Hacking Disease: The Ethics of DIY Medicine

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INTRODUCTION

Imagine a life of strict diets, no cake and champagne on your birthday, lest you suffer incapacitating pain, jaundice, and diabetes, with the threat of pancreatic failure always looming overhead. This was the inevitable life of a patient with lipoprotein lipase deficiency (LPLD), a rare genetic disease, until Glybera burst onto the scene. Glybera was a veritable scientific breakthrough – the world's first gene therapy to be approved for use in the European Union, and a one-time cure.[1] However, Glybera came with a caveat – a price tag of $1 million. It was developed at University of British Columbia (UBC) and marketed by uniQure, and while it was on the market, only one insurer covered the drug, and only one patient received the drug outside of clinical trials. This resulted in Glybera being a commercial failure, haemorrhaging $2 million a year.[2] uniQure tried to save the drug by entering the American market, but the burden of further post-market evaluations and risk-benefit analyses proved to be too much for uniQure.[3] It failed to receive FDA approval and was pulled from the European market in 2017. This was going to be the end of what was then the world's most expensive drug, until a group of biohackers based across the United States and Europe announced that they would reverse engineer the drug and release it to any patient who needed it for free. The biohacked "Slybera" is to be, we're told, the same drug, synthesized using published literature to be an inexpensive gene therapy. While we await evidence that this can be done, the biohackers claim that Slybera is in development, and that it will be delivered soon, pending further testing.[4]

ANALYSIS

It's easy to assess this situation and immediately level accusations of unethicality towards the biohackers, for a multitude of reasons. For one thing, their actions violate the intellectual property of uniQure, and for another, it is difficult to validate if biohackers can synthesize Slybera in a safe and effective form. However, I believe that the biohackers are carrying out their ethical duty, by trying to release this drug to patients who need it. While there have been instances when pharmaceutical companies and the FDA have acted heroically, against their own financial interests to save patients' lives, in this specific instance, the FDA and uniQure are acting unethically by decreasing access to medicine through financial and regulatory means.

Underlying this controversy is the question of access, and the role of social justice in medicine. The biohackers present themselves as the answer to this situation, in which a slighted patient population has had

its only chance at a cure stripped of them through overregulation by the FDA and pharmaceutical mismanagement of Glybera by uniQure. Biohackers purposefully exist outside of established research systems, to sidestep the regulatory and ethical barriers that slow scientific research down. This 'outside-the system' experience gives biohackers a great opportunity, not only to help a struggling patient population, but also to disrupt and reform the current drug regulation system in the United States. The aim of expediency for a suffering patient population is a morally admirable one, but we must be critical of the biohackers, and demand rigour and safety from them, if they want to be viewed as a legitimate force for change.

To make decisions about the moral acceptability of the invested parties' actions, we have to consider these principles. First, are they trying to alleviate suffering? Second, are they respecting all people? Finally, are they exploiting vulnerable populations? Moreover, we must also consider the actions of the FDA and uniQure, as they are instrumental to understanding the systemic backdrop surrounding Slybera.

The FDA has taken a hard-line stance against such biohacking initiatives, with recent directives warning that the "sale of these products is against the law."[5] Biohackers have circumnavigated this law by promising to release Slybera for free. It is no secret that there is disdain towards the extensive drug approval process (which can take up to ten years), which has been criticized for depriving patients of life-saving treatments.[6,7] In cases such as Glybera, where there is no alternative treatment, an inefficient drug approval system causes harm to all the patients who can't access the medications they need. The delayed release of drugs not only has a social, physiological, and economic cost, it harms patients and has an ethical cost associated.

However, the FDA is not the only ethically compromised body – uniQure, the pharmaceutical company that developed Glybera also holds significant blame. UBC's Michael Hayden led the original Glybera research team, noting that when Glybera was first formulated and shown to be effective in mice, uniQure was formed in order to market the drug, which is when the mismanagement began. "As the clinician scientists, we lost control of the project completely [...] [uniQure executives] decided that they were going to charge a million dollars a shot."[4] uniQure tried and failed to uphold its fiduciary responsibility to its investors and in the process hurt both its own revenue as well as LPLD patients. Since withdrawing Glybera, uniQure has reinvested the money into a promising haemophilia B gene therapy which is in Phase III studies right now. [2] However, this doesn't mitigate the fact that they slighted the members of the LPLD community through the financial mismanagement of Glybera.

Now, we can turn our attention to the biohackers themselves. In the case of injury, they would be legally culpable, but this doesn't equate with moral responsibility. Unlike uniQure and the FDA, they are upholding the No Harm principle—alleviating suffering through the drug that they are trying to develop. However, it is not clear whether they are respecting people's right to autonomy, and whether they are exploiting vulnerable populations. In previous years, biohacking has comprised of self-experimentation in order to determine toxicity, efficacy and other relevant clinical factors.[8] If Slybera were in this stage of development when it was released, they would not be able to supply an exhaustive evidence-based list of risks and benefits of the treatment to the patient, violating the patient's right to informed consent. Moreover, patients with LPLD are members of a vulnerable class, as there are no other treatment options for them; hence, presenting a glorified research project as a treatment option can easily be seen as abusive, self-serving, and exploiting a vulnerable patient population.

Thus, biohackers and other open-science enthusiasts who insist on operating outside of the purview of the regulatory system must self-regulate in a manner that both encourages research expediency, as well as respecting the rights of the patients. Crucially, this involves acknowledging the intellectual and physical

limitations that being outside the pre-established system of research places on them. Encouragingly, the issue of standards and self-regulation have been raised at biohacking conventions, with Gabriel Licina, one of the lead scientists on the Slybera project, warning the community that preliminary data doesn't license them to run straight to patients with their DIY treatments. In Licina's words "This is the time for us to stop playing around with our petty self-centred little projects and actually do something that matters."[9] Since then, Licina has started a peer-review system of independent biologists, and said he will begin a dialogue with the FDA and traditional biological science researchers in order to ensure that patients have access to the best drug possible.[10] Given the lack of action from the pharmaceutical side, the biohackers should work with institutions in order to test efficacy and safety, and share their science with those with the funding to deliver it to regulatory bodies to manufacture the drug safely. However, they can no longer hide behind the thin shroud of anti-establishment rhetoric – if they would like to make a difference to patients, they need to engage in a mature conversation with the current systems at play.

CONCLUSION

The biohacking movement is currently at a crossroads, straddling the line between ethical and unethical practise, and their choices will define the movement and its legitimacy in years to come. It's no secret that the FDA and pharmaceutical companies need reform in order to return to their supposed primary aim – serving the patient population. Open science has, on occasion, shown itself to be immature and overzealous, however, it has successfully resisted some of the regulatory issues that plague our current system. History has taught us in graphic terms that bioethics needs to be central to clinical practise, and the Slybera researchers should consider ethics as important, if not more important, as the science they are doing.

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