The Dilemma of Outsourcing Drug Trials

By Somjit Barat*

As ubiquitous as drug trails are becoming, more and more marketing companies in the western world are looking beyond their own borders to recruit participants and conduct such experiments. While this has led to faster turnaround times and higher number of potential drugs being pushed into the market pipeline, such practices often raise questions about procedural thoroughness, propriety and marketing ethics. Are participants being provided the full and unbiased information? Are the recruits educated enough to comprehend the risks? Do the drugs being tested have any relevance at all in the host country? Are the same standards of rigor and oversight being followed in the host country as in their western counterparts? Consequently, the study achieves the following objectives: 1. Helps us better understand the extent of the loopholes that pharma companies exploit while marketing the ‘benefits’ of such drug trials to the intended participants and 2. Encourages more researchers to innovate better marketing strategies, so that future drug trials can be conducted in a systematic, ethical and yet rigorous manner.

Keywords: Emerging economies, ethics, drug trials, theory of reasoned action

Introduction

The importance of conducting thorough trials before a drug can be officially approved for the market is beyond dispute. However, research companies often push the envelope when it comes to best practices for conducting such trials, especially in non-Western countries. Faced with a domestic shrinking market and increasing oversight from their own regulatory agencies, western countries are increasingly ‘outsourcing’ such trials to other countries. Concurrently, a sizeable segment of low-income, under-educated population resides in developing countries, who are often promised a cure for their disease under study or their future medical expenses to be borne by the drug company conducting the research. Given the ubiquity of drug use, it may, therefore, be no surprise that the rate of drug trials for commercialization purposes has assumed astronomical proportions. Consequently, the current study explores different dimensions of ethical marketing issues, which have made some developing countries the ‘guinea-pigs’ of the Western labs.

Basing the research on the Theory of Reasoned Action (Ajzen and Fishbein 1980), the author argues that the individual’s beliefs about the outcomes and consequences of conducting drug trials influence his/her attitude towards conducting such trials. The study will achieve the following objectives: 1. Help us better understand the extent of the loopholes that pharma companies exploit while marketing the ‘benefits’ of such drug trials to the intended participants and 2.

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Encourage more researchers to innovate better marketing strategies, so that future drug trials can be conducted in a systematic, ethical and rigorous manner.

The paper is organized as follows: The author introduces the concept of and concern about marketing ethics in outsourcing drug trials, using hard data. In the next section, the author reviews extant literature focusing on the topic of discussion and identifies gaps in literature. This section is followed by a discussion of the major perspectives on ‘ethics’, given that this article relies heavily on the role and interpretation of ethics. Next the author introduces the theoretical framework, while the next section focuses on how and why such marketing practices raise serious marketing ethics concerns. The penultimate section titled *marketing drug trials in an ethical manner* talks about how we can market such trials in a more ethical manner and yet, maintain the rigors of the testing procedures. The concluding section briefly discusses the limitations of the research, and provides ideas for future studies on this highly relevant topic.

Western countries frequently outsource their drug trials to Third World countries. According to one Duke University survey (2007), more than two-thirds of US clinical trials were conducted outside the US (see Glickman et al. 2009). The Office of Inspector General (OIG) noted in a 2010 report about the increasing use of locations outside the western world for clinical trials, and highlighted FDA statistics pertaining to the same (Levinson 2010):

- Over half of all clinical trial sites are outside the U.S.
- 35% of non-U.S. clinical investigators were conducting trials under independent agencies.
- 80% of applications for drugs and biologics contain data from ex-U.S. studies.
- 78% of all subjects were enrolled outside the U.S.
- 87% of all subjects in recent biologics trials were enrolled outside the U.S.

Trial-participants also indicated that drugs and supplies were shipped throughout the world, with North America topping the chart at 78%, followed by Western Europe (66%), Eastern Europe (63%), Latin America (29%), Asia-Pacific (22%), and Rest of World (18%). In order to make the movement of equipment and supplies more efficient, companies often set up regional hubs such as in a wheel-and-spoke system (for example, Western Europe tops the list at 38%, followed by Asia-Pacific (31%), and Rest of World (13%). Similarly, top local depot locations are located in Latin America (49%), North America (41%), and Asia-Pacific (36%) regions.

