Crisis Communication and Crisis Management

Principles of Ethical Practice

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ETHICS UP FRONT

This case is both an example of a crisis within a crisis and a demonstration of the fact that stakeholders external to an organization, not the organization itself, sometimes determine whether an organization is in crisis. Specifically, Chimerix found itself in the position of deciding whether to provide a child with a potentially lifesaving experimental drug that was in limited supply. One challenge with limited resources—including drugs, replacement organs, and other health care resources—is ensuring equitable distribution. As this case study shows, a complicating factor, and one that contributed significantly to the creation of a crisis for the company, was the presence of social media commentary on Chimerix's initial decision to deny seven-year-old Josh Hardy access to the drug. Much of social media commentary included condemnations of Chimerix’s decision, which raised further questions about how decisions governing the distribution of scarce resources ought to be made. Another morally relevant concern in this case is that the drug in question was an experimental treatment, meaning there remained a degree of uncertainty regarding the potential harms and benefits of using the drug. Arguably, companies have
an obligation to ensure the safety of the products they market and distribute, especially to vulnerable populations, including children. When questions remain regarding whether a drug will effectively address a problem and leave the recipient of the medication unharmed, reservations about providing it appear morally legitimate, given the moral obligation to refrain from harming others unjustly.

**WHAT HAPPENED**

According to the Centers for Disease Control and Prevention (CDC), adenoviruses cause only mild illnesses in people whose immune systems are not compromised. For individuals with weakened immune systems, however, adenoviruses can cause serious and sometimes lethal infections. Seven-year-old Josh Hardy had survived a few rounds of cancer treatment at St. Jude Children’s Research Hospital in Memphis, Tennessee, including a bone marrow transplant, but the intravenous delivery of a standard antiviral drug was causing serious kidney damage. Hardy was in need of a drug that could knock out the virus without destroying his kidneys, and the doctors at St. Jude, where Hardy was being treated, thought Chimerix’s oral-delivery version of the experimental antiviral drug brincidofovir could treat Hardy’s infection without the serious negative side effects.

Hardy’s parents made a “compassionate use” request for brincidofovir, which reportedly showed no adverse effects in 900 patients who received the drug in a Phase II drug trial that closed in September 2013. Expanding or compassionate use refers to the use of an investigational drug (i.e., drugs that have not yet been proven to be safe and effective) by individuals that are not enrolled in a drug trial. Expanded use of investigational drugs is limited for a variety of reasons, including concerns about avoiding adverse effects, releasing a drug too soon, sparking demand for the drug in the face of limited supply, delaying wider release of the drug unnecessarily, and the costs of obtaining the drug. Authorizing expanded or compassionate use of an investigational drug is determined on a case-by-case basis by the Food and Drug Administration (FDA). Because insurance companies usually do not pay for experimental drugs, the cost burden typically falls on the patient or the company that manufactures the drug. In some cases, like Hardy’s, philanthropic groups (e.g., the Max Foundation) may contribute to the cost of obtaining the drug. In others, a company may absorb the cost of providing the drug to a limited number of patients. Chimerix, a 54-person company, did not view this latter option as financially feasible. Chimerix’s primary concern, however, was not financial.

In early March 2013, Chimerix denied Hardy’s request, citing concerns that, if it approved expanded use, the company would have to divert its limited resources from existing research and development activities, including drug trials that were already underway. This would lead to delays in bringing brincidofovir to market by its target date. Among other things, according to then CEO Kenneth Moch, expanded use cases require time and personnel to process the FDA application and monitor adverse events.
Chimerix had reportedly received and refused “hundreds” of expanded use requests for the drug in 2012 and 2013, including demands from children in a situation similar to Hardy’s. A central consideration was whether it would be fair to grant Hardy the use of the drug when others had been turned away. There was also the concern that others would go without the drug due to delays in FDA approval that might result from diverting resources to Hardy and away from moving forward with the investigational trials. An additional concern with expanded use is that, because patients requesting special permission to use the drug are usually extremely sick, even interventions that appear to be most promising may prove ineffective. When the drug fails to ameliorate the patient’s problem or the patient dies, this still counts as a “negative” that must be reported by the company when applying for FDA approval. CEO Moch was firm in his initial refusal, yet he also expressed sympathy for Hardy’s plight. For example, he pointed out that (a) he also had a child, (b) he would probably act no differently from Hardy’s parents, and (c) he would feel “horrible and heartbroken” if the child died.

