). The consequence of the lack of such a donation system was that China was "a major destination for "transplant tourists", who cannot get the life-saving surgery they need in their own countries" (Watts 2007, p. 1917). As hospitals and doctors often lacked funding in China they were tempted to engage in organ transplantations for wealthy foreigners (Watts 2007). As discussed earlier, most of these organs came from executed prisoners who often did not voluntarily agree to be organ donors.

In 2007, the Chinese government introduced new regulations to ban organ trafficking. The Human Transplantation Act stated that organ donors had to be at least 18 years old and outlined a registration framework for hospitals that intended to conduct organ transplantations (Watts 2007). Also, this regulation banned organ transplantations to foreigners. The aim was to fight international organ tourism. However, recent news indicated that there was still significant organ tourism in China (Phillips 2012). Given the organ shortages worldwide, for some people the organ black market was the only opportunity to receive an organ in a timely manner.

Despite China's efforts to regulate organ transplantations, some questions remained open. For instance, there was no clear regulation regarding allowing or forbidding sourcing from brain dead but cardiac alive people. For followers of some religious orientations this caused an ethical dilemma as organ donation and/or organ sourcing from cardiac alive people was perceived as immoral for both the organ donor and his/her family and the organ recipient.

China's Organ Transplantation Practices in the Spotlight

Already in 2005 the Chinese government indicated that most of the organs that were used in transplantations in China came from executed prisoners (Actares 2008a; Keller 2010). Soon after, Matas and Kilgour (2006) published their preliminary report about organ sourcing in China and confirmed that executed prisoners (especially Falun Gong followers) were the main source for organs. Some countries and international institutions quickly responded: The United Nations, for example, approached the Chinese government in 2006 to clarify the allegations about organ sourcing from Falun Gong practitioners (Kilgour 2012). Similarly, the European Parliament discussed the issue of organ sourcing from executed prisoners and Falun Gong practitioners and condemned such practices (Kilgour 2012). Some pharmaceutical corporations that were conducting clinical trials involving organ transplantations in China at that time decided to voluntarily end their trials given the organ harvesting controversy. Novartis and Pfizer, for example, ceased their clinical trials and business operations related to organ transplantation in China (Kilgour 2012). Roche, however, continued its business operations in China and initiated new clinical trials for CellCept in 2008.

Focus on Roche

While the organ sourcing issues were raised in 2005 and 2006 in the media, human rights groups approached pharmaceutical corporations directly already at the beginning of the 2000s.

Amnesty International Switzerland, for example, raised the issue of organ harvesting of Chinese executed prisoners with Novartis in 1999 and with Roche in 2003. Novartis was relatively responsive to Amnesty International's inquiries and started discussing the problem with the NGO at the beginning of the 2000s. Roche, however, was less responsive and took a rather defensive position.

At the end of the 2000s human rights organizations started approaching Roche more directly (Actares 2008b): Actares, an organization that represents shareholders for a sustainable economy, approached Roche during its 2008 annual meeting and criticized the company's sale of CellCept and related clinical trials in China (Roche 2008b). Actares referred to the controversial human rights situation in China and highlighted that most of the transplanted organs in China came from executed prisoners and concluded that Roche could be perceived an "accessory" to human rights violations in China (Roche 2008b, p. 5). During the 2008 general meeting Roche's chairman reacted to Actares' allegations by stressing the importance of drugs such as CellCept. According to Roche the company's priority had to be the safety and wellbeing of its patients and the participants of its clinical trials. Therefore, it would be wrong to stop delivering CellCept to China. Besides, China accounted for only 1 % of the market for immunosuppressants (drugs used during or after organ transplantations) (Roche 2008b). Actares and other human rights organizations criticized that Roche focused on the clinical trial participants only and ignored any ethical concerns regarding the organ donation side (The Public Eye Award 2010). Actares continued its pressure on Roche and regularly addressed the issue of organ transplantation during the company's annual meetings.

During Roche's 2010 general meeting a representative of the Swiss NGO Berne Declaration criticized Roche's clinical trials in China once again and described them as "running counter to international efforts to end unethical transplantation practices in China and as inconsistent with Roche's own corporate principles" (Roche 2010b, p. 6). Also, he went beyond criticizing the unethical human rights context under which organs were donated and questioned the general medical value of Roche's clinical studies in China. The Berne Declaration and Greenpeace claimed that Roche was conducting the clinical trials less for scientific purposes than for marketing purposes to gain access to hospitals and thereby increasing its market share in the country. Roche objected this allegation stating that the company had its patients' interests in mind and needed further trials to optimize the drug and investigate any potential side effects (Roche 2010b).

