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Promoting Ethical Ultrasound Use in India A BLIHR Emerging Economy Case Study from GE – January 2009 Introduction: The Benefits and Burdens of Ultrasound Technology The distribution of compact, portable ultrasound technology in India offers significant potential health benefits to millions who suffer from painful or potentially lifethreatening diseases, such as breast cancer, uterine fibroids, cardiac disease and gynecological disorders. Ultrasound technology also has the potential to increase efficacy and early detection in diverse medical fields such as anesthesia delivery, cardiac surgery, sports medicine, and emergency medicine.

Ultrasound is also uniquely powerful in that it is the only imaging technology that can be transported to a patient or used where a patient might most urgently need it – whether on the side of a road after a serious motor accident or in remote communities where a patient may have to travel for several hours just to reach a basic primary health center. When one considers this vast scope of medical applications, along with the great need for imaging technologies among rural and urban populations in India, it is clear why India’s ultrasound market poses both a significant business and public health opportunity. Over the last decade, however, some civil society groups have focused on ultrasound technology as a cause of increased rates of female feticide in India. In India, as in certain other countries and cultures, there exist deeply rooted historical preferences for male children. Observers have noted that these preferences are driven by a combination of cultural and economic factors.

Traditionally, Indian parents are expected to pay expensive dowries to their daughter’s future husband’s family to which the parents then “ lose” her. In a country without a social security system, male children are often viewed as their parents’ long-term security when girls are expected to marry and eventually leave home. Yet, the economic concerns are only one part of the story. In fact, the numbers of female vs. ale births have been dropping most quickly among wealthy, urban populations, specifically in northern Promoting Ethical Ultrasound Use in India A BLIHR Case Study from GE 1 India.

This trend suggests that economic security alone will not safeguard female fetuses. Allegations that ultrasound technology is misused to facilitate female feticide in India have arisen despite government legislation and action to reduce rates of female feticide through prohibition of sex-selective abortions. In 1998, the Indian government authorized the “ Pre-Natal Diagnostic Techniques” (PNDT) Act of 1994, a law that prohibits any person or body from using equipment or techniques for the purpose of detecting the sex of an unborn child. There are exceptions for diagnoses of specified sex-linked diseases or disorders. The law also prohibits anyone from communicating the sex of the fetus if it is detected during a pre-natal examination or diagnostic test.

The law requires, among other things, that all practitioners, clinics, genetic counseling centers, etc. hat perform pre-natal diagnoses register with the government, obtain a certificate of registration, and display a notice regarding the prohibitions on fetal sex detection. Then in 2004, the government implemented the 2002 amendments to the PNDT Act, explicitly recognizing the responsibility of manufacturers and distributors to assure proper use of ultrasound equipment, prohibiting them from selling, renting, permitting or authorizing the use of ultrasound machines for fetal sex determination, and imposing criminal punishment such as fines and jail time. Manufacturers must confirm that the customer has a valid PNDT Certificate and has signed an affidavit stating that the equipment shall not be used for sex determination. Manufacturers also must provide the government with a quarterly report disclosing to whom the equipment has been sold. GE has observed that these laws are weakly enforced by the government, that reports of female feticide are still commonplace, if not increasing, and that other reports point to declining numbers of female live births relative to male live births in many areas of both rural and urban India.

While the spread of ultrasound technology certainly is not the root cause of the increase in reports of female feticide, the compact, portable and relatively low-cost nature of this technology does increase the complexity of administratively overseeing and prosecuting medical practitioners, companies or other individuals who violate the PNDT Act and misuse the technology to assist in sex-selective abortions. In addition, couples may now use other technologies such as in-vitro fertilization and prePromoting Ethical Ultrasound Use in India A BLIHR Case Study from GE 2 mplantation genetic diagnosis to determine sex and implant male embryos selectively, thereby further skewing the sex ratio without having to resort to sexselective abortion. While the exact scale of the challenge in India—in terms of the numbers or statistics on female feticide—is unclear and contentious, reports suggest that this is a societal problem that is on the rise. Against the backdrop of deeply rooted cultural-economic biases and weak government regulation in India — the spotlight shifted to the corporations that produce and sell ultrasound technology in this emerging economy. GE Healthcare (GEHC), which had the benefit of experience addressing similar issues in China, worked with GEHC India to respond with increased safeguards against illegal sales and support for campaigns to increase awareness of the human rights issues at stake. GEHC India’s ongoing experience demonstrates how a major corporation can act, through CSR and education campaigns, in a manner that advances important human rights yet fits within the bounds of its commercial strategy.