The statistics in Table 1 proves, beyond reasonable doubt, that even though the numbers of sites in most western countries is considerably higher compared to their non-Western counterparts, the trend is exactly the opposite in terms of average relative annual growth rates (ARAGR) percent. For example, Canada hosted 3032 testing sites while the UK had 1753 sites. Compared to those, China (which is only the fourth largest country) has only 533 sites, while Peru and Malaysia had only 125 and 161 sites respectively. In contrast, the ARAGR for Switzerland, Sweden, Belgium and the UK were all in the negative territory (with
the exception of Canada, which had a 12% ARAGR). In contrast, China, Estonia, Russia, Peru and Malaysia exhibited ARAGR of 47%, 35%, 33%, 33% and 32% respectively.

Table 1. Sample of Countries Ranked by Average Relative Annual Growth Rates of # Sites (2007)

<table>
<thead>
<tr>
<th>Ranking</th>
<th>Country</th>
<th># Sites</th>
<th>% ARAGR</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>China</td>
<td>533</td>
<td>47</td>
</tr>
<tr>
<td>2</td>
<td>Estonia</td>
<td>83</td>
<td>34.6</td>
</tr>
<tr>
<td>3</td>
<td>Russia</td>
<td>1084</td>
<td>33</td>
</tr>
<tr>
<td>4</td>
<td>Peru</td>
<td>125</td>
<td>32.5</td>
</tr>
<tr>
<td>5</td>
<td>Malaysia</td>
<td>161</td>
<td>32.1</td>
</tr>
<tr>
<td>45</td>
<td>Switzerland</td>
<td>309</td>
<td>-7.6</td>
</tr>
<tr>
<td>46</td>
<td>Sweden</td>
<td>739</td>
<td>-8.6</td>
</tr>
<tr>
<td>47</td>
<td>Belgium</td>
<td>986</td>
<td>-9.4</td>
</tr>
<tr>
<td>48</td>
<td>UK</td>
<td>1753</td>
<td>-9.9</td>
</tr>
<tr>
<td>49</td>
<td>Canada</td>
<td>3032</td>
<td>12.0</td>
</tr>
<tr>
<td>50</td>
<td>Norway</td>
<td>290</td>
<td>-14.7</td>
</tr>
</tbody>
</table>

Adapted from Table S4: Thiers et al. (2008).

While the reasons for such trend are beyond the scope of the current review, it can be surmised that most Western countries had either reached their capacity or found economically and logistically infeasible to set up more testing sites (again, with the exception of Canada, which has significant vacant landscape). On the other hand, several non-Western countries (India and Thailand being the topmost) quickly developed the infrastructure to host medical testing sites and as such, found a ready market among Western research labs and drug testing agencies eager to outsource their work.

An identical trend, especially in phase 1 and phase 3 of the trial process, is corroborated further by Jeong et al. (2017). For example, the author notes that phase 3 trials were more popular in India, whereas phase 1 trials were predominant in other countries compared to the US. Interestingly, as well, a larger number of ‘child’ age group trials were conducted during the same time period (2011-2013) in Poland, Israel, and South Africa compared to the US.

As indicated in another study by Lexchin et al. (2003), there is also an increasing role of industry sponsors of such trials, sometimes making it all the more difficult to adhere to ethical standards; consider the following findings that buttress what the author surmises: all 16 studies showed favorable outcomes for company-sponsored trials compared to only 10 for non-sponsored trials and industry-sponsored trials were more likely to report favorable qualitative conclusions compared to their non-sponsored counterparts (for further details, see Table 2 in Lexchin et al. 2003).

Paradoxically, scant literature has been devoted to this issue from a marketing perspective, which will be evident from the review in the next section. Therefore, the author’s contribution fills a considerable void, and bridges the gap between the medical and ethical marketing worlds.
Literature Review

Researchers in the medical community have long bemoaned the lack of oversight in conducting drug trials. On the other hand, discussions focus on a range of issues starting with the history of drug trials going all the way to some of the most recent developments in this field. Consequently, for the reader’s convenience, this review has been segmented under two headings: antecedents and consequences of medical trials.