The confrontation between Roche and several human rights organizations regarding the company's clinical trials in China climaxed when the Swiss NGO Berne Declaration and Greenpeace awarded Roche the "2010 Public Eye Award" which was given to corporations for their irresponsible behavior. According to the Berne Declaration and Greenpeace Roche deserved this shame award because most of the organs used in the company's clinical trials in China came from executed prisoners, and Roche ignored the human rights violations related to this form of organ donation (The Public Eye Awards 2010).

At the time when the Berne Declaration and Greenpeace initiated its campaign and awarded Roche the Public Eye Award, Roche was the only pharmaceutical corporation conducting clinical trials involving organ transplantation in China. Novartis and Pfizer had already stopped their clinical trials in China because of the rising organ donation controversy (Kilgour 2012). Already in 2006 Novartis had announced ending its clinical trials involving organ transplantations in China (Bryskine 2012).

The Berne Declaration and Greenpeace invited Roche to the award ceremony in January 2010, but Roche did not attend. In March 2010 the Berne Declaration tried to hand over the award a second time during the company's annual meeting, but again Roche denied the award stating that the company did not deserve it (Roche 2010b). Roche defended its position by stating that it respected Chinese regulations and adhered to the WHO guidelines. Roche admitted that the company did not know where the organs for its clinical trials came from (Recht ohne Grenzen 2010), but it was beyond the company's responsibilities to investigate or know where the organs came from. This was rather the responsibility of the Chinese authorities (Roche 2010b).

In Spring 2010 NGOs continued criticizing Roche's defensive position and also started to encourage pharmaceutical corporations to draft an industry-wide code of conduct to define guidelines how to conduct clinical trials involving organ transplantations in China (Koller 2010). While Novartis responded positively and signaled its willingness to discuss such a code of conduct, Roche remained silent and did not react to the invitation of Amnesty International to discuss the possibility of such a code of conduct (Koller 2010).

When NGOs demonstrated in front of Roche's headquarters in Basel in Spring 2010, some activists were invited to talk to some Roche managers about their concerns. During this conversation, Roche continued justifying its clinical trials in China by pointing out the importance of such trials for its patients in China and worldwide. Their drug could save lives and therefore the company could not stop its trials in China. Also, Roche frequently referred to the fact that it was not doing anything illegal as the company adhered to local Chinese regulations. Roche admitted that it did not know where the organs came from (Recht ohne Grenzen 2010), but stressed that the company was not legally obliged to supply the organs or ask where the

organs were coming from (Triodos Bank 2010). In addition, Roche stressed that the company had already positively contributed to crucial changes in Chinese regulation regarding organ transplantation: Roche had been instrumental in improving Chinese legislation to ban organ transplants for foreigners in 2007 (Roche 2010b).

Despite Roche's defense, human rights organizations kept criticizing the corporation for its complicity in human rights violations in China and demanded that Roche stop its clinical trials in China immediately. For the NGOs it was irresponsible that Roche ignored the organ donation process.

This ongoing public criticism did not only cause bad publicity for Roche: Some investment banks and CSR rating agencies reacted to the controversy and excluded Roche from their investment offers such as the Dutch investment banks Triodos Bank and ASN Bank (ASN Bank 2010; Matas 2012; Triodos Bank 2010). Triodos Bank (2010) justified Roche's exclusion from its portfolio like this:

> Roche does not take full responsibility for its clinical trials in China. In our final assessment we balanced the gathered information and concluded that Roche's approach to clinical trials in China is not acceptable. The company's size and influence warrant a much clearer position on the origin of transplanted organs. Since the company no longer meets our human rights minimum standard, it has been excluded from the Triodos sustainable investment universe and will be removed from all Triodos investments within the short term (Triodos Bank 2010).

ASN Bank (2010, p. 38) included the following paragraph in their annual report to inform their stakeholders of their decision to exclude Roche from their portfolio:

> Roche, a pharmaceutical company, employs approximately eighty thousand people worldwide and has production facilities in various high-risk countries, including China. In principle, Roche has an extensive sustainability policy with clear views on major industry issues such as animal testing, clinical trials and stem cell research. Moreover, it makes an active contribution to making medicines available against diseases such as HIV/AIDS in developing countries. However, last year Roche proved unable to guarantee that it does not use organs from executed Chinese prisoners in testing its medicines. Roche states that all test centers have been approved by the authorities and satisfy the standards set by the World Health Organization (WHO). Nevertheless, we have removed the company from the universe.

