Student

Tutor

Course

Date

Therac-25 Case Study

Ethical Issues in the Case

The Therac-25 case raises many ethical issues. The primary subject of concern in the case is safety (Bozdag 5). An analysis conducted at the three levels of the case (national, group, and individual levels) gives insights on the ethical issues raised in the case study. The three levels are unique and give rise to different ethical issues. The first ethical issue in Therac-25's case concerns the quality of life. The decision by the Atomic Energy of Canada, Ltd. (AECL) to computerize a machine that would improve the treatment of cancer was a quality of life issue. AECL did not decide to make a new technology; instead it cooperated with CGR, a French firm, to improve the Therac-20 version (Spinello 161). The two companies believed that the new technology would improve the quality of care that cancer patients received. However, a culture of negligence in the company resulted in the design and manufacture of a medical equipment that betrayed its intended purpose.

The second ethical concern in the case is the issue of self-protection. Despite having good intentions of improving the quality of care delivered to cancer patients, the company did not outline mechanisms for protecting patients. The manufacturer did not perform tests on the new equipment to ascertain it was safe for use (Bozdag 5). Safety at the individual level concerned

the equipment's programmer and operator. The programmer owed a responsibility to his or her employer (AECL), and the patients supposed to use the equipment. From the facts of the case, the system developer also failed in his or her responsibility to make the company aware of the safety issues of the equipment. The specialist failed in his or her responsibility to design a medically safe device. The operators of the medical equipment also had responsibilities to the patients and employers (health facilities). For instance, they had duties of ensuring the machines functioned efficiently and posed no danger to the patients. Operators should be highly skilled and certified to detect malfunctions in medical devices.

The group level concerns two organizations: AECL and the health facilities (e.g. hospitals) that used the equipment. AECL maintained that their devices were safe for use until the Food and Drug Administration (FDA) and the Bureau of Radiation and Medical Devices raised doubts about their safety (Spinello 163). The other group of organizations concerned at this level was the cancer treatment centers (e.g. hospitals). Even though they did not have an inherent responsibility to ascertain the devices were safe for use, they had a duty of ensuring the machines were safely operated and repaired regularly. At the national level, ethical issues concern the responsibility of the FDA to oversee the production and use of safe machines. The FDA failed to certify the safety of the machines and depended on the manufacturer to inform it of accidents (Bozdag 7). Besides, there were no laws at the time to mandate treatment facilities (hospitals) to notify the Food and Drug Administration of problems associated with the equipment.

Legal Issues in the Case and Conflicts of Morality and Law

The safety issue arising from the case is the issue of liability. The manufacturer and the cancer treatment facilities are at a risk of lawsuits from their patients. The machines affected cancer patients, and their families had the right to hold the manufacturer responsible for their medical predicaments. These patients could sue the company for neglecting safety measures in the design and manufacturing of the machines. Some victims sued the company and received out-of-court settlements. The victims could also sue the treatment facilities for neglect and unprofessionalism. At the group level, it was evident that the health centers did not have practitioners and technicians with the capacity to effectively operate the machines. For instance, the technician in Linda Knight's case did not realize he had burned the patient until Mrs. Knight went for another checkup (Leveson and Turner 21). The case also exhibits a conflict between morality and law. An example of such a conflict is evidenced at the national level. The Food and Drug Administration relied on the manufacturer to alert it of accidents or safety issues arising from the use of the equipment. According to Bozdag, there were no laws to mandate the hospitals and cancer treatment centers to report accidents to the administration (7). The decision to rely on the manufacturer to notify it of the problems encountered with the use of the machines was misguided as the manufacturer had direct interests in the devices. In other words, the manufacturer lacked moral uprightness to present unbiased reports on the defects of machines to the FDA.

Moral Intuition on the Action or Policy under Consideration

The action or policy under consideration in this case is the reporting of medical devices or equipment. Therac-2's case raises concerns about the roles of various stakeholders in reporting

medical equipment failures. Deaths and injuries in the case study resulted from the failure by concerned stakeholders to report equipment malfunctions on time. My reaction to this action is that manufacturers and user facilities should report any equipment malfunctions or problems to the oversight authority. According to the FDA, Medical Device Reporting (MDR) helps stakeholders in the health care sector to monitor the performance and safety issues of medical devices. My moral intuition says that all the stakeholders should fulfill reporting requirements when faced with a situation as Therac-25's. For instance, equipment manufacturers should inform the relevant authority (e.g. the Food and Drug Administration) of any malfunctions in a medical device. They should also report to the authority immediately they become aware that their equipment is likely to cause injuries or death to patients. Such communication should be done on time. In Therac-25's case, the manufacturer did not report to the administration on time. The manufacturer only did so after the second incident. Apart from manufacturers, users of medical devices (hospitals and other health facilities) should also report any malfunctions in the equipment. These facilities should report breakdowns, deaths, and injuries to the manufacturer, vendor, or the oversight authority (e.g. FDA). According to the FDA, such facilities should not only report equipment glitches but also advise the oversight authority on the problems they experience from using the machines.