Antecedents: As indicated earlier, drug trials on human subjects have been a prerogative of western countries for multiple reasons, such as higher testing standards and requirements, more extensive use of drugs by patients and prescriptions written by doctors (Bachman et al. 2016, Grigoryan et al. 2006, Birke et al. 2016). A stark indicator of this chasm between the two worlds is reflected in Figure 1, which shows the preponderance of antidepressant medication use in western countries compared to their non-Western counterparts.

**Figure 1. Use of Antidepressant in Select Countries**

![Graph showing antidepressant use in select countries](source)

Adapted from Gould and Friedman, 2016.

Given that per capita consumption of medications is significantly higher in western than in other countries, western countries pioneer pharmaceutical research and drug trials at an unprecedented rate, saturating their domestic population for such purposes.
At the same time, the standards and rigors of pharmaceutical trials have become more stringent, with regulatory bodies requiring pharma companies to employ a higher sample size for testing purposes. Getting such a higher sample size and conducting the trials within the time frame in-country was simply getting economically infeasible. Consequently, Western pharma companies were left with no choice but to look outside of their geographical boundaries.

This is where many of the non-Western countries, with a vast population, and lagging in healthcare infrastructure, proved to be a goldmine for Western nations. Pharmaceutical companies and research institutes hired marketing agencies with knowledge of and presence in non-Western countries to tout the benefits of drug trials to a hotbed of potential participants. And the marketing agencies haven not looked back since then. In addition, the following factors appeared to have played a significant role in globalization of such trials: 1) lower operational costs, 2) ready availability of subjects and in vast numbers, 3) mushrooming of marketing agencies specializing in pharmaceutical trials, and 4) standardization of clinical guidelines and research methodology, including in non-western countries (Thiers et al. 2008, Retti 2000, Zarin et al. 2007, Jia 2005).

In addition, higher requirements (such as larger sample, more testing before commercialization), expansion of high-incidence drug introductions (such as hypertension) and the pressure to bring new drugs to the market even faster, have all contributed to the globalization of drug trials (Petryna 2005, 2007).

Finally, many researchers have highlighted the role of ‘treatment naivete’ in popularizing drug trials in Asian, Eastern European or African countries. Treatment naivete refers to the incidence of patients who have not been exposed to any drugs yet. Such patients are highly sought-after by pharma companies because there is none to very little drug interaction. Naturally, given the preponderance of drug use in Western countries, finding ‘virgin’ patients in Western countries for drug trials became increasingly challenging. Consequently, pharma companies marketed their trials to non-Western countries (Good 2001, Das 1996, Biehl 2001).

Discussion

The author’s research also revealed significant literature about the consequences of this trend. Once again, for the reader’s convenience, the author has classified the literature under two sub-headings: benefits and disadvantages

- Benefits: As indicated at the very onset, the main objective of conducting drug trials is to establish the efficacy of treatment, patient reaction and possible side-effects of a medication or procedure. This is especially critical for regions that are economically poorer and/or have a weaker medical infrastructure (Petryna 2005, 2007). The diffusion of medical knowledge and information has long-term implications that might impact the entire evolution of certain populations in terms of physical, emotional and psycho-social development (de Zulueta 2001, Crouch et al. 1998, Bothwell et al. 2016, Darrow et al. 2015).
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There is no question that different drugs should be tested on subjects, barring which, their effects cannot be compared, nor will it be possible to prescribe the most effective cure for serious diseases. Gupta et al. (2015) opine that drug trials on pregnant and post-partum women are critical, especially for epidemics such as HIV, because it affects not just the patients but future generations as well. From a marketing perspective, therefore, the benefits of such trials far outweigh the costs and risks.

Finally, Davis et al. (2017) put forth the argument that drugs may not necessarily cure all chronic diseases such as cancer, but can potentially improve the quality of life of the patients. In other words, the benefits of drug trials may not always be obvious to ‘healthy’ people but can potentially be a game changer for chronically ill patients.

- Disadvantages: Marketing companies (aka Contract Research Organizations or CRO-s) often resort to increased pressure and suppression tactics, which lead to bypassing due process (such as Institutional Review Board or IRB review) in such trials. One study, for example, found that only 69% of the trial studies had IRB approval (Samuel et al. 2016).

