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Mariam Fatima

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# MANUFACTURING BLOOD DRUGS

Mariam Fatima

**Abstract:** Developing countries are hotspots for research and development of new drugs. In recent years, Western pharmaceutical companies have increasingly establish drug testing centers in countries such as India and Africa where the poor natives are in desperate need of medical care and the local doctors have started to rely on the high salaries paid to them for conducting clinical trials. If the clinical trials are conducted in the U.S., authorized government agencies monitor the activities taking place at domestic clinical trial centers. However, overseas clinical trials are monitored by the local government and have to follow less stringent regulations of the local countries. Although U.S. government officials can inspect these overseas testing centers, the inspections almost never take place because of insufficient funding for the inspections. This paper highlights the unethical treatment of research test subjects in developing countries and proposes that the FDA should be authorized to perform remove video surveillance of research testing centers in the U.S. as well as overseas.

## INTRODUCTION

“There’s an app for that,” is the phrase used by the innovative smart phone application developers’ who advertise their new applications to the savvy smart-phone users. Borrowing from the same concept, it would be apt for the multi-million dollar pharmaceutical giants to boast, “there’s a pill for that.” From a simple common cold to more fatal diseases, there is a pill for all. Leaving behind the days when conniving charlatans took advantage of the naïve consumers by passing off low-grade and falsely-labeled products in the name of medicine, today, our society comprises of FDA regulated drugs, most of which go through a rigorous test in order to be determined safe for consumer use. Because these drugs need to be tested on human subjects before they are approved and sold in the marketplace, the demand of human test subjects has increased with the development and production of new drugs. However, it is not always easy to find a large number of test subjects in America because of well-publicized allegations of the failures of drug companies to warn patients of side effects associated with the drug.<sup>1</sup>

In contrast, pharmaceutical companies have an easier time recruiting human test subjects in foreign countries. For instance, India, a country that is nicknamed the “guinea pig of the world” offers a large number of clinical test subjects.<sup>2</sup> This large turnout is because the volunteers who are poor, or in poor health, are willing to gain access to healthcare by

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<sup>1</sup> Yevgenia Shtilman, *Pharmaceutical Drug Testing in the Former Soviet Union: Contract Research Organizations As Broker-Dealers in an Emerging Testing Ground for America's Big Pharma*, 29 B.C. Third World L.J. 426 (2009) citing Marcia Angell, *The Truth About the Drug Companies*, N.Y. REV. OF BOOKS, July 15, 2004 at 52

<sup>2</sup> Jennifer Kahn, *India: A Nation of Guinea Pigs*, Wired Magazine, Mar. 1, 2006, at 142 (the article describes India as “global hot spot” for foreign pharmaceutical companies' drug trials and also describes how poor Indians volunteer for clinical trials without any information about the adverse effects of the drug).

participating in risky trials.<sup>3</sup> The average cost of recruiting patients is 40% of the trial's budget, making it the most expensive part of drug development.<sup>4</sup> It is evident that the shift of clinical testing to developing countries is largely driven by economics because poorer countries allow the drug to be approved faster and the trials are also cheaper.<sup>5</sup> Secondly, citizens of developing countries are attractive targets for these clinical drug trials because they usually lack information about the reputations of the drug companies, and don't have the same degree of access to their countries' courts.<sup>6</sup> In addition, clinical testing on human subjects in foreign countries makes it easier for the drug manufacturers to satisfy the FDA's New Drug Application.<sup>7</sup> Furthermore, because the pharmaceutical companies test their new investigational drugs on native populations of foreign countries, they are far from the regulations and reaches of the FDA, because the FDA's limited financial capacity does not allow on site inspection of clinical testing centers, especially those that are located in foreign countries. While FDA rules must be satisfied for any drug approval in the U.S., the agency's oversight of distant trials is tenuous at best.<sup>8</sup> Because of this oversight in regulation, the American consumers are sold "blood drugs," which are drugs that reach the American homes at the cost of human lives and liberties due to foreign clinical

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<sup>3</sup> Abraham Lustgarten, *Drug Testing Goes Offshore*, FORTUNE, Aug. 8.2005, at 67, 69-70

<sup>4</sup> *Id.*

<sup>5</sup> *Id.*

<sup>6</sup> Shtilman, *Supra* note 1, at 427.