Roche was the industry's leader in CSR (Roche 2011a), but still faced criticism from human rights groups, activists, and investment banks. How should the company respond to the Public Eye Award and the negative publicity? Was Roche in any way responsible for the sourcing of the organs that were used in its clinical trials? How could a company be responsible for something that it did not support, and did not do? What should the company do?

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Appendix A: WHO Guiding Principles on Human Cell, Tissue, and Organ Transplantation

1. Cells, tissues, and organs may be removed from the bodies of deceased persons for the purpose of transplantation if:
   a. any consent required by law is obtained, and
   b. there is no reason to believe that the deceased person objected to such removal
2. Physicians determining that a potential donor has died should not be directly involved in cell, tissue or organ removal from the donor or subsequent transplantation procedures; nor should they be responsible for the care of any intended recipient of such cells, tissues and organs
3. Donation from deceased person should be developed to its maximum therapeutic potential, but adult living persons may donate organs as permitted by domestic regulations. In general living donors should be genetically, legally or emotionally related to their recipients.
4. No cells, tissues, or organs should be removed from the body of a living minor for the purpose of transplantation other than narrow exceptions allowed under national law. Specific measures should be in place to protect the minor and, wherever possible the minor's assent should be obtained before donation. What is applicable to minors also applies to any legally incompetent person.
5. Cells, tissues, and organs should only be donated freely, without any monetary payment or other reward of monetary value. Purchasing, or offering to purchase, cells, tissues, or organs for transplantation, or their sale by living persons or by the next of kind for deceases persons, should be banned.
6. Promotion of altruistic donation of human cells, tissues, or organs by means of advertisement or public appeal may be undertaken in accordance to domestic regulation.
7. Physicians and other health professionals should not engage in transplantation procedures, and health insurers and other payers should not cover such

procedures, if the cells, tissues, or organs concerned have been obtained through exploitation or coercion of, or payment to, the donor or the next of kin of a deceased donor

8. All health care facilities and professionals involved in cell, tissues or organ procurement and transplantation procedures should be prohibited from receiving any payment that exceeds the justifiable fee for the services rendered.
9. The allocation of organs, cells, and tissues should be guided by clinical criteria and ethical norms, not financial or other considerations. Allocation rules, defined by appropriately constituted committees should be equitable, externally justified, and transparent.
10. High-quality, safe, and efficacious procedures are essential for donors and recipients alike. The long-term outcomes of cell, tissue and organ donation and transplantation should be assessed for the living donor as well as the recipient in order to document benefit and harm.
11. The organization and execution of donation and transplantation activities, as well as their clinical results, must be transparent and open to scrutiny, while ensuring that the personal anonymity and privacy of donors and recipients are always protected.

The full list and explanation of the guidelines can be found here: http://www.who.int/entity/transplantation/Guiding_PrinciplesTransplantation_WHA63.22en.pdf

Appendix B: Methodology

The teaching case study is mainly based on an analysis of secondary data resources. In addition, the author contacted several human rights organizations to receive further details on how the NGOs handled their campaign and how Roche reacted to their campaign and activities. The case focuses on the 2010 Public Eye Award for Roche. Therefore, most of the secondary data sources are from 2010 or earlier. To obtain a balanced overview of the narrow issue of clinical trials in China and the broader human rights situation in China, information was gathered from the pharmaceutical industry, industry associations, the media, academic publications, and non-governmental organizations.

As the focus of this teaching case study is the moment when Roche received the Public Eye Award in 2010, mostly corporate communications such as the annual report or trial information until 2010 were consulted to provide an overview of what was communicated until the moment when Roche received the award. Luckily, pharmaceutical companies provide a lot of information on their websites regarding their current clinical trials. Besides corporate communications, data from industry associations or international institutions such as the World Health Organization were also reviewed to receive a solid overview of industry standards regarding clinical trials and organ transplantation.

As the Public Eye Award given by the Berne Declaration and Greenpeace was the starting point of the teaching case study, data from various NGOs were consulted to verify the claims made by the Berne Declaration. Reports and other publications by Amnesty International and the Berne Declaration were reviewed. In addition, the author talked to representatives of the NGOs to get additional information about Roche's reaction to the issue and the campaign, and the reaction of Roche's competitors to the issue. All these NGOs have a reputation of being serious, providing conscientious research, and abstaining from any scandalous activities. To further balance the information received from NGO sources, data from the media and as well as academic publications were reviewed (Santoro 2009; Harney 2009).