A second factor is the lure of money and/or quick ‘cure’ that CRO-s sometimes use as an added incentive to recruit subjects. Such incentives cloud the participant’s ability to make a medically informed decision regarding participation. Often a patient who is desperate for a cure, fails to realize that a ‘trial’ is not a cure, but only a possible path towards a cure, and is, therefore, prone to making hasty decisions. In other words, irrespective of the outcome of the trial, the process of conducting the trial does not necessarily seem to in the best interests of the patient (Ahmed et al. 2014, Jacob 2018, Limbu et al. 2018, Heneghan et al. 2017).

A yet third criticism arises from the perspective of lack of follow through after the conclusion of the trial. Once again, this can most likely be traced back to insufficient information for the participants, who either fail to adhere to the proper protocol, precautions, best practices or to continue follow-up procedures. This leads to tainted or biased results, thereby nullifying the entire trial procedure, sometimes without the lack of knowledge of the pharma company. The subject suffers from financial, physical and emotional distress (Goyal et al. 2014).

Many researchers are concerned that the absence of strong legal infrastructure in non-Western countries makes them a hotbed for drug trials by research companies. This is important, because citizens of those countries (especially the economically disadvantaged) have little to no legal recourse, should something go wrong during or after the trials (Petryna 2007, Angell 1988, 1997, 2000, 2005).

There also exists considerable literature about controversial use of ‘placebo’ in drug trials. Pharma companies have failed to provide the same level of care for subjects who were administered the placebo during a trial in Africa in 1994 for example, even though providing similar level of care was the norm in the US at that time. Researchers have lamented that dual standards are practiced by pharma companies. For more on the disadvantages of drug trials, the reader can consult

Critics argue that pharma companies conduct trials in countries where the drugs being tested are least likely to find a large market, such as India, China, Eastern European and South American nations. The reason is that, very few of these trials involved diseases prominent in third world countries. Many doctors also raise questions whether participants were volunteers or coerced into such studies, not to mention that many of the drugs in question are too expensive for the local people to afford.

While a lot can be gleaned about the multiple research perspectives from the previous section, there is seldom any doubt that little attention has been paid to the topic from a marketing-ethics perspective; while reference to ethics in drug trials is copious, the role that marketing agencies (CRO-s) play in popularizing this phenomenon has been consistently overlooked.

‘Marketing’ according to the American Marketing Association’s definition, is basically creating, communicating, delivering and exchanging offerings that have value for consumers for members of the society at large.¹ In the current context, while the potential benefit of drug trials may be significant, the shortcomings and questionable marketing tactics described above raise the questions whether ‘even exchange’ and ‘value creation’ are taking place at all! For example, one of the fundamental requirements for ‘exchange’ to take place is that it should not be conducted under duress. However, as indicated earlier, the lure of money and a false promise of cure influence the potential subject’s ability to make an informed decision regarding participation in the study; clearly, such participants are subject to psychological duress. Consequently, the behavior of pharma companies is subject to ethical scrutiny to say the least -- an issue that is further discussed in the following section.

Ethics and Proposition Development

‘Ethics’ is often identified with jello: the more one tries to nail it to the wall, the messier it gets. It is no surprise, therefore, that the topic of ethics has been discussed and interpreted from multifarious perspectives. Given that an exhaustive discussion is neither possible nor necessary in the present context, the author presents a limited view of only those perspectives that are the most relevant for the medical field. It must be noted that ethics is an even bigger concern when it comes to the healthcare field, especially for issues such as, patient recruitment, drug testing, administering a test, side effects of administering a drug etc. The reason for such complexities arises from (but not necessarily limited to) technical language, methodology involved, rules about proper disclosure of possible risks and side effects and ability of potential subjects to comprehend the instructions and technical language. As such, major bodies such as Food and Drug

¹American Marketing Association: https://www.ama.org/AboutAMA/Pages/Definition-of-Marketing.aspx.
Administration (FDA), European Federation of Pharmaceutical Industries and Associations (EFPIA) and Good Clinical Practice (GCP) have very strict ethical guidelines to deal with such issues.

**Figure 2. A Simplified Model of Ethics**

Adapted from Kerin, Roger A. and Hartley, Steven W. (2018). Marketing: The Core; McGraw Hill Education, page 81, Figure 3-2.