It also provides Box 2: Several Human Rights At Stake UDHR Articles 2 ; 3: Equal rights without reference to sex ICCPR Article 2: Non-discrimination on the basis of sex in relation to all rights ICESCR Article 2 ; 12: Nondiscrimination in relation to all rights; Highest attainable standard of physical and mental health CEDAW Article 1, 5: No discrimination based on sex; Eliminate prejudices, customs and practices based on idea that women are inferior CRC Article 2: No discrimination based on sex xamples of steps a manufacturer can take to reduce the risk that its products will be misused in ways that violate human rights. Respecting Many Human Rights. This case presents several important human rights considerations and quandries including how to balance various human rights at one time and respect culutral differences. Clearly, fetuses against the selective and violates practices human (See Box 2)1 of female protections based on abortion rights customs – – – prejudices against women. Given the number of uses of ultrasound in obstretics andReferences are as follows: “ UDHR” is the Universal Declaration of Human Rights; “ ICCPR” is the International Covenant on Civil and Political Rights; “ ICESCR” is the International Covenant on Economic, Social and Cultural Rights; “ CEDAW” is the Convention on Elimination of All Forms of Discrimination Against Women; and “ CRC” is the Convention on the Rights of the Child. Promoting Ethical Ultrasound Use in India A BLIHR Case Study from GE 1 3 gynecology, restricting women’s access to the technology would conflict with the human rights goal of reaching the highest standards of health.

In addition, while There sex-selective abortion is technically illegal in India, there is evidence that noncompliant or unscrupulous practitioners still perform sex-selective abortions. is a good chance that these illegal procedures are performed under less than adequate conditions. Thus, if abortions are performed outside of hospitals or by unlicensed practitioners, it is more likely that the medical procedure would put mothers’ health at risk and jeopardize their future reproductive abilities, if not their lives. There is also concern that women may be forced to undergo coercive These rights are also indirectly referenced by two of the eight UN abortions when they do not share the discriminatory views of their families or communities. Millenium Development Goals: “ Promote gender equality and empower women” and “ Improve maternal health.

” On the other hand, one might also advance a human rights argument on behalf of the millions of Indian citizens whose health or well-being could be severely harmed by limiting the use and proliferation of ultrasound technology. If we imagine a scenario in which the use or spread of technology is severely curtailed in order to “ solve” the female feticide problem, then the rights to life, health and well-being of those citizens would also be threatened. Indeed, the use of ultrsound goes well beyond obstetrics and gynecology, and GE has donated ultrasound technology throughout the developing world for many years in connection with established product donation programs and in response to human health crisises, such as those caused recently by the Indian Ocean Tsunami and South Asia earthquake. be misused in a way that greatly undermines other human rights. Finally, the principle of non-complicity is thought provoking in this case. While there has been much debate over what constitutes “ complicity” by a business, the principle speaks to the idea that a company may be considered complicit in human rights abuses if, for example, as set forth in the U.