Overall, the various sources of secondary data and personal conversation and correspondence with members of NGOs provide a good overview of the problematic discussed in the teaching case study.

Appendix C: Teaching Guidance

Suggested Questions

1. Do a stakeholder analysis: When deciding how to respond to the recent NGO campaign and activities, which stakeholders should Roche consider?

The key question for students is to think about how Roche should react to the recent events (NGO criticism and the reaction of some investment banks to exclude the company from its portfolios). Obviously, there is a conflict between the company's economic objectives (i.e., making profit), responsibility towards its patients (providing a well-functioning drug), and ethical considerations (human rights violations related to organ transplantations in China). Thinking about this conflict in terms of stakeholders might help students in judging the corporation's responsibilities towards each stakeholders and evaluating the company's options.

Students will probably list the following key stakeholders: organ donors and their families, donor recipients and their families, hospitals and their personnel, future consumers (i.e., patients) that benefit from the clinical trials; the media, international organizations such as the United Nation or the World Health Organization, NGOs, CSR rating agencies, investment banks, business partners, and the government (the Chinese government as well as the Swiss government). As a follow-up question, students can be asked to rank the

stakeholders and list the top three stakeholders and provide a concrete action plan per stakeholder. Discussing the different stakeholders, their priorities, and Roche's responsibilities towards each of the stakeholders, will illustrate students the complexity of making decisions when a company is faced with a dilemma between its economic objectives and ethical responsibilities.

2. Is Roche complicit in any of those human rights violations?

The concept of complicity is anchored in the legal concept of aiding and abetting under international criminal law (Ruggie 2008b). It implies that actors are responsible for harm if they assist, encourage, or morally support a crime before, during, or after the execution and if they know about the crime intention of the party conducting the abuse (Clapham and Jerbi 2001). In particular there are three different understandings of complicity:

Direct complicity is the narrowest form of complicity and assigns responsibility to actors for harmdoing if they knowingly contribute to or assist in violations (Ruggie 2008a). A wider interpretation of complicity is *beneficial complicity* according to which corporations are responsible for human rights violations if they benefit from them without having initiated or influenced the action leading to the abuse (Clapham and Jerbi 2001). Finally, s*ilent complicity* builds on the assumption that corporations are responsible for human rights violations even if they do not benefit from them, have not initiated or influenced them (Clapham and Jerbi 2001). Depending on what has been discussed during the course, the students can list the various forms and conditions of complicity.

The question is whether students agree with the allegations of NGOs that Roche is beneficially and silently complicit. According to the NGOs, Roche benefits from the availability of organs in China. This enables the company to conduct its trials in the first place and to monitor, and improve its drug CellCept. Without the organs from prisoners the clinical trials might not be possible. Roche might also be silently complicit, as the company has not objected to the human rights abuses or conditions under which the organs are sourced. Here, students can also discuss the different reactions of pharmaceutical corporations. Novartis and Pfizer left China early to avoid any potential complicity while Roche stayed in China and initiated new clinical trials for CellCept.

3. In 2008, UN Special Representative John Ruggie introduced a framework on business and human rights to the UN Human Rights Council. Please apply Ruggie's framework on "protect, respect and remedy" to the case. What are the relative responsibilities of the different actors?

According to Ruggie's framework (Ruggie 2008b), it is the state's duty to protect human rights, the corporations' duty to respect human rights, and the state's and corporation's duty to provide access to remedy.

Protect

The case study makes clear that the state (Chinese government) fails to protect its citizens from human rights violations. The state does actually the opposite: It conducts or supports various human rights violations. Looking at China's long-term record of human rights violations, it is unlikely that the government changes in the near future. Students can discuss whether any other state would have a responsibility to protect Chinese citizens from human right abuses. Also, students might want to discuss whether corporations have any responsibility to protect human rights when governments fail to do so. Wettstein (2009), for instance, provides some arguments why corporations have the positive moral obligation to protect citizens from human rights abuses.

Respect

Ruggie assigns corporations the duty to respect human rights—especially when local regulations or enforcement do not exist. The corporate duty to respect translates into due diligence. Students might discuss whether Roche (and other pharmaceutical companies that conduct clinical trials in China) failed its (their) duty to respect human rights. China's human rights violation record and execution policies were publicly known, and criticized worldwide (as early as 1999 and 2000). The question is whether pharmaceutical companies should have known that there is a significant likelihood that organs used in their clinical trials are taken from executed prisoners. Ethical standards of medical associations are clearly opposed to such a sourcing on ethical grounds.