Ethics are the moral principles and values that individuals imbibe throughout their lifecycle, and influence their everyday behavior, whether alone or in a group (Murphy et al. 2005). From a very rudimentary standpoint, ‘ethics’ is the distinction between what is right and what is wrong. However, everyone’s assessment of what constitutes right or wrong may be potentially different from another. Consequently, it is important that the individual lay out certain guidelines in making critical decisions. From a personal standpoint, ethics are as much the result of individual judgement as they are the products of the societal norms and practices that we have grown up with and what we have seen our parents, friends and relatives practice. This ethical perspective, as such, is more inclined towards the deontological school (morals and principles) compared to the teleological school. From the teleological prism of ethical viewpoint, the distinction between what is right and what is wrong is governed more by the consequences of the individual’s action and less by what the individual’s moral standpoint is. Thus, for example, even though someone personally believes that stealing is unethical, the person will nonetheless steal money from rich people and distribute it to the poor. From a utilitarian standpoint, more poor people will benefit compared to the handful of rich people who will be harmed because of the person’s action. For drug testing conducted on people on non-Western countries, the author proposes that researchers and recruiters look at the long-term profits of the pharma companies, even if it means going against their personal ethical standards, which leads to: **P1: Drug trial subjects recruiters are guided by profit-based utilitarian objectives rather than personal ethical principles.**

From a business standpoint, likewise, it is important that the company design a ‘code of ethics’, which will help its employees make responsible business decisions. At the same time, it is important to distinguish between societal
norms/ethics, business ethics and corporate ethics. Societal norms are governed principally by what is ‘socially acceptable’ and therefore, may vary from culture to culture. In many countries where social norms and structures may not be as rigid as in Western countries, cutting in line may not be a big deal but in other cultures, that perpetrator will most likely be scoffed at and called out by others whom he cut in front of. In many traditional cultures, subjects may refuse to participate in drug trial studies because of fear of social ostracization, which leads us to: **P2: Potential subjects in non-Western countries may be hesitant to participate in drug trials due to social and normative concerns.**

Business ethics, on the others hand, are guided principally by and subservient to, the profit motive. Businesses exist to make profits. Typically, a business will stretch the limits of ethics in order to make profits, but largely stay shy of breaking the law. In other words, personal ethics are different from business ethics, a dichotomy that has existed for ages (Crane and Matten 2016). While industrial psychologists argue that it is possible to make profits even while following the standards of business ethics (Taylor 2013), it actually depends on two factors: 1. How seriously the business executives themselves follow ethical principles and 2. How well the company can convince its employees to do the same. As reflected by the data in Table 2, industry and ‘other’ industry sponsors seem to play an increasing role in conducting drug trials on a global basis. Consequently, lack of strong business ethics at the top often drives pharma companies to drive their employees to act in an unethical manner, which motivates: **P3: Unethical practices in drug trials frequently result from greed for profit by pharma companies and external industries that often lack a strong business ethic.**

This brings us to the third component of our ethics model, which is corporate culture and expectations. Charity begins at home. When a business displays strong ethical practices at the helm, it also expects that such spirit will percolate to the bottom ranks. In contrast, if the top corporate culture itself is fraught with unethical practices, the employees will consider it their prerogative to indulge in similar behavior, as is exemplified by Wells Fargo (Verschoor 2016) in its recent acts of multiple gross violations. Thus, even though we might blame the field practitioners for misrepresenting and/or suppressing information from the poor and gullible people into participating in drug trials, the trail of evidence might point the finger of suspicion towards the company executives, thereby resulting in: **P4: Unethical practices by top executives at pharma companies can encourage field level recruiters to engage in unethical practices while conducting drug trials in non-Western countries.**

Data suggest that close to 60% of Fortune 500 companies surveyed in 2000 had a ‘code of ethics’ but only a fraction of those (41%) implemented them (Smith 2012). Having a code of ethics in place but not implementing the same defeats the whole purpose of abiding by corporate ethics standards. Nonetheless, according to the following graphics, empirical data reveal that employees are more likely to indulge in unethical acts when such code is non-existent as compared to when such code exists on paper. For example, only 32% reported misconduct of those who observed wrongdoing in large companies without and effective ethics
program, whereas the corresponding percentage was 87 in companies with an effective ethics program in place.

