

Exploitation of Homeless Populations in Phase One Drug Trials

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Last semester I read Carl Elliott's "The Best-Selling, Billion Dollar Pills Tested on Homeless People." He introduces a concerning ethical dilemma, namely, the use of homeless populations as participants in phase 1 drug trials. Learning about this practice made me very uncomfortable. As a student at a Jesuit university, my concern for the homeless is often prevalent when walking around New York City. Furthermore, as a scientist, I care for the integrity of research and participate in discussion and planning on how to conduct ethical research. Elliott describes phase 1 trials, the first test of drugs in humans, as "all risk, no benefit." These trials entail risky biomedical research, but their occurrence through private companies excludes them from governmental ethical regulation, like *The Belmont Report*. *The Belmont Report*, issued in response to unethical treatment of human subjects in experiments during World War II, outlines a basic set of ethical principles to guide biomedical and behavioral research involving human subjects. Although these guidelines cannot legally govern private drug trials, consideration of these principles highlights the unethical nature of drug testing on homeless populations and the need for ethical regulation of private sector research.

The three basic ethical principles identified by *The Belmont Report* were respect for persons, beneficence, and justice which can be applied to research through informed consent, risk/benefit assessment, and the selection of research subjects (*The Belmont Report*, 4-6). To provide respect for persons, researchers must respect their subjects' autonomies, and a way to do this is by ensuring their participation is voluntary (7). This proceeds the need for information about the trial and comprehension of that information and ensures that participants are not coerced or exposed to undue influence to participate in the study. According to the report, "undue influence...occurs through an offer of an excessive, unwarranted, inappropriate or improper reward or other overture in order to obtain compliance" (8). Violation of this principle

is exasperated when dealing with vulnerable populations such as the homeless or mentally ill. Beneficence involves the assessment of risks and benefits ensuring proper study design on the part of the researcher and ensuring that the ensuing risks for the participant are justified (8). However, the nature of phase 1 drug trials is to determine the risks of the drug. While pharmaceutical companies cannot avert this phase of testing, I believe the responsibility of the researcher to care for participants and monitor risks greatly increases. Lastly, the principle of justice, which includes fair selection of research subjects, is of great ethical importance to phase 1 drug trials. *The Belmont Report* states, “the selection of research subjects needs to be scrutinized in order to determine whether some classes are being systematically selected simply because of their easy availability, the compromised position, or their manipulability, rather than for reasons directed related to the problem being studied” (6). The use of homeless people in phase 1 drug trials directly contradicts this guideline and highlights the injustice of drug research on homeless populations.

Assessment of these practices with consideration of basic ethics highlights the need for ethical regulation for drug trials and protection for the homeless, especially those who are mentally ill. Although drug-testing companies do not need to follow governmental ethical guidelines, as a company of researchers they should uphold these basic ethical principles. Carl Elliott provides many examples from the field which point to the ethical wrongs committed by drug companies. However, before we identify these wrongs, we must first understand why pharmaceutical and drug-testing companies recruit homeless populations.

Pharmaceutical companies make a utilitarian argument for the use of homeless people in phase 1 drug trials; namely, that they need a population of mentally ill people who are willing to participate in these unavoidable trials. Elliott describes the rapid production of antipsychotics for

treatment of diseases such as schizophrenia and bipolar disorder, and the presence of the diseases among the homeless. He states, “Drug companies need mentally ill research subjects, and homeless shelters are full of them” (Elliott, 14). This directly contradicts the principle of justice as it exploits homeless people’s compromised position and manipulability. Despite their availability, researchers also highlight the benefit of testing drugs on the mentally ill. According to Elliott, “If you talk to the researchers who do the testing, they’ll say that this makes sense because patients with schizophrenia tolerate antipsychotics better, and at much higher doses” (14). This argument counters other scientists’ accusations that testing drugs in patients creates a confounding factor in profiling side effects. Furthermore, healthy subjects often cannot handle antipsychotics, “as even small doses...will cause some subjects to experience a sudden drop in blood pressure and faint” (14). While these arguments are compelling regarding the efficacy of the study, they do not solve the ethical problem at hand. Homeless people are still being exposed to extreme risk and acquiring more harm than benefit through participation in phase 1 trials. Researchers also argue that no healthy person would participate in these trials, but this argument benefits those on the side of the homeless as well—homeless populations are vulnerable to exploitation and should not be taken advantage of. Thus, their arguments do not validate the scientific integrity of their work.

Two characteristics of phase 1 drug trials that exhibit its unethicalness are that the risks outweigh the benefits and homeless people are coerced into participation. As pharmaceutical companies argue, no healthy person would participate in phase 1 drug trials because the risk is too high. In his study, Elliott observed many homeless shelters, primarily in Philadelphia, and he reports observing many residents with visible side effects common to antipsychotic drugs. Antipsychotics are associated with significant weight gain and a condition known as tardive

dyskinesia, a motor disorder that causes a permanent writhing and twitching movement of the mouth and tongue (Elliott, 10). When antipsychotics were first put on the market, they were reserved for serious mental illness like schizophrenia, but more recently, many new antipsychotics were developed to treat a wide range of illnesses, all of which required drug trials (11). Thus, Elliott describes drug-testing recruiters visiting every homeless shelter he visited, offering rewards for participation and leaving business cards behind. This recruitment is unique to homeless shelters, as you would not see a drug-testing company recruiter going door to door in any other neighborhood. By targeting a specific vulnerable population, their recruitment techniques directly violate the basic principle of justice.

Intense recruitment leads to exploitation of the homeless and potentially coerces them into participation. Elliott reports one man's story, saying, "Imagine, in 40 days you'll have \$4000!" The recruiter made testing drugs sound like a vacation in a five-star hotel, Burns said. "It's like a resort selling time shares. They talk about all the benefits first, and it sounds great, but then you start to ask: What do I have to do?" Burns emphasizes that he was hungry, tired, and had been mistreated before meeting this recruiter. This representation clearly highlights the unethical approach that pharmaceutical companies take to recruit test subjects. Beyond the compromised position of homeless populations, pharmaceutical companies also target them because many have mental illness. These illnesses put them at an even lesser ability to consent to the study trials. A supervisor of a shelter in Philadelphia emphasizes that the main ethical issue is "the competence and judgement of prospective subjects" (9). *The Belmont Report* lists respect for persons as the first basic ethical principle, which includes protection of persons who have limited autonomy. Whether in the field of biomedical research or in daily life, these basic principles should guide the actions of all people, especially researchers. These examples

demonstrate the failure of drug-testing in adhering to the guidelines of *The Belmont Report* and basic ethical principles.

Elliott exemplifies the unethical treatment and exploitation of homeless populations by pharmaceutical companies for drug-testing. Elliott's examples generate an uncomfortable response because they violate our basic ethical principles, especially those that honest researchers should uphold. I find these experiments especially unsettling because the participants are returned to the streets with potentially debilitating side effects. Thus, I agree with Elliott that the use of homeless people in phase 1 trials is unethical and wrong in their current state. However, I would not say that the homeless population should be off-limits; rather, ethical guidelines such as *The Belmont Report* need extension into the private sector of research. Whether in academia or industry, researchers have a duty to protect their research subjects. As we have seen throughout history and in these examples, this care is unfortunately not inherent to researchers and needs to be guided by predetermined ethical principles. Although mandating review boards for drug-trials may slow down their progression, lack of ethical regulation has demonstrated its necessity.

Works Cited

Elliott, Carl. "The best-selling, billion-dollar pills tested on homeless people." *Matter*, July 27 (2014).

The **Belmont Report**: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. [Bethesda, Md.]: The Commission, 1978.