Appropriate Formal Guidelines

Companies that manufacture medical equipment should abide by a corporate code of conduct. A corporate code of conduct guides a company's employees to engage in activities that conform to proper legal and ethical standards. A corporate code of conduct contains various elements. For

instance, it should include the company's mission and vision. The code should also reveal a company's commitment towards producing quality, effective, and safe machines. Third, the code should describe the necessary steps or actions the company has taken to minimize or prevent conflicts of interests in its operations. For example, the company should spell the criteria for full disclosure when associating with firms with which it has direct interests. A company's code of conduct may also reveal a statement of compliance with relevant regulations and laws.

Apart from having a corporate code of conduct, a company dealing in medical equipment should also have a professional code of conduct. Such a code contains the ethical standards set for medical practitioners and operators handling the equipment. The Chartered Financial Analyst (CFA) Institute writes that a professional code of conduct reveals the commitment of the professionals to act with professionalism and integrity (1). The code also mandates professions to demonstrate duties of care to their employers and clients (CFA Institute 2).

Therac-25 and Consequentialism

The ethical theory of consequentialism can describe the issues raised in Therac-25's case. The theory of consequentialism holds that morality should yield right consequences. According to Shaw (12), consequentialism occurs when individuals engage in actions whose outcomes have the greatest expected value. The theory also holds that if a person takes two actions at a particular time, the first action would be considered better than the second action if its overall consequences or outcomes are greater than the overall outcomes or consequences of the second action. In Therac-25's case, the players at the three levels had at least two options from which to choose. At the individual level, the programmer had the options of inserting the safety interlocks

in the hardware, software, or both. Unfortunately, he decided to add the emergency locks only in the software. As a result, the equipment scrambled when the operators fed it with multiple instructions, causing injuries and patient deaths.

At the group level, the company had the option of conducting or not conducting comprehensive tests on the machines to establish their safety. Regrettably, it chose not to perform these tests, resulting in the release of unsafe devices to user facilities. At the country level, the FDA had the choice of inspecting the equipment itself or waiting for notifications from the manufacturer. Ill-advisedly, it chose to rely on notifications from the manufacturer. Evidently, the actions taken by the players at these levels led to severe overall consequences in the form of patient deaths, injuries, and lawsuits.

Courses of Action and Normative Conclusion about the Case

The theory of consequentialism points to two courses of action: reporting and testing. Individuals and organizations at the individual, group, and national levels should have taken unique courses of actions to report the issues arising from the equipment or test the devices. For instance, the programmer of the equipment should have informed the Atomic Energy of Canada that failing to insert a safety interlock in the hardware and software would be catastrophic. This course of action would have prevented deaths and injuries as it would have enabled the operators to reset the device in case they fed it with wrong instructions. The manufacturer should have tested the equipment before selling it to hospitals and other treatment facilities. This course of action would have ensured the company detects the defects in the equipment. The oversight authority should

have inspected all the equipment before hospitals purchase them. Inspecting the machines would have ensured all flaws are detected before the manufacturer releases the devices to the market.

Public Policy Implication of This Case

The recommended behaviors should be mandated by laws, policies, and regulations. There should be a legislation that mandates medical equipment manufacturers to conduct comprehensive tests on their machines before releasing them to user facilities. In Therac-25's case, the manufacturer did not conduct a thorough test to check the correctness of the software designs. Failure to conduct this test led to the release of dangerous machines to consumers. The health sector should also create a legislation that requires oversight authorities to check all medical machines before they reach the market. The absence of stringent laws, policies, and regulations encouraged the oversight body to rely on the manufacturer for information about the accidents that occurred from operating the machines. Laws, regulations, and policies are also necessary to compel health facilities to report safety incidents directly to the oversight authority. According to Leveson and Turner (23), the situation in Therac-25's case worsened because the FDA was ignorant about the number of injuries and deaths in the hospitals. Having knowledge of the incidents would have guided the oversight authority to stop the company's production on time.

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