Here students can discuss how far the corporate responsibility to respect human rights goes in regards to clinical trials. Roche has been stressing that its primary duty is towards its patients and the participants of its clinical trials. The company has not considered being responsible for the organ donation side of the whole process. The key question is whether pharmaceutical corporations are responsible for human rights violations related to organ recipients *and donors*?

Remedy

Both, governments and corporations, have the duty to provide access to remedy. This might include regulations and systems for investigating and punishing human rights abuses. Since the Chinese government engages in (authorizes) human rights abuses, it is unlikely that the state government establishes remedy procedures. Corporations can of course not directly establish any official regulations

or procedures for remedy. However, corporations can demand more transparency and request information about the origin of the organs. Students can discuss in how far pharmaceutical companies can provide remedies, and how such remedies could look like.

4. Please list different options that Roche could do. How might each of these options be supported using consequentialist and non-consequentialist ethical arguments?

The teaching case study focuses on the moment when the critique against Roche's trial becomes public through the Public Eye Award. The key question of the case is then how a company with a good CSR reputation can react to such allegations.

Most students will probably propose two opposing options: (1) do nothing and continue business as usual, or (2) stop the clinical trials. However, there are some intermediate options as well. Depending on the ethical theories and concepts discussed during the course, students can evaluate and justify any of those options using consequentialist and non-consequentialist ethical arguments. Alternatively, students can also sort the arguments per option along the following categories: legal, economic, and moral arguments. In class, students can be asked to issue a press release in which they summarize the company's position and further approach to China. When students discuss the different options and arguments, they might also want to compare Roche's activities to the company's competitors (e.g., Novartis).

	Legal	Economic	Moral	
			Consequentialist	Non-consequentialist
Continue trials, and do nothing	No legal violation in China or in the company's home country (Switzerland) Avoid legal consequences from Chinese partners for breaking the contract by simply stopping the trials	Cost effective to conduct clinical trials in China Keep good relations with China and Chinese partners Existing contracts need to be fulfilled	Maximizing profit. China is a lucrative outsourcing location (low costs, lucrative regulatory framework) Ends justify the means: The clinical trials will benefit lots of patients worldwide	Duty to stockholders, who expect sound and profitable business decisions Duty to patients, and participants of the trial.
Stop current clinical trials immediately	Avoid any future legal restrictions by being proactive Avoid potential lawsuits by families of executed prisoners whose organs were used without consent	Avoid negative effect on reputation, or stock prices. Potential to be perceived as a leader in CSR in the industry through such a drastic action	Roche's reputation has already suffered following the bad publicity of the Public Eye Awards in 2010. Stopping the clinical trials immediately might help Roche in damage control, and rebuilding public trust	Duty to adhere to the ethical standards in the industry It is Roche's responsibility as a good corporate citizen to stop the clinical trials immediately Duty to respect religious beliefs. Some organ donors might not have wanted their organs being used
Finish current clinical trials, and then stop doing any clinical trials in China until problem is solved	Respect current existing contractual agreements	Keep relations with contract partners in China Option to continue partnerships once issues are resolved	Considering the current trials, harm is done. By finishing the trials as planned, more people gain than lose Announcing not to conduct any future clinical trials in China signals company's goodwill and might help Roche in reestablishing its reputation and reestablishing public trust	Roche has a duty to the current participants in the clinical trials to finish the trials as planned
Initiate change by collaborating with stakeholders to find long-term solution	Avoid any legal restrictions by offering a voluntary industry standard	Positive effect on the company's reputation Achieve competitive advantage if Roche is the initiator of such a multi-stakeholder initiative	Increase credibility among its critics If various actors work together, they are more likely to achieve something Keep your "enemies" close	Part of Roche's duty to respect (and even protect) human rights If an actor is in a position to improve a situation, he has the obligation to do so

Courses

The case study is primarily written for business ethics and CSR courses at all levels, undergraduate and graduate level. The case study has been successfully discussed in both, undergraduate and MBA classes. Also, the case was used as an in-class exam at both levels, undergraduate and MBA levels.