**Figure 3. Ethical Practices at Large Organizations**


One such school of thought suggests that certain individuals act under the pretext of ‘pre-conventional morality’, which refers to the notion that an individual will do whatever it takes to fulfill that individual’s self-interests without breaking the law or getting punished; others follow ‘conventional morality’, where the individual conforms to what is socially acceptable rather than the individual’s self-interests. Finally, ‘post-conventional morality’ offers more importance to social expectations and norms, where the individual in questions makes well-informed decisions only after examining all perspectives of the given scenario (Kohlberg 1976, D’Souza and Gurin 2016, Northouse 2018).

Another school of ethics principles centers around virtue ethics, consequentialism and deontological strains of what is right or what is wrong, collectively referred to as ‘normative ethics’. Normative ethics basically refers to what is most acceptable under the given circumstances, and involves actions taken by ‘moral agents’, who are considered to possess the mental capability to decide right from wrong and act accordingly. As indicated before, a terminally or several ill patient cannot, by any stretch of imagination, be considered a moral agent, because his/her desperation to live overpowers his/her sense of judgment (Taylor 2013). In many cases such as this, researchers and drug companies take advantage of the patients’ helpless situation to conduct tests and trials, thereby making such actions unethical.
Our spotlight on the role and perspectives of ethics, therefore, helps us understand and appreciate how conducting drug trials in countries where ethical guidelines are either not clear or not implemented rigorously may lead to questionable practices by pharma companies and marketing firms. The next section discusses the theoretical framework of our article.

**Theoretical Framework**

The Theory of Reasoned Action (TRA) provides an appropriate framework within which the current research can be anchored. Extrapolating this theory to the current context, the author argues that the individual’s beliefs about the outcomes and consequences of conducting drug trials influence his/her attitude towards conducting such trials. His/her attitude, in turn, influences the individual’s intention to conduct drug trials (Ajzen and Fishbein 1980, Fishbein and Ajzen 1975, Fishbein and Jaccard 1973). On one hand, if the researchers foresee significant potential, they will conduct such trials; participants will volunteer to be a part of such trials if they expect the potential gains and remuneration from such participation to outweigh the associated risks.

Moreover, the individual’s normative beliefs about the feelings of his/her close friends and relatives towards participating in drug trials also affect the individual’s subjective norms (refer to Figure 4). For example, the individual might believe that participating in drug trials is a “smart” thing to do, leading to a positive attitude towards study participation. If, on the other hand, the individual or any of his/her acquaintances has had a bad experience with clinical trials in the past, then the individual will most likely have a negative attitude towards participation.

**Figure 4. The Theory of Reasoned Action as Applied to Outsourcing Drug Trials**

Adapted from Ajzen and Fishbein, 1980, 8.

There exist several disconcerting issues why random outsourcing of drug trials may be detrimental not just for the participants but also for the entire medical community, some of which are discussed below in accordance with the theoretical framework of Figure 3.

1) Based on trial-participants’ input gleaned from multi-country studies, it appears that prohibitive costs of conducting such trials in western countries on one
hand, and unfettered access to a huge pool of patients eager to earn a ‘fast buck’ on the other hand are the primary motivators that lead pharmaceutical companies and researchers to conduct trials outside western countries (Ali et al. 2018).

2) Given that the easy availability of and access to such vulnerable population in many of the African, Asian, East European and South American regions, it is of utmost importance that such targets of drug trials be protected from, and adequately informed about the potential risks associated with drug trials if proper protocols are not followed (Rajadhyaksha 2010).

3) There remain serious concerns as to whether external marketing agencies fully reveal the rigors and risks of participation while promoting trials in foreign countries and 4) From a global marketing perspective, cultural issues such as diet and popular herbal remedies etc. can considerably skew the results of such trials. However, such factors are rarely addressed while selecting participants, thereby leading to a system that can potentially skew the results.

What medical researchers and authors often have failed to take into account is the role that normative beliefs and subjective norms play a role in the potential subject’s decision whether or not to participate in a trial. From a marketing perspective, the author believes that this is one of the most significant contributions of the current paper. Many Asian, South American and African cultures have deep-seated taboos about drugs and their effects on humans. For example, friends and relatives who consider the participant to be ‘greedy’ and ‘needy’ might socially ostracized the participant. Nonetheless, given the economic struggles that these people must go through, they participate in drug trials even if doing so is against their will and morals. In other words, economic conditions, normative beliefs and subjective norms often moderate the influence of beliefs about participation in drug trials on the intention to participate in drug trials. Clearly, this cannot be considered ‘ethical’ by any standards. Once again, the literature on this dimension is almost non-existent, hence the current paper is an attempt by the author to stimulate thinking in that direction (Piantadosi 2017, Anglada et al. 2015, Leon et al. 2015, Chow et al. 2015).

