

Week Five Reading Responses

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When Experiments Travel by Adriana Petryna

P 1-10; P 10-19; P 89-109; P 186-195

Adriana Petryna is an anthropologist who started researching clinical trials to better understand what drives them, what makes different parties participate in them and why is this industry booming. Along their research another key question arose, are clinical trials exploitative or are they for the good of society, or maybe some combination? Petryna brings forth the reality that many clinical trials are offshored due to the fact that they are too expensive, too slow and too regulated within the confines of the United States. Contract research organizations are able to get around this by finding countries and communities that are more willing to participate in these trials. CRO's use two criteria when finding a place to conduct a trial, the time it will take for the trial to be approved and the time it will take to get the trial up and running. Oftentimes this is done in areas where there are less regulations and the people do not have regular access, if any, to western medicine.

It becomes apparent at this point in the reading that many of these clinical trials are highly exploitative. They choose areas where people are more likely to participate because it seems like their only choice. Clinical trials are also exploitative in the way the testing is done. The goal of these trials is to get the drug approved, not to find all the risks and weigh them with the benefits. This is apparent in the example Petryna gave with HRT's in 2002. Many CRO's try to create the appearance of data integrity by having many well qualified "monitors" or medical professionals that look over and maintain the data of the trials. The key issue here is that these monitors are looking over the data, not the patients involved, which brings the ethical validity of the trial into question. But even with these negative aspects of clinical trials, they are not wholly evil, they do bring out medication that can help people who are in need.

One of the ways that medical research and clinical trials have evolved with the rise of globalization is that of the four phases of a trial, phases two and three, are often offshored to bypass many of the regulations imposed in a more developed territory, it allows for a quicker trial. The lack of transparency within industries and CRO's makes it difficult to keep track of all the clinical trials, making it more difficult to validate the integrity of the trials. As of 2009 when Petryna wrote this book, the FDA has been responsible for creating new initiatives that

fast track many trials by shortening drug approval time. These regulations that allow for less testing, meant drugs would hit the markets that may not be safe. Petryna highlights this exact issue with the example of Vioxx.

The FDMA act of 1997 mandated the registration of all major (life or death) clinical trials, yet based on the data it seems that many trials were not registered. Between 2005 and 2006, Petryna noticed that about half the trials took place in the US but industry leaders have been increasingly offshoring their trials, like in the case of GlaxoSmithKline. It would seem that these companies are offshoring the trials to avoid the regulations of the FDA to hold trials that may not have the safety of the patient in mind but rather the financial benefit. Even with all the pitfalls of corrupt industry led medical research, people are given the opportunity to receive medical treatment. Many of the areas where these trials are located do not have a robust medical system in place. Poland was one of the examples Petryna covers. The Polish people receive medical treatment not from the existing medical systems in place but rather the vast array of clinical trials that are taking place. These people are impoverished and are desperate, which calls the ethical standing of these trials into place, but these trials do give them an option normally not viable. Once again, these are desperate people, even if a trial is dangerous, they are willing to partake for the chance of treatment.

Clinical trials are a crucial part of creating new treatment options for various degrees of illness. Petryna highlights many concerns with the globalized nature of the clinical trial world, but they also highlight some benefits. By having trials offshored, more trials can occur and treatments can reach people who have no medical options. At the same time, as more trials are offshored, it becomes increasingly more difficult to regulate and track the multitude of clinical trials that are happening. With the need to navigate international policies and the black boxes of industries to create an organized list of clinical trials, the ability to create a fully documented and exhaustive list of all existing trials becomes daunting if possible. Based on the reading, it seems that with the current state of regulations, clinical trials are a combination of both exploitation and social good, but do lean more toward exploitation.