Case Objectives

- Become aware of ethical challenges that can arise in business
- Evaluate the strengths and weaknesses of various moral beliefs and ethical theories relevant to business practice
- Analyze the role of due diligence in outsourcing decisions
- Familiarize students with Ruggie's "protect, respect and remedy" framework
- Examine the role of corporate complicity in human rights violations

Teaching the Case

The case can be discussed in one class period lasting 60 to 90 min. It is advisable that students prepare the case in advance, so that they are familiar with the issue. The preparation can range from simply reading the case to writing a short summary of the case, or to answer some of the questions. A suggested class outline (75 min) is provided below:

Introduction (10–15 min)

The instructor might begin the class by asking students what they know about the human rights situation in China. Here, students are likely to refer to the human rights abuses mentioned in the case.

Group Discussion (20 min)

Following this short introduction, the instructor could divide the class into several groups of four to six students each, depending on class size. Each group is asked to represent one of the stakeholders of the case: Roche, Chinese prisoners (and their families), Chinese clinical trial participants (and their families), patients, the Chinese government, and the Swiss government (Roche is a Swiss company). Each group is asked to discuss the case from their stakeholder's point of view. The instructor can use some of the suggested questions, and ask the groups to answer them from their stakeholder's point of view.

Alternatively, the instructor might want to focus on the following question: Who is responsible, and what should be done regarding the clinical trials using organs from executed prisoners? The stakeholder groups have very diverse attitudes towards the issue. For instance, the Roche group will argue from an economic and legal perspective; the participants of the clinical trials will argue for the continuation of the trials as the trials are the only option for most of them to receive treatment; the prisoners might criticize the human rights violations and unfair treatment and expect help; or the Chinese government group will argue that no one has the right to criticize the country's way of governance. If students are given their stakeholder group and the questions in advance, they can prepare their argumentation in advance. In that case, the internal stakeholder group discussion can be shortened to 10 min, so that there is more time for class discussion (see below).

Alternatively, the instructor can also divide the class in groups and ask each group to focus on a specific question (examples are given above).

Class Discussion (30 min)

Coming together again as a class, the instructor can ask each group for a stakeholder statement regarding who is responsible and what should be done. To facilitate the discussion, the instructor can summarize key arguments per stakeholder group on a whiteboard or blackboard while students are presenting their considerations. To trigger a more focused discussion, the instructor could also present the different options (continue trials now and in the future, stop trials after the current ones are finished, initiate changes together), and ask each stakeholder group to evaluate them from their point of view.

Conclusions (5–10 min)

If there is time left, the instructor wraps-up the debate. Students might want to know what Roche did following the critique in 2010. In its 2010 Annual Report, Roche stated the following:

> "**Organ transplantation**. In 2010 an NGO raised concerns that organs used in two Roche clinical trials in China may have been harvested without consent, and possibly from executed prisoners. The trials into the use of the immunosuppressant CellCept in organ transplants involve 298 patients at 16 accredited transplant centres, and are being carried out to establish whether the standard CellCept dose will safely and effectively prevent organ rejection in people of Chinese origin. For clinical trials in China we follow the same scientific, medical and ethical

standards as in all other countries. We support a worldwide ban on any use of organs from executed prisoners, as well as on the death penalty. However, as in many countries, Chinese legislation prevents pharmaceutical companies from determining the origin of transplant organs. We will complete the two trials but have no plans to carry out further transplantation trials in China at this stage. Any future trials will continue to adhere to the Declaration of Istanbul on Organ Trafficking and Transplant Tourism and the WHO Guiding Principles on Human Cell, Tissue, and Organ Transplantation. We contributed to changes in Chinese legislation in 2007. As a result of these changes, the number of transplants from living donors has increased. Efforts to introduce a system for people in China to sign their consent to donate an organ are also having a positive effect. We strongly believe that organ do-nation by freely consenting donors is the most effective way to contribute to an ethical and sustainable solution in this area of medical practice. We welcome all support in this area, to improve the situation for patients in need of organs" (Roche 2010c, p. 113).

Updates: 2011 and 2012

In May 2011 Roche confirmed that it will not conduct any new trials in China involving organ transplantation, but intended to finish its ongoing clinical trials (Roche 2011f). The problem of organ donation from executed prisoners continued and doctors called for a boycott of "Chinese science and medicine pertaining to organ transplantation" (Caplan et al. 2011, p. 1218).

While China recently announced to ban organ donation from executed prisoners (Bradsher 2012), human rights organizations continue to address the issue (Strassheim 2011) and encourage pharmaceutical corporations to draft an industry-wide code of conduct that would explicitly outline ethical guidelines for organ harvesting and respect the rights of organ donors and their families.

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