N. Global Compact, the company The potential for misuse of products is, of course, not unique to ultrasound or GEHC. GE has discussed its responses to the potential for misuse of ultrasound and other technologies in its Citizenship Reports in an effort to increase transparency of the Company’s actions and to diffuse concern about its products. Visit http://www. ge.

com/citizenship Promoting Ethical Ultrasound Use in India A BLIHR Case Study from GE 2 An obvious paradox results: The same technologies that further some human rights can 4 “ knowingly ignores human rights abuses committed by an entity associated with it, or if the company knowingly provides practical assistance or encouragement that has a substantial effect on the perpetration of human rights abuse. ” Could a viable charge of complicity attach to GE based on human rights violations with respect to such violations commited by on-state actors who ignored the Company’s warnings regarding PNDT compliance and were acting in violation of the Indian law? Indeed, critics of GEHC India argued that the Company’s sales of ultrasound technology were enabling doctors to illegally determine sex thereby contributing to human rights violations. Legal debates aside, the first challenge for GEHC India, which strenuously denied such accusations, was to ensure and communicate that the Company was taking all necessary measures to avoid even the appearance of any form of complicity. In India, the threats to GEHC’s business posed by these human rights allegations were significant. First and perhaps most important, the criticisms threatened GE’s corporate reputation in India as a multinational company, not just within the GEHC unit. The effects on corporate reputation were particularly apparent when allegations began appearing in international media outlets, such as the Wall Street Journal.

The highly negative association of GE’s name with such an emotional human rights issue, female feticide, posed a threat to GE’s reputation world-wide, even as to products that had no direct connection to ultrasound or GEHC India. Second, if left unchecked, the criticism from activists potentially could threaten GEHC’s access to the Indian ultrasound market, which the Company currently holds the largest market share. For example, in 2006, GEHC claimed about 51% of the ultrasound market share in South Asia. Moreover, ultrasound is a significant portion of GEHC’s current sales and plans for growth. In South Asia, where high-end imaging systems like MRI is limited due to cost, and relatively few in the medical field are trained in these advanced imaging technologies, the growth potential for ultrasound is significant.

It could be argued that GEHC’s view of female feticide as a threat to its international business reputation undercuts any claim by the Company that it was truly concerned about the issue as human rights violation. Others might argue that GEHC has demonstrated a lack of sensitivity towards local cultural differences by acting out of concern for its international reputation and/or by imposing international human Promoting Ethical Ultrasound Use in India A BLIHR Case Study from GE 5 rights values on Indian customers since many parts of Indian society do not agree with the Act’s prohibitions (as demonstrated by the weak enforcement of the PNDT Act and rising rates of female feticide). GE rejects the view that a company’s This case study concern for preserving its reputation is somehow inconsistent with its ability to advance human rights or to respect important cultural values. interests. GEHC India’s approach to this human rights dilemma has evolved over time and can be compared and contrasted to the Company’s response to reports of misuse of ultrasound technologies for gender selection in China, which initially received greater focus due in large part to China’s controversial “ one child” policy. (See Box 3) Like in India, preferences for male children exist in some societies in China.

Also, like India, China passed legislation outlawing the use of ultrasound for gender selection (yet Chinese law does not place liability for misuse on manufacturers). In both India and highlights, however, how difficult it can be to balance those sometimes competing Box 3: GEHC’s Sale of Ultrasound in China In early 1996, GE’s General Counsel, Ben Heineman, asked the GEHC legal team: “ What are we doing in China which may cause us to have a human rights problem, and what can we do to mitigate any risk? ” Risks Identified: – Cultural preferences for male children. Government’s controversial “ one child” policy had received worldwide attention and criticism from human rights, feminist and religious groups. – Despite legislation that prohibited medical professionals from identifying gender of fetus unless medically necessary, family planning clinics charged with enforcing one child policy had been accused of performing abortions that were genderbased. – Alleged abuses highlighted by Tiananmen Square events, subjected Western MNCs to greater scrutiny from human rights groups for doing business in China.

Some of GEHC’s Responses: – Refused to sell ultrasound technology to family planning clinics, or to sell products below a certain price point to reduce chance that products would enter the birth control market. – Advised customers by placing stickers on machines, and in writing and advertising that using ultrasound to detect gender of fetus was illegal. Chinese joint venture partners also undertook these actions. – Trained sales and marketing personnel about illegal use of ultrasound and to avoid sales where misuse was suspected. China, GEHC took actions that went beyond what was legally required. However, human Company when rights in 2006, Indian through the these activists began linking GE with this dilemma that international media outlets, understood criticisms posed even greater threats to its reputation and market growth and that more action was needed.

