An ethical dilemma and corporate game changer

U.S. v Norian Corp
U.S. District Court for the Eastern District
Of Pennsylvania
Case No. 09-403-03-06

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Abstract:

This case is intended to have the student apply knowledge in both the ethical and criminal area as it relates to corporate responsibility. It concerns a corporation and its executives that knew that its product had a deleterious effect, but for the profit motive continued to sell and test market the product. The officers who had knowledge of this matter were charged criminally and found guilty, convicted and sentenced to incarceration for a period of time. The case is suited to be used in a business/ethics course of general students and the accounting students as well as in the senior level Business Policy course. It will enhance the critical thinking skills and expose the student to real world conflicts of interest and the ultimate downside if you do not do the right things.

Keywords: Criminal liability, corporate responsibility, responsible corporate officer and bone cement.

Introduction:

Four former executives at medical device manufacturer Synthes Inc. were sentenced to prison terms ranging from five months to nine months each for their roles in the unapproved trial of a bone-cement in which three patients died.

United States District Judge Legnome Davis of the United States District Court for the Eastern District of Pennsylvania, sentenced Michael Huggins and Thomas Huggins to nine months in jail, three months probation and a fine of $100,000.00 each. He sentenced John J. Welsh to five months in jail and a fine of $100,000.00. The fourth defendant, Richard Bohner was sentenced to eight months in prison.

Although each of the former executives had plead guilty to a single misdemeanor of introducing adulterated and misbranded medical devices into interstate commerce in violation of federal food and drug law, each sought probation and a $100,000.00 fine instead of a jail sentence. In contrast, the government argued that all the executives should serve prison time because of the egregiousness of their conduct.

Synthes, is the world's largest maker of bone-related medical devices, its Norian Corporation unit and the four executives were indicted in June, 2009 over claims they conspired to conduct unapproved clinical trials of Norian-branded cements from May, 2002 to late 2004. The cement approved for elsewhere in the body, was used in the spines of 200 patients with fractured vertebrae. Three patients died from a rapid drop in blood pressure during spinal surgeries.

The sentencing of the four defendants illustrates a trend toward the government ramping up prosecutions of corporate officers and managers of drug and device companies for health care fraud at their companies. The "responsible corporate officer" doctrine, known as the Park Doctrine, named after United States v Park, 421 U.S. 658, (1975), in which the Supreme Court affirmed a misdemeanor criminal conviction of a company officer who was held responsible for regulatory violations in a food storage warehouse, even though he denied any knowledge of the conditions.

Government officials have said that the government likely will bring an increasing number of such cases against individuals at both drug and device companies.

Premise:

The indictment charges that from the beginning, the intended market for Norian XR[1] was for an unapproved use, i.e., in surgeries to treat VCFs.[2] According to the indictment, the company recognized early on that there were two possible solutions to this problem: (1) the legal solution, which was to disclose to the FDA the intended use of the product and then to try to secure FDA approval of XR for use in surgeries to treat VCFs after obtaining an investigational device exemption ("IDE") to investigate the safety and efficacy of the product, and (2) the illegal solution, which was to promote XR for use in VCFs through a limited so-called "test market,"

[1] Norian SRS and Norian XR were bone cements that were used in treating fractures

[2] VCF stands for vertebral compression fracture

during which the company would evaluate the safety and efficacy of the product in unapproved clinical trials and judge their success according to its own standards.

The indictment charges that the company and its coconspirators consciously and deliberately chose the illegal solution. That is, according to the indictment, the company intentionally bypassed the requirement that it obtain permission from the FDA to conduct clinical trials of the XR device on human beings for an unapproved use – permission that it knew it needed.

With the so-called "test market," the company allegedly tried to save time and money by cutting out the FDA's oversight of clinical trials of its device. The indictment charges that the company did this for two principal reasons: to rush XR to the market first, before its competitors, and to generate published studies that it could use later to convince other surgeons to use XR off-label to treat VCFs.

Starting as early as late summer 2002, the company allegedly approached selected spine surgeons and asked them to use a predecessor device, SRS, in VCF procedures as part of an initial Synthes "test market" for SRS. Despite a June 2002 plea from one of Synthes's own surgeon consultants that conducting such a "test market" would "amount to human experimentation whose only defense seems to be that it will be a small study [,]" Norian and its coconspirators allegedly embarked on the SRS "test market." According to the indictment, the company taught the selected June 16, 2009 surgeons the recipe for mixing SRS with barium sulfate to make it more radiopaque, a process called "back-table mixing," and trained two groups of surgeons in the use of SRS to treat VCFs. After training the two groups of surgeons as initial "test market" sites, the company allegedly enlisted these "test market site" surgeons to train other surgeons on how to use XR to treat VCFs.

