
Roberto Abadie’s publication presents the results of an ethnography of human drug trial participants. For researchers in the field of risk analysis, participation in drug trials is an interesting case and is certainly one that is ripe for analysis. In a drug trial conducted in London in 2006, six healthy ‘volunteer’ subjects were injected with an experimental anti-inflammatory drug. All six men suffered multiple organ failure. Although all survived the initial adverse event, one man required the amputation of fingers and toes and all six men now have an elevated risk of contracting serious disease due to an impaired immune system. Although this event was an extreme and unusual outcome of a clinical trial, it drew much attention to the risk of participation in clinical trials.

The research reported here focuses on the experiences of a group of regular phase I drug trial participants (healthy individuals testing the safety of a drug) who are part of an anarchist community based in West Philadelphia in the United States. Abadie also includes some Phase I participants not part of this community, and Phase II volunteers (individuals suffering from the target disease testing the therapeutic benefits of the drug). Abadie’s findings are based on 18 months of fieldwork which involved the investigator living with the anarchist community and in hostels used by participants outside this community, and interviewing trial participants, and professionals in the industry. The results of this study are numerous and multifaceted, and while the author offers a fascinating analysis of his results, the reader is also left aware of several areas which were not analysed, or only touched upon.

For a reader with limited knowledge of drug trials, the book offered much practical knowledge on their historical development and modern day organisation. Abadie describes how moves towards greater regulation produced the randomised control trial as best practice. However greater regulation and awareness of ethical issues have frequently not extended to drug trial participants. Although the blatant abuses of using captive populations such as prisoners has been outlawed, Phase I research participants are frequently poor, unemployed or under-employed, for whom payment for drug trial participation is an essential income, irrespective of the risk. Throughout the book the author draws attention to the exploitation of drug trial participants and ethical concerns about their treatment.

The issue of risk for drug trial participants is an important aspect of this study. As witnessed by events in the above discussed trial, there are serious risks inherent in drug trials. Abadie outlines various theoretical understandings of risk. While these enable the reader to theorise about risk perceptions of participation in drug trials in a general sense, the relevance of these approaches to this group of trial participants could have been extrapolated more thoroughly. For example, it is described how those individuals who become regular ‘professional’ trial participants regard trial participation as lower risk than the general public, or those doing their first trial. The author discusses how regular trial participants gain experience and knowledge of drug trials. This may also lead them to gradually perceive less risk in participation. In addition, this group of trial participants had developed their own dialogue and stratification of risk, placing trials for psychiatric drugs as the most risky. Their understandings appeared to have developed out of a shared dialogue between trial participants rather than from trial organisers. A further analysis of the participants’ changing attitudes, and their techniques for dealing with risk would have enhanced this part of the study.

Much of the focus of the book is on trial participants who are members of the anarchist community. The book offers much description of this group and their relationship with the trial economy. This group’s activities to counteract feelings of commodification and alienation generated by trial participation, and their conflict over participating in the corporate world of pharmaceutical development, is well analysed by the author. It was legitimate to focus on this group as they offered much insight into commodification and alienation of drug trial participants. However the reader is provided with less insight into the experiences of regular trial participants who are not part of the anarchist community. The author offers some observations about wider trial participation, but this is insufficient, considering that most regular trial participants do not belong to a specific community.

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To conclude, Abadie has conducted illuminating research into this topic and the reader is left with the hope that the author continues in this area and offers more detailed insight into the experience of research participants outside his core group for this book, including the issue of clinical trials conducted in the developing world, which has become a increasingly frequent site for drug trials, forming a new and very problematic ethical dimension in drug development research.

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When it comes to sociological studies of pharmaceuticals, the question among social scientists is not whether the global system for drug development and regulation is broken. The question is just how broken.

In 2004, global financial markets reeled from the recall of Vioxx, labelled the ‘single greatest drug safety catastrophe in the history of this country or the history of the world’ by Federal Drug Agency (FDA) staff member David Graham in testimony before the US Senate. Since then, there has been little doubt that links between industry and regulators have compromised the ability of regulators to ensure manufacturers are forthcoming with clinical trial data, and to swiftly disclose evidence of adverse effects to the public.

In the UK, regulators have admitted they were powerless to penalise GlaxoSmithKline for withholding data on the safety of Seroxat in children and adolescents. In the US, as Marcia Angell writes, the FDA’s relationship to industry ‘has resulted in the sale of drugs of uncertain benefits, some with serious side-effects, and in the agency’s failure to respond promptly to evidence that a drug is dangerous’ (Angell, 2010: 66).

Angell’s comment comes from a recent review of political theorist Daniel Carpenter’s (2010) Reputation and Power: Organizational Image and Pharmaceutical Regulation at the FDA, a timely history of the US agency. In her review, Angell blasts Carpenter for being too ‘impartial’ and remaining ‘oddly aloof’ from the question of whether the FDA has become too dependent on the industry it is meant to regulate.

If Angell finds Carpenter too tepid in his analysis, the same could not be said of Donald Light’s recent edited collection, a vital book that offers new insights into time-honoured problems of iatrogenesis – the question of whether cures developed to help save lives do more harm than good. The collection brings together eminent contributors – Howard Brody, Allan Horwitz, Cheryl Stultz and Peter Conrad – to examine how the marketing and consumption of prescription drugs may be endangering individual lives and the financial sustainability of healthcare systems.

The chapters are varied in content. Light offers a chapter on the FDA’s history, exploring the evolution of the agency from an organisation geared to protecting the public health to one that has failed, in Light’s view, to carry out its central mission of public safety. Brody’s chapter shifts the focus to physicians themselves. Using the example of statins, he suggests doctors are too reliant on industry generated medical literature, leading them to prescribe drugs which can augment the medical risks doctors are meant to mitigate. Horwitz’s chapter addresses a familiar theme – perhaps too familiar. He looks at the ‘medicalization’ of social life, and how typical life phases such as childhood unruliness are being treated as pathologies requiring medical care. Horwitz writes fluently, but the chapter largely reiterates familiar claims within medical sociology rather than introducing new ones. In a jointly written piece, Stultz and Conrad examine the treatment of menopause with hormone replacement therapy, introducing the term ‘risk scare’ to describe the development and distribution of drugs which exacerbate medical conditions rather than alleviating them.

A highlight of the book is the links it draws between the costs (both purported and actual) of bringing a new drug to market, and how lagging drug productivity affects access to drugs. Rather than simply focus on drug licensing procedures, as Carpenter’s book does, Light’s collection emphasises the ancillary problem of how drug development and licensing influence drug cost and availability, both in the US and beyond.

Light’s key aim is to stress that, on average, most new drugs offer little or no additional benefit over existent therapies. Despite this reality, the industry has managed to remain one of the most