Concerns about Marketing Ethics and Laws

Ethics can be defined as the moral principles or values that generally govern the conduct of an individual or a group (Lamb et al. 2018). Arguably, different people have different standards and interpretations of what is ‘ethical’ and what is ‘unethical’. On the other hand, some ethical rules and guidelines are often codified into laws. Laws are typically created by governments and are then enforced by governmental authority. By definition, therefore, ethical guidelines are more prone to misinterpretation and distortion compared to laws. Such behavior often leads to self-regulation, which involves the voluntary acceptance of standards established by nongovernmental entities.

The tenets of Utilitarian ethical theory are founded on the ability to predict the consequences of an action. Unfortunately, many of the participant subjects have relatively low levels of education, which severely limits their ability to foresee the consequences of their participation in such clinical trials. To be sure, the author
argues that the marketing and research agencies operate with calculating, self-serving and selfish motives, where they look for every opportunity to evade the long arm of the law by resorting to notions of pre-conventional morality (Lamb et al. 2018).

The author also notes that in certain circumstances, as per the code of deontological ethics (Paquette 2015) the morality of an action or decision should be based on whether the action itself is right or wrong in the eyes of a series of rules, rather than on the consequences of the action. Regrettably, whether we look at the issue from a deontological perspective or the theory of Reasoned Action perspective described under our theoretical framework, many of the actions perpetrated by pharma companies can be considered unethical in both categories.

The author’s main concern, therefore, in the current research is how marketing companies and pharma organizations take advantage of such moral bankruptcy. They stretch the boundaries of ethical behavior in their recruiting of subjects, in providing the subjects the right and accurate information, gathering their consent for participation through full disclosure, in conducting the clinical trials, and finally, in presenting and interpreting the results of the study.

In an open, democratic society, the media plays a key role in informing the public about the actions of individuals and organizations—both good and bad. At the same time, an active civil society works as an informed and engaged entity that can help mold individual and corporate behavior. Ironically, none of these two characteristics exist in many non-Western countries, where drug trials are rampant.

Consequently, the marketing agencies conducting such trials do seldom get caught, and much less prosecuted, because of lax legal loopholes in non-Western countries. According to a report published in Applied Clinical Trials about resource-limited sites, the author raises serious concerns about the following (Garg 2017): 1) Dearth of trained personnel; 2) Training materials (either face-to-face or online webinars conducted right before the commencement of the trials) focus more on the human subject requirements and protections thereof but lack the rigors of operational procedures and the consequences of failure to adhere to the protocols; 3) Training courses include case-studies, but seldom relate to the specific trials that will be conducted on site. Site personnel often take shortcuts in daily procedures because they fail to appreciate the impact of their (in)action on the studies’ outcomes.

In another recent survey, regional experts and study participants raised the following concerns, which raise ethical red flags about the conduct of such drug trials. 22% of the respondents were concerned about the process of ‘informed consent’, which remains questionable for many reasons. The participants are either not provided full disclosure or do not fully understand the complexities of such trials. For others, the promised monetary or non-monetary rewards from participation cloud the individual’s ability to make an unbiased decision (Bentley et al. 2004, Russell et al. 2000, Bigorra et al. 1990).

22% of respondents also lamented the lack of health literacy. This is a concern because it influences the ability of the participant to comprehend directions, requirements, warnings, precautions and to-do lists and other such obstacles (Tanner et al. 2015, Bonevski et al. 2014, Alemayehu et al. 2018).
Another concern among the respondents was lack of qualified translators or regions that are capable of accurately creating materials for participants in native language (25%). This concern is graver than what appears on the surface, because medical terminology and specifications often do not lend themselves to easy ‘translation’. Some terminologies and names simply do not have a local language synonym (McNeish et al. 2015, Daley et al. 2001, Ford and Norrie 2016).