According to the indictment, the company conducted two XR "Test Market Kick-Off" surgeon meetings, and one surgeon forum, from August of 2003 through mid-January 2004, training approximately 52 spine surgeons how to use Norian XR to treat VCFs. It is charged that, after the third person died on the operating table during a surgery in which a Norian cement was used to treat VCFs, the company cancelled the future surgeon forums. The indictment alleges that the company considered, but rejected, the idea of recalling or removing XR from the market, either of which actions would have required them to notify the FDA.

Three months later, according to the indictment, when the FDA conducted an unannounced inspection at the Norian plant in West Chester, focused on whether or not Norian and Synthes had conducted an unauthorized clinical trial of XR, a number of Synthes employees, including individual defendants Huggins, Bohner and Walsh, made materially false and misleading statements to the FDA investigator.

Discussion Questions:

1. Do you feel that imposing criminal liability on corporate executives has a chilling effect in the medical field of introducing these drugs?
2. What items should a company include in its Code of Ethics?
3. Do you think that the corporate culture influences the actions of the executives?
4. Is it ethical for a company to perform cost-benefit analysis when lives are involved?
5. Could it be possible for upper management to not understand the issues involved?

6. Suppose you are an employee at the company in question and you just discovered the problem. You discuss the situation with your supervisor and he/she tells you that they do not see a problem. What, if anything, do you do next?
7. Should a profession impose ethical obligations which are more stringent than legal obligations? If so, why? If so, how should they be enforced?
8. Do you think the public was adequately informed concerning the dangers involved? Did they need to be or was the responsibility only to the patient?

APPENDICES:

Teaching notes

Questions:

l. Do you feel that imposing criminal liability on corporate executives has a chilling effect in the medical field of introducing these drugs?

In order to have criminal liability, there must be the criminal intent and the criminal act. The burden of proof is higher in a criminal case since the Judge or Jury must be convinced beyond a "reasonable doubt and to a moral certainty" compared to the general civil standard of being convinced by a "preponderance of the evidence". This translates to not requiring absolute certainty to convict in a criminal matter, but to put a number on it, being convinced by over ninety percent for a conviction. In a civil case, the preponderance of the evidence translates into more likely than not standard: you are convinced by fifty one percent or more.

The "responsible corporate officer doctrine" known as the Park Doctrine which came from the United States v. Park, 421 U.S. 658 (1975) indicated that a corporate officer could be held responsible for regulatory violations even though he or she has denied any knowledge of the conditions because businesses which affect public health are held to a strict and rigorous standard under the Food, Drug and Cosmetic Act.

In Norian, there is ample evidence that the executives knew what was going on and were simply trying to do an end run around the FDA regulations so this should not have a chilling effect in the medical field of introducing the drug because the officers had both the intent and the criminal act.

The Park Doctrine is more problematic because it allows for a criminal conviction even though someone has denied any knowledge of the conditions, but someone must have the responsibility as a matter of public policy to protect the consuming public. This should not amount to a chilling effect if the Company has employed rigorous standards.

2. What items should a company include in its Code of Ethics?

The Sarbanes Oxley Act of 2002 under Section 406 requires a Code of Ethics for Corporate Officers and enforcing procedure covered by the Fiscal period after July 15, 2003. It applies to recording companies under the Securities and Exchange Act of l934 and under Sarbanes Oxley, the Code of Ethics under Section 406 (Codified) at 15 U.S.C. 7264, Section C "defines a "Code of Ethics which means such standards as are reasonably necessary to promote honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships and a full, fair and accurate, timely and understandable disclosure and to be in compliance with the applicable governmental rules and

regulations". As a suggested architecture for a Code of Ethics, the Code should be prefaced or end with a signed statement from the Chairman of the Board and/or CEO emphasizing the importance of the document; that the Code represents the practices and values of the company and the legal compliance statement that the Board, managers and all employees will comply with all applicable laws and regulations in the course of business and also contain the values and principles the Company holds. The Code should state what the company sees as its responsibilities to its clients, customers, suppliers and shareholders. It should also have the proper maintenance of accounting records and that all public disclosures will be complete and understandable and necessary to protect the assets of the company. There should be a procedure by which a person can submit his concerns and contact an ethics officer or committee and the process by which the concern or disclosure can be made. The process should be confidential and should encourage anonymous submissions of concern and the disclosure and a statement that there will be no penalty for reporting violations and the Code of Conduct is reinforced by the "Whistleblower Provisions" in Sarbanes Oxley.

3. Do you think the corporate culture influences the actions of the executives?

The most important input to corporate decision making is how the action influences the company's bottom line, i.e.: profits. There are numerous examples where decisions, when viewed in a vacuum, are ostensibly very simple decisions. However, when they are looked at through corporate glasses, the decisions become distorted. The most recent example is the Enron Debacle where, not unlike this Norian Corporation matter, the management turned a blind eye to transactions which were clearly detrimental to the corporation as well as the Chief Financial Officer using creative accounting methods to hide the extent of the company's financial obligation and potential liabilities. Clearly, this bottom line approach (culture) influences executive actions.

