Case Study Report
Ethical Dilemma Framework - How A Bone Disease Grew To Fit The Prescription

Identification of Principles Involved

The ethical principles and values involved in the case are beneficence, non-maleficence, respect for autonomy and justice.

Specification of Principles Involved

In the diagnostic device case, there is a clear conflict between beneficence and non-maleficence as Merck created the drug called "Fosamax" for the cure of osteoporosis but in order to increase the volume of sales for their drug they promoted the new portable diagnostic machines so that more women can get their bones tested.

The other conflicting principle was the respect for autonomy for the women taking the tests. The women weren't aware of the fact that osteopenia is a slight thinning of the bones that occurs naturally as women get older which do not require any medication and taking the drug for that may cause an ill effect on their bodies and mindset.

The problem with the smaller peripheral machines is that "It was diametrically opposed to what the academics thought was best for diagnosis" because taking a measurement of someone's heel or forearm isn't going to tell you what you need to know about the bones in the parts of the body that, if fractured, increase a woman's risk of death. So, Justice was another conflicting principle from the perspective of the company's CEO, he can either do the justice with the company and let the users suffer or with the users of the diagnostic device and let the company go out of business.

Also questionable is, if it is right as Jeremy Allen did, by buying a device manufacturing company in order to prove the competitors wrong about their strategy. And is it also appropriate to target the milder sections like the ones having osteopenia?

Prioritization

Among all the ethical principles, we think justice is more important than the others in this case because Jermy Allen, when discovered about the loopholes in the portable machines was in the conflict to do justice with the company that hired him or with the women testing for osteoporosis.

Perspective Taking

This case involves multiple perspectives thrown by different stakeholders. Jeremy Allen did what he did thinking of public good while also dealing with his competitors like Richard Mazess, founder of the Lunar Corporation, one of the largest producers of bone density machines who believed the approach to be a misdiagnosis. After the Bone Mass Measurement Act, which changed Medicare reimbursement rules, new set of perspectives came into the picture. All in all, the term osteopenia in itself added the perspective of it being an abnormal condition which in reality is not.

Stakeholder Analysis Matrix: This matrix takes into consideration the two variables, Power and Interest. Power is the ability of the stakeholder to stop or change the project whereas Interest is the size of the overlap between the stakeholder and the project's goals, like in this scenario increasing the sales of a particular drug by also increasing its diagnosis for a disease which is not really an abnormality.

With the help of this matrix we have identified the key players in each of the four categories.

Keep satisfied Medical Device Company (High Power, Low Interest: For any minor issue if they stop the production of the diagnostic equipment, drug sales might also reduce.)	Manage Closely Merck (via Jeremy Allen) (High Power, High Interest: They have led this whole case from literally creating a problem from a non problem and are heavily invested)
Monitored Clinical Researchers (Low Power, Low Interest: In case, their research becomes more powerful and affect the scenario, hence requires close monitoring)	Keep informed Patients (Low Power, High Interest: They are the ultimate users, hence can create high influence if they don't get what they want.)

Digging a little deeper with the help of Ethical Matrix Analysis:

Groups	Well Being	Dignity	Justice
Patients	If the patients are healthy without any side effects and less fear	Right to know a detailed report of their condition and the consequence if any	Fair treatment for their condition without involving consumption of redundant drugs
Merck, Bone Measurement Institute	The company earns huge profits and is recognised as doing public good	Freedom to manage technology for the best of society without dependency	Fair researches and development of quality products
Device suppliers, regulators, competitors	Healthy competition, Effective regulations	Respect of their needs as well as others needs	Fair access to the resources
Global society	Quality of life	Respect for emotions, and harm as limited as possible	A balanced approach between producers and consumers of drugs affecting no one with freedom of choice

This matrix has not been adequately discussed in scientific or practical settings and should, therefore, be perceived as the author's suggestion. However, as the case involves patients as the target group, it is important to give them the priority in terms of resolving the ethical conflicts.

Reflectivity

Clinical advisor shared the opinion of supporting the production because it is good to diagnose more not just for osteopenia but also for any other bone related malfunctions with an emphasis on ensuring a way patients don't consider osteopenia as a major setback until the data reveals anything. Osteoporosis is an extreme condition with a chance of misdiagnosis using this device, and hence supporting the idea of using this device as a precursor to actual diagnosis.

Marketing manager from the very start was fixated on increasing the sales and complying with Merck's requirement as that has been benefiting the company till date, in fact FDA also approved the device. Although he came across facts that peripheral device isn't effective in detecting osteoporosis, but considered to go ahead with the production and bring about the debate again next year, hopefully with some plausible data.

The engineering manager considered the 5 years as a long time to wait for the results and chose to instead go with the production with enhanced features in the equipment. And also thought that it made no sense to go backwards and do any further research on what could go possibly wrong in future rather try to focus on present improvisation.

Regulatory officer considered the basis of this situation would be the credibility of the decisions made intuitively. As internally, being not aware of how to quantify the correlation of the technology with an actual diagnosis for an osteoporosis. And without numerical values provided, introduced bias towards firm's profits.

As observed, all the 4 members involved shared the same mentality of supporting the sales but also expressed their varied concerns of its impact and decided to go ahead keeping in mind the shared responsibility of also making the society aware of osteopenia being a very normal condition that shouldn't be over treated.

Justification

The information we had at this point is that FDA has approved the device, the device is also already in production at scale. It is obvious that manufacturing of the machine and marketing will help the company to grow it's business and make it profitable. Here the Ethical dilemma strikes. While the Engineering manager and marketing manager were focusing on the sales and the manufacturing of the peripheral bone testing machine, the clinical advisory wants to make people aware about the reality of the osteoporosis. Apart from this the thoughts of Regulatory officer are very different. She somehow wanted to draw a line between the company's benefits and patient's benefits but stuck with a certain bias towards the firm. Each and every stakeholder was right from their perspective, now it became very difficult to put ethical values before company's benefit.
After a long discussion the final points gathered are as follows:-

1.) It is the company's responsibility to let the women aware about the fact that osteopenia is a normal condition which doesn't require any medication whereas osteoporosis is a condition which affects the bone density of the women.
2.) Before manufacturing the peripheral bone density scanning device company should have researched about the efficiency of the machine whether it is able to detect osteoporosis by just measuring someone's heal or forearm, at least now it should be done sooner than later.
3.) Company should help in gathering the data and researching more about osteoporosis, so that the work will take less time than 5 years and the trust of the people is maintained.

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Case study: https://www.npr.org/templates/transcript/transcript.php?storyId=121609815