Following Chimerix’s refusal to provide the drug on an extended use basis, the Hardy family established a Facebook page (SaveJosh) and a Twitter account (#savejosh), created an online petition, and made calls to the media, including CNN and Fox. Two days later, on March 8, 2014, the FDA contacted Moch. Thereafter, the FDA agreed to help Chimerix develop a Phase III trial with a 20-patient cap in which Hardy could enroll. Unlike the other trials that Chimerix was conducting at the time to determine the effectiveness of brincidofovir to treat cytomegalovirus (CMV), this trial, in which Hardy was enrolled, was investigating the use of the drug to treat Hardy’s adenovirus. On March 11, 2014, Chimerix reversed its refusal and Hardy began receiving the drug. In a press release issued that day, Moch made the following statement:

Being unable to fulfill requests for compassionate use is excruciating, and not a decision any one of us ever wants to have to make. It is essential that each individual in a health crisis be treated with equal gravity and value, a principle we have upheld by pursuing further clinical study of brincidofovir that will inform its use in adenovirus and other serious DNA viral infections.

According to news reports, Hardy’s viral load dropped significantly from 250,000 to 100 from March 12 to 25, indicating the antiviral drug was working for him.

FOR DELIBERATION

Though Hardy’s father proclaimed that his son would die if Chimerix refused to provide Hardy with the drug, the fact that the drug was still experimental meant that it remained unclear whether the drug would save the child’s life. A press release issued by Chimerix stated the following:
Brincidofovir has the potential [emphasis added] to be the first broad-spectrum antiviral for the prevention and treatment of clinically significant infections and diseases caused by DNA viruses. Brincidofovir has shown a favorable safety and tolerability profile, with no evidence of kidney or bone marrow toxicity in nearly 900 patients dosed to date.7

While the drug had shown great promise in early trials, the jury was still out at the time of Hardy’s expanded use request. Desperately ill patients and their families, however, find hope of a cure compelling. The belief that a drug under investigation will provide therapeutic benefit to trial participants was one underlying problem in the Chimerix case. This is known as “therapeutic misconception.” The discussion of the case in traditional and social media indicated that therapeutic misconception was widespread. With no evidence whatsoever, individuals assumed that Hardy was being deprived of a lifesaving drug rather than a drug whose safety and effectiveness had not yet been established. Twitter included many tweets along the following lines:8

@RobZyo please . . . help save my nephew #savejosh @chimerix is refusing him a drug he needs to survive

What kind of evil would deny a little boy the medicine he needs to save his life? @Chimerix #savejosh #morningjoe

Tweet to @chimerix and tell them to give josh his meds so he can live #SaveJosh http://wh.gov/lyfHk” #PleaseRetweet URGENT

it sickens me to know this company @chimerix is denying treatment to a little boy who will die without their medicine

“@Max_Cure: This boy can be saved by @chimerix and they say no. #savejosh There is no more time. pic.twitter.com/enlEUrlqLy” Save Josh!!!

The preceding tweets imply that the drug is unqualifiedly good and that the company is acting malevolently in withholding a drug that will prevent Hardy’s death. Both Chimerix and the FDA, however, are justified in continued testing to ensure that the drug does not have as yet unknown adverse effects.

PUTTING IT ALL TOGETHER

Among the changes to the world of crisis management is the increasing influence of social media. In contrast to traditional media, social media have transformed the relationship between organizations and their stakeholders. Lyon and Montgomery noted the following characteristics of social media: nonhierarchical, lack of gatekeepers, rapid and dynamic response, free to use, two-way rather than unidirectional communication and public, among others.9 Organizations no longer have the same level of control over information
about their operations or even over communication about their actions. This case illustrates the power of social media to both generate a crisis and facilitate resolution.10