4. Is it ethical for a company to perform cost-benefit analysis when lives are involved?

Under Sarbanes-Oxley a Code of Ethics sets forth, among other things, the company's values or principles as well as the company responsibility. It is not only unethical, but exposes the company to serious legal repercussions if this cost benefit analysis approach is used. The history of corporate America is replete with examples of this. Probably the best is the Ford Pinto case. Here, there was a defect in the gas tank in that it ruptured when there was a rear end impact and caused gas and gasoline fumes to come in contact with the super heated exhaust system causing an explosion.

There are two kinds of damages which are recoverable in a product liability action. The first is compensatory damage including medical expenses, loss income and pain and suffering of the Plaintiff. The second is punitive damage where the conduct of the Defendant is wanton and reckless and in disregard of human life. Damages are assessed against defendant based on the financial worth to ensure that the penalty is in fact significant enough to deter the same conduct in the future.

Ford's accounting records showed that it would be less costly to pay the estimated legal damages than it would be to redesign and retool the gas tank. Obviously, the company made a conscious decision to trade dollars for human suffering. In a number of suits, Plaintiffs were awarded punitive damages as well as compensatory damage for trading dollars for human suffering.

5. Could it be possible for upper management to not understand the issues involved?

The Norian case would seem to clearly indicate that it would not be possible for upper management not to understand the issues involved. The company had to know that the "test market" was employed to get around the more stringent FDA oversight clinical trials. This was done to get the product market first and to generate published studies that they could use to convince other surgeons to use the product. In June, 2002, a plea from one of the company's surgeon consultants that conducting such a "test market" amounts to human experimentation fell on deaf ears. Further, the company tried to cover up their actions by not issuing a recall, which would have required it to notify the Food and Drug Administration and the individual defendants mislead the Food and Drug Administration investigator who had made an unannounced inspection at the Norian plant. The facts here are just so overwhelming to show the management understood exactly what they were doing.

6. Suppose you are an employee at the company in question and you just discovered the problem. You discuss the situation with your supervisor and he/she tells you that they do not see a problem. What, if anything, do you do next?

There are two avenues which the employee could explore. If this is a publicly traded company, he should go to the website of the company where the Code of Ethics is displayed. Most often, there is information how to contact an ethics officer or committee and a process by which a concern or disclosure can be made. Often this is allowed to be done anonymously. Alternatively, the employee could contact the Food and Drug Administration directly and voice concern. Sarbanes Oxley, Section 806 allows for Whistleblower protection. If there is retaliation by the employer, paragraph C, Section 806, "the employee should be entitled to all relief necessary to make the employee whole". For example, recover his lost wages, reinstated to his position and recover attorneys' fees.

7. Should a profession impose ethical obligations which are more stringent than legal obligations? If so, why? If so, how should they be enforced?

A comparison of ethical obligations and legal obligations are very often two separate issues. The ethical standards arise from the Common Law, Statutory Law or a private company Code of Ethics. An example of a Common Law ethics is the agency theory (employer and employee) where an agent owes a fiduciary duty of good faith and disclosure and not makes any secret profit because of his position. The Company Code of Ethics is what has been put in place and not only incorporates parts of the Common Law aspect but is much more specific in enumerating what constitutes a violation. For example, the proper use and maintenance of company assets or proprietary information of the company are all a part of the ethical case.

On the legal side, there are various burdens of proof discussed earlier. In a criminal matter the level of proof is high. In a civil matter there is a high level of liability. The standard that is used for product liability is a no fault standard called "strict liability". One only needs to prove is that the product is defective and the defect existed at the time the product left the manufacturer. The defect can be a manufacturing defect, or can be failure to warn of the product's dangerous aspects or a failure to give the proper instructions on how to use the product. In the product liability area, the legal obligations are much higher than the ethical obligations because one can have ethical actions which results in legal liability. For example, assume for the sake of argument that Norian Corporation had gone through all of the Food and Drug Administration's testing of the product and did not discover some latent defect in the

product. When the defect became known, i.e., injury causing aspects, the company could be liable to the injured individual in damages even though it acted ethically and without the intent to cause harm.

8. Do you think the public was adequately informed concerning the dangers involved? Did they need to be or was the responsibility only to the patient?

Obviously the public was not adequately informed concerning the dangers involved. The Company controlled the flow of information to surgeons in training other surgeons to use the product, Norian was representing to the public that it was safe. However, by not recalling the product when they knew it caused three deaths, Norian attempted to hide the dangers which it discovered. The reason that we have Food and Drug Administration procedures prior to putting drugs on the market is to have an approval process which allows people to make informed decisions with the help of their physicians about a proposed treatment. Without this information, it is not an "informed consent" which has been given to a procedure which would allow a person to assess the risks involved and make an informed decision.

Attribution:

See the Internal Auditing Journal, July/August, 2004 Issue "Complying with the Sarbanes Oxley Requirements, W. Michael Seganish and Norma C. Holter.

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