Promoting Ethical Ultrasound Use in India A BLIHR Case Study from GE 6 Company Response: Increasing the Stringency of Safeguards Like GEHC in China, GEHC India wanted to demonstrate that it was stringently screening potential ultrasound sales and taking precautions to avoid the misuse of the ultrasound technology after it had been sold. Indeed, since 2000, GEHC India has worked through a combination of training programs, amendments to legal contracts, regular auditing, and rigorous sales screening and tracking, to increase the stringency of the sales review process. (See Table 1) These actions were taken well prior to 2004, the year when the PNDT Act’s amendments imposing liability for manufacturers were implemented, and go beyond the manufacturers’ legally required controls. Table 1: Timeline of GEHC India’s Actions and the PNDT Act 1990s GEHC India Actions 1998: PNDT Act of 1994 is authorized. Manufacturers are not covered by the Act. Began proactively communicating through customer magazines and website to all hospitals, nursing homes and diagnostic centers about the PNDT Act and the need to adhere to the law – Began first training for sales agents on legal implications of PNDT – Instituted mandatory training (on PNDT legal implications) for all sales/service employees and dealers who are involved in ultrasound sales – Implemented internal policy on PNDT compliance which is updated or renewed annually – Added explicit warnings about PNDT law to terms ; conditions sections of all sales contracts – Added strict PNDT obligations to all dealer and dealership agreements; clearly state that non-adherence will result in termination of sales relationship – Began osting on GE ultrasound machines clearly that “ Fetal Sex Discrimination is Illegal” (See Box 4) – Instituted quarterly PNDT audits of dealer sales ; direct sales to ensure that 100% of completed sales are to customers with valid PNDT certificates – Began work on PNDT “ Playbook” for use as a training manual.

The Playbook explains the law and GE’s policies for salespeople to follow. 2004 2006 2007 2002 Amendments to PNDT Act are implemented. Manufacturers can be held liable for violations of the Act. – Finalized and distributed the Wipro GE Healthcare PNDT “ Playbook” – Held first meetings with critical social activist groups and representatives 2000 2002 Promoting Ethical Ultrasound Use in India A BLIHR Case Study from GE 7 2008 Began poster campaigns to promote “ Rights of the Girl Child. ” Began funding educational programs for girls. Began sponsorship of young Indian female tennis star.

At present, a single sale of ultrasound equipment goes through up to five internal checks—from the initial sales contact to equipment installation—to verify that the customer has a valid PNDT registration certificate. As noted above, a valid PNDT registration certificate means that the clinic or the user is registered with the local government and provides an affidavit that it will not conduct fetal sex selection using the equipment. Machines are labeled with a sticker that warns that “ fetal sex determination is illegal & punishable by law. (See Box 4) GEHC sales contracts and dealer agreements contain standard terms and conditions to effect compliance with the PNDT Act, such as: “ You agree not to use or permit the products to be used in any manner that does not comply with any applicable laws, rules or regulations. Further, you represent that you do not intend to re-sell the products to any other party or to export the products outside India. More specifically, contracts state, “ except when required by medical necessity .

. . [i]t is illegal to use pre-natal diagnostic techniques like ultrasonography, amniocentesis etc. , to determine and communicate the sex of an unborn child . .

. With respect to the requirement to produce PNDT certificates, contracts state in part, “ In case you are unable to provide us with the required documents as per the Act and Rules, at the time of invoicing, we shall have the right to cancel your order without incurring any liability to you for the same. ” Sales people are trained on how to advise end users of the equipment on the implications of the PNDT Act and to escalate any concerns about observed or suspected non-compliance to their managers. They are also encouraged to balance their desire to increase equipment sales with the caution to not participate in sales Promoting Ethical Ultrasound Use in India A BLIHR Case Study from GE 8 that may end up in the hands of unscrupulous or unlicensed practitioners. Even if a potential customer has a valid PNDT certificate—but the sales person senses from a customer’s comments or behavior that the equipment may be used unethically or fall into the wrong hands—the sales person is required by GEHC to terminate all sales discussions.