This power of social media is evident in this case: With some exceptions, Chimerix was portrayed as a cold-hearted corporation that lacked both compassion and moral scruples. Social media commentary appeared to present Chimerix in a more negative light, whereas traditional media presentations mixed both positive and negative views of Chimerix's initial decision to refuse Hardy's expanded use request for brincidofovir. One reporter observed that “television news programs depicted the situation as a simple case of corporate bad behavior that was corrected by the righteous attention of the media combined with the power of millions of people who became aware of Josh Hardy and joined the campaign to save him on Twitter.”11 The negative view of Chimerix was evident in headlines such as “Company Denies Drug to Dying Child,”12 “Bowing to Public Outrage, Pharma Company to Give Dying Boy Experimental Drug,”13 “Company Denies Drug to 7-Year-Old Boy Struggling Against Curable Virus,”14 and “Drug Company Refuses 7-Year-Old Boy Life-Saving Medicine Despite Donation.”15 However, the headlines and the article contents were comparatively mild when contrasted with comments on social media. While mainstream media articles often included statements from Moch indicating a sympathetic view of Hardy’s situation, social media posts were frequently more unilateral in presenting an anti-Chimerix perspective.16 A common theme was that Chimerix valued profits more than Hardy’s life.17

Given the “profits over people” prioritization by many companies, including some pharmaceutical companies, painting Chimerix as a malevolent actor was an easy sell. However, as Klugman pointed out, we should commend Chimerix’s commitment to being thorough instead of rushing a drug through the approval process so that the company can begin raking in profits.18 Following the principles of nonmalevolence and benevolence dictates that we not subject people to unjustifiable risk of harm and that to the extent possible, we also attempt to do good for them. A commitment to fairness dictates that we distribute risks and benefits equitably, which implies that diverting resources to a select few people at the expense of helping numerous others is not morally permissible. This concern is further exacerbated by the fact that the “selection process” that favors those who “yell the loudest or are media savvy”19 is entirely arbitrary. One daily newspaper proclaimed that such crowdsourcing is “no way to make health-care decisions.”20

Despite the justified concerns about crowdsourcing medical decisions, it appears as though the use of social media accelerated a conversation about the problematic compassionate use policy and also promoted a relatively quick resolution, albeit a limited and temporary one, to the problem at hand. According to one news report, Chimerix ultimately benefitted from the social media blitz: “No[t] only did it solve its public relations crisis, it allowed the company to cut through the red tape that is typically required to get another clinical trial approved.”21 The report also noted a 29% increase in the company’s stock following the announcement of the Phase III trial in which Hardy was enrolled. Chimerix’s unpopular but principled management
of this crisis allowed it to garner much needed assistance from the FDA in navigating a very complex situation. While expressing compassion for Hardy’s situation, Chimerix also held fast to its long-term goal of developing a treatment that would be available for everyone.

DECISION POINT

Although Josh Hardy was faring well by mid-May 2014, suppose that after a few more months of experimental treatment with brincidofovir his condition took a turn for the worse. Despite the initial rapid drop in viral load, a previously unobserved negative side effect emerges, causing Hardy to suffer from another life-threatening condition. Though Hardy’s family and supporters were outraged that Chimerix would withhold this drug from Hardy, they are now equally outraged that this child appears to have been negatively impacted by the use of the drug. As the new CEO of the company, how do you respond to the resurgence of social media commentary about Chimerix’s “unethical” experimentation on sick children?

DISCUSSION QUESTIONS

1. Social media played a significant role in prompting Chimerix’s decision to offer the drug brincidofovir to the Hardy family. Should social media play a significant role when it comes to making this kind of decision? What is ethically problematic about social media having such a role?

2. Therapeutic misconception involves overestimating the potential benefit of participating in a clinical trial. Though this is usually restricted to individual trial participants and those individuals close to them, how did this appear to extend to the public at large? How did the phenomenon of therapeutic misconception impact the crisis and Chimerix’s ability to manage it?

3. This chapter cites reservations against the “crowdsourcing of medical decisions.” Assuming that crowdsourcing did have a prominent role, what concerns may this present for ethical crisis management?

NOTES


3. Ibid.
6. The viral load is a marker of the infection. A higher load of the virus indicates the virus is more active, signaling a more severe infection.
8. See @chimerix Twitter posts at https://twitter.com/search?q=%40chimerix&src=typd.
17. See @chimerix Twitter posts at https://twitter.com/search?q=%40chimerix&src=typd.