Wonder Medicine for Cancer Treatment

In 2011, Nick Auden was diagnosed with stage 4 melanoma, an aggressive form of skin cancer that kills 90 percent of patients.[1] Although combinations of various drugs helped temporarily reduce the growth of Auden's tumors, doctors determined that a new drug developed by only two drug companies could eliminate the tumors altogether and save his life. The medication, which was not yet approved by the FDA, was used in clinical trials that were open only to patients with specific stages of the cancer or people who did not have cancer at all.

The medication was not being offered for "compassionate use," meaning it was not available for people who were not technically eligible for the trials but still wanted the drug. According to the FDA, patients can be denied compassionate use if there is not enough data on the drug's safety. However, other reasons to deny use of medication include ensuring that the scientific method is being properly carried out and that "including a particular patient [does not] dilute the data or confuse the results of the trial and so delay the ultimate approval for the drug and its time to market."[2]Such delays harm patients who would have been able to receive the drug earlier had it emerged on the market.

The clinical studies of the melanoma drug revealed that 38 to 52 percent of participants benefitted—their tumors successfully shrank. "[It] is not the kind of medicine that if it works, it works for a few weeks and stops working. If medications like this work, they tend to benefit people for months or years. Some people might even be 'cured,'" said a melanoma specialist at Memorial Sloan-Kettering Cancer Center in New York.

However, oncologists acknowledged that the medication could cause fatal brain swelling. The drug companies also cited safety concerns when asked why they could not allow the drug to be used by cancer patients who did not qualify for trials. One company claimed that although it was trying to find a way to make the drug accessible, "all available supplies were being used in clinical trials." Production was accelerated "faster than any other research program in nearly 20 years," said a drug company representative.[3]

Auden's wife said that they "had no idea how difficult it would be to convince the drug companies to give it to [Nick]." One of the companies "said they would open compassionate use trial in the third quarter of 2014. It was their last offer to us."[4]According to Auden, who passed away from his illness on November 22nd, 2013, "When you've been given a terminal diagnosis, you're prepared to accept a drug that's 50 percent effective...Safety concerns don't really figure in the same way."

Although patients who are denied use of drugs in trial have the right to bring drug companies to court, Auden and other patients turned to organizations such as Change.org to garner support through virtual petitions. The petition quickly reached its original goal of 150,000 signatures and later reached 500,000.[5]

Study Questions:

1. Under what conditions is it ethical for drug companies to allow compassionate use of drugs?
2. Was it morally permissible for the drug companies to deny the treatment to Nick?
3. To what extent is it ethical to consider the scientific method over the open distribution of drugs that are still in testing stages?

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[1] http://gma.yahoo.com/dying-dad-pleads-unapproved-cancer-drug-101306450--abc-news-topstories.html
[2] http://www.acegroup.com/us-en/assets/ace_compassionate_care_whitepaper.pdf.pdf
[3] http://abcnews.go.com/Health/dad-pleading-unapproved-cancer-drug-dies/story?id=21004482
[4] http://www.denverpost.com/breakingnews/ci_24625182/nick-auden-who-lobbied-use-experimental-ski
[5] https://www.change.org/petitions/merck-bristol-myers-squibb-save-locky-s-dad-provide-nick-auden-access-to-the-pd1-drug-on-a-compassionate-basis