This screening process does not end after the equipment’s sale. A practitioner must also present a valid PNDT registration certificate before having the equipment serviced by GEHC India or purchasing updated accessories. These internal policies and trainings were seen as necessary steps in increasing safeguards during the sales process to lower the risk that the equipment would be misused. In an effort to further address the issue of female feticide head on, GEHC India recently launched a campaign to raise public awareness of this human rights violation. GEHC India distributed a series of educational posters to its customers, the end-users of the ultrasound equipment. The posters were designed to be attention grabbing, raise awareness about female feticide, and discourage the practice.

The campaign is viewed as a long-term approach to addressing this human rights issue as opposed to one that is directly linked to managing the public’s perceptions of GE’s business practices. The goal is to expand the public’s awareness raising campaign beyond its immediate customer base by distributing a series of these posters through the national government of India. See Box 5) Stakeholder Perceptions: Criticism Shifts to Doctors and Other Manufacturers Vocal stakeholder groups in India, including NGOs and social activists, have a multidecade history of publicly opposing feticide and infanticide in India and advocating for government action and societal change. For example, the research and advocacy group CEHAT (Centre for Enquiry Into Health and Allied Themes) played a pivotal role in ensuring that the PNDT Act was implemented. Since 2001, CEHAT, the Forum against Sex Determination and other groups have focused the spotlight on the role they claim ultrasound manufacturers play in enabling or increasing the rate of sexselective abortions.

Dr. Sabu George, a researcher and one of the most outspoken activists on the subject, began openly criticizing GEHC India’s sales practices in 2002 through an article in the international journal Reproductive Health Matters. While GEHC has also taken the initiative to meet and work with Indian government officials to identify proactive ways to educate doctors against misuse, such as with the stickers, labels, PNDT audits and reporting concerns about non-compliance. Promoting Ethical Ultrasound Use in India A BLIHR Case Study from GE 3 9 activists also have noted that a significant part of the challenge was the history of inequality of women in Indian society and the national and state government’s weak enforcement of the PNDT Act, they also targeted GEHC India for, in their opinion, not doing enough to ensure that the technology GEHC sold was used ethically and legally by customers. In 2006 and 2007, a number of spokespersons from these groups were quoted by national and international media criticizing ultrasound manufacturers for facilitating or enabling the rise in sex-selective abortions.

Since 2007, GEHC India executives have met with many of the critical activist group leaders including Dr. Sabu George. Through these meetings and through GEHC India’s systematic efforts to increase safeguards in the sales process, executives feel they have been successful in engaging and educating these stakeholders about what GEHC is doing to lower the risk of misuse of its ultrasound equipment. A February 2008 Times of India article quotes Sabu George as stating that, in his opinion, “ doctors are to be blamed” for the misuse of ultrasound technology. While this article suggests a change in some activists’ focus away from manufacturers, the same article mentions that several manufacturers have not submitted customer sales data to the government as required under the PNDT law, which threatens the government’s enforcement efforts.

In contrast, since 2004, GEHC consistently has submitted its quarterly sales data and customer lists to the Indian government. This demonstrates that notwithstanding GEHC India’s efforts, it bears the burden of being lumped together with all other ultrasound manufacturers – those that are compliant and those that are not – on this emotional human rights issue, female feticide. The Boston Globe, 10 January 2006. “ A girl deficit grows in India. ” The Times of India. 4 February 2008.

“ The girls never born. ” GE does not express an opinion on such views. The Company observes that many in India’s medical community and medical organizations, such as the Indian Radiology and Imaging Association, have been vocal in their objections to the practice of female feticide and have provided assistance to the government and education on complying with the PNDT Act to their members and others in the medical community. See www. iria. in and www.

ijri. org. 5 4 Promoting Ethical Ultrasound Use in India A BLIHR Case Study from GE 10 GEHC India cannot ignore the role and track record of some of its competitors in the ultrasound market because any company that does not address the human rights concerns of female feticide can bring disrepute to this technology and GEHC as a leading manufacturer. Competition is rising from other Western MNCs and from 6 other countries, such as China, that are entering the Indian ultrasound market with less expensive products. If GEHC India’s competition fails to comply with or If human rights otherwise flouts the PNDT Act, GEHC India could lose brand familiarity among all customers, including its customers who comply with the law. violations by the end users increase, even if that increase is tied to a different manufacturer’s activity, it is possible that GE would suffer reputation backlash or a loss of brand capital in India—simply due to its association with an industry viewed by some as “ irresponsible”.