Finally, the ability to predict the utility of such trials in a Western setting is a critical factor that can help drug companies justify their experiments. For example, the food habits, lifestyle, family history and gene structure of Western people are significantly different from those of their Asian and South American counterparts. Consequently, the validity of trials pertaining to a specific disease such as cancer or diabetes, for example, may be irrelevant to the Western population (Kordes et al. 2015, Green et al. 2015, Lewis et al. 2011). And yet, these trials appear to be the most widely conducted ones that Western countries outsource to other countries, simply because those diseases are among the most prevalent in Western countries. In other words, as has been pointed out by oversight and regulatory agencies, the responsibility lies with the drug companies or the research institutes to make their case that the results of the drug trials in offshore locations are valid, reliable, complete, unbiased and most importantly—relevant to the Western patients and Western clinical system.

Marketing Drug Trials in an Ethical Manner

Given that health literacy and informed consent are two critical factors, experts suggest that marketing materials must be made available in the native language. Consequently, availability of and ability to generate translators from English to the native language will alleviate many concerns. Another solution is choosing a country/region that already has an existing supply chain (including cold chain) infrastructure. According to a study conducted by the Tufts Center for the Study of Drug Development (CSDD) in 2016, the economics of supply chain management and distribution have become exponentially complex. Therefore, the marketing agencies need to enforce proper coordination, collaboration and professional training of vertical and horizontal members of the supply chain network. Such measures will help market drug trials in a more ethical manner by providing a more realistic view of the challenges that the host country might face.

The silver lining is that some non-Western countries have recently woken up to this very serious issue and begun to take positive steps. India, which is among the largest host of drug trials outside the western world, has instituted a requirement of video recording of the subject’s consent (Kulkarni et al. 2014). In addition, the government has instituted more stringent compensation guidelines in case of physical harm or death of trial subjects. This has significantly reduced the number of trials conducted in India since 2010-2013-time period.

The case of China, on the other hand, is that of extremes. In 2016, the Chinese Food and Drug Administration found out that as many as 80% of drug trials results were fabricated following which, the regulatory authority came down heavily on
such practices (MacDonald 2016). It reduced the approval times from 12-18 months to a period of 60 days, not to mention the imposition of hefty fines and penalties for violation. Nonetheless, as of June 2016, China ranked 13th in world in terms of drug trial hotbeds.

**Implications for Business Marketing Practice**

In a clinical trial conducted in Guatemala in 1946-48 and supported by the US Public Health Service, patients and inmates were intentionally infected (Wechsler 2011). While such blatant misuse and lack of protocol was not very uncommon in the past, it remains to be seen how far the situation has improved in non-Western countries. Recent trends in outsourcing of drug trials suggest that India, Russia/Eastern Europe and China top the charts. While this is a positive trend from the perspective of global marketing, as academics, we must weigh such ‘advancements’ against increasing scrutiny whether desired participants are being provided complete information regarding the rigors and potential risks of participation.

This is where the author believes the current research fills a notable void. Citing glaring examples and statistics on marketing ethics violation and basing his research on the Theory of Reasoned Action, the author draws the readers’ attention towards the role that marketing ethics and communication loopholes play in the medical field.

Future researchers can also learn from current study and devise better marketing strategies where the interests of both parties can be preserved. An interesting aside of the study is that it encourages new debate about the benefits of global marketing. Thanks to the mobility of expertise and of intellectual capital, scientific research can have a lasting impact on remote locations. This trend has been further boosted by availability of speedy and cheap Internet connectivity.

One obvious limitation of the study, on the other hand, is gathering current data from regions where drug trials are most popular. Given the reluctance of study participants to either share their concerns with researchers or simply failure to recognize the potential harm that can be caused to themselves are reasons for serious consideration.

**Conclusion**

As long as humankind exists, there will be diseases, and as long as there are diseases, there will be a need to test drugs to bring out a cure for the disease. We are skilled at formulating smart alternatives whenever we face challenges. That is how the practice of outsourcing drug trials came into being. We reviewed its history, the advantages and its shortcomings. But an unbiased review leads is to conclude that the advantages easily outweigh the challenges, especially because the challenges can be overcome with prudent measures that drug testing companies can undertake. As such, the author believes that one major contribution
of this discussion is the ability to bring awareness of this issue within the medical and patient communities.

References


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