GEHC India faces the challenge of convincing skeptical competitors that the efforts GEHC India has made to avoid sales to unscrupulous practitioners actually have been effective. One can point to data on sales volume and internal audits, such as in 2002, the first full year after GEHC had begun implementing the new measures in India, when the Company’s ultrasound sales growth declined from the previous year by approximately 22% and the sales decline for black-and-white ultrasound machines was especially sharp. 7 also could be attributable to increased competition from Yet, such a drop other ultrasound manufacturers and changing preferences among buyers. Undoubtedly, in addressing challenges presented by a competitive market, the Company will have to rely on all of the lessons it has learned about the human rights problem of female feticide in India and elsewhere. Lessons Learned: Respecting Human Rights through Outward Looking Educational Campaigns and Promotion of Standard Practices In reflecting on their experiences in India, GEHC executives focus on the idea that the most effective approach to these types of challenges requires action on several levels.

For a report on local responses to new entrants see The Tribune, India (online ed. ), 22 June 2007. “ Cheap Chinese ultrasound machines flood Indian market. ” 7 Wall Street Journal Europe. 18 April 2007. Promoting Ethical Ultrasound Use in India A BLIHR Case Study from GE 6 11 Enforce Rigorous Internal Controls.

Of course, the first step in approaching uman rights challenges requires an internal look to make sure that the Company is not only obeying the rule of law, but also conducting itself in a way that is effective and culturally sensitive. GEHC India has attempted to do this through its rigorous sales process review that goes beyond basic legal requirements to avoid risks where possible and by training its employees to keep their eyes open and to know the customer. These efforts are consistent with GE’s Company-wide integrity policies which not only require GE employees to obey the applicable laws and regulations governing the Company’s business conduct worldwide, but also to promptly report any red flags or potential issues that may lead to a regulatory compliance breach. The second step, GEHC India has learned, is to move beyond vigilance of one’s own operations and think creatively about how the Company can contribute to the wider societal change that must take place in order to tackle the root cause of these challenges to human rights, such as: Work with Government and Promote Standard Industry Practices. GEHC India has met with government officials to share information about its internal controls and sales practices that go beyond the PNDT Act’s requirements and the Company has called upon the government to increase enforcement activities and education programs.

GE also has pushed for industry-wide action. With the support of activists, GEHC India executives have reached out to other companies through the Confederation of Indian Industries (CII) to address the problem of female feticide. GEHC believes this type of engagement has paid off by boosting the Company’s reputation among reputable practitioners and by changing public attitudes of the social activists towards GEHC India and its sales practices. Raise Public Awareness of Human Rights. GEHC India’s poster campaign is one effort to think creatively about how to change attitudes about female feticide, the status of girls and women’s rights. In addition, GEHC India has designed at least two new CSR programs: social investment in initiatives that promote education and equality among girls in India, and sponsoring a young, female, Indian tennis star.

While GEHC India’s CSR initiatives in this issue area are still nascent, they reflect a maturing business strategy of addressing human rights issues that moves beyond Promoting Ethical Ultrasound Use in India A BLIHR Case Study from GE 12 addressing non-complicity concerns and begins to integrate human rights into its implementation of corporate social responsibility. Note to Readers: This case study was prepared by GE with the assistance of Business for Social Responsibility (BSR), which consulted publicly available secondary sources and direct input from GE executives who are familiar with this case. For more information on this case, please contact: Frank Mantero, Director, Corporate Citizenship Programs at General Electric Company, at frank.[email protected]com Promoting Ethical Ultrasound Use in India A BLIHR Case Study from GE 13