<sup>7</sup> FDA is committed to protecting the participants of clinical trials, as well as helping to ensure that reliable information is provided to those interested in participating. FDA requires that potential participants give their informed consent before testing begins. Informed consent requires that the participants be given appropriate information about the study to enable them to decide whether to enroll in the clinical trial. FDA often provides extensive technical input to researchers conducting clinical trials, which may help them design better trials that can characterize effects of a new product more efficiently, while reducing risks to those participating in the trials. In addition, the clinical trial team includes doctors and nurses, as well as other health care professionals. In contrast, many developing nations do not have an effective regulatory or effective infrastructure and trial subjects are at risk of severe exploitation and harm with little chance of compensation.

<http://www.fda.gov/forconsumers/consumerupdates/ucm134723.htm>;

<sup>8</sup> Samantha Evans, *The Globalization of Drug Testing: Enforcing Informed Consent Through the Alien Tort Claims Act*, 19 Temp. Int'l & Comp. L.J. 477, 479 (2005).

participants being deprived of informed consent. This lack of informed consent proves to be disabling and deadly for the human test subjects who are unaware of the adverse effects of a potentially new and dangerous drug that is tested on infants, children and adults.

Other scholars have suggested allowing the victims of unethical drug testing a cause of action by demonstrating the violation of one or more principals of the Nuremberg Code<sup>9</sup>, and requiring Congress to enact a mechanism of criminal sanctions to deter human subject abusers. Unfortunately, both suggestions present solutions that will almost be unavailable to the mostly poor and illiterate human test subjects of developing countries who will neither have the resources nor the money to file an action against the wealthy pharmaceutical companies that are equipped with some of the best defense attorneys in the U.S. Therefore, in order to protect research test subjects from unethical treatment at these research test centers around the world, the FDA should require drug manufacturers to install video cameras at all of their clinical testing centers, whether it be domestic or international. This solution is better than the other solutions that have been presented because this requires the pharmaceutical giants, not the poor and abused trial subjects, to take action to protect the test subjects. In order to explain this solution more in depth, this paper will discuss: (I) the Legislative history of drug regulation; (II) How the FDA Approves New Drugs; (III) Ethical Concerns About Treatment of Test Subjects (IV) International Regulations Regarding Treatment of Test Subjects; (V) The Solution; and (VI) Conclusion.

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<sup>9</sup> Shtilman, *Supra* note 1, at 452.

## I. LEGISLATIVE HISTORY OF DRUG REGULATION

Congress passed the Food and Drug Act in 1906.<sup>10</sup> In 1938 Congress passed the Federal Food, Drug and Cosmetic Act (FFDCA), which required that drugs be proven safe before they could be sold in interstate commerce.<sup>11</sup> Later, in 1962, Congress passed the Kefauver-Harris Drug Amendments to the FFDCA.<sup>12</sup> The Kefauver Harris Drug Amendments required that drugs be proven effective as well.<sup>13</sup> Today, for a drug to be approved under the FFDCA, the FDA has the responsibility of finding “substantial evidence of effectiveness.”<sup>14</sup> The statute states that substantial evidence consists of adequate and well-controlled investigations, including clinical investigations by experts who are qualified by scientific training and experience to evaluate the effectiveness of a new investigational drug.<sup>15</sup> Therefore, in order to protect the safety of consumers, the legislature has amended the FFDCA and given authority to the FDA to find that a drug is safe and effective through thorough investigations and evaluations by experts.<sup>16</sup> The

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<sup>10</sup> Federal Food and Drug Act of 1906 (F&DA), P.L. 59-384, 1906

<sup>11</sup> Federal Food, Drug and Cosmetic Act (FFDCA), P.L. 75-717, 1938.

<sup>12</sup> Kefauver-Harris Drug Amendments to the FFDCA, P.L. 87-781, 1962. (50 Years: The Kefauver-Harris Amendments. [www.fda.gov/Drugs/NewsEvents/ucm320924.htm](http://www.fda.gov/Drugs/NewsEvents/ucm320924.htm). The Kefauver-Harris drug amendments, which have ensured prescription drug effectiveness and safety for 50 years. *Id.* But the legislation may not have been proposed if it had not been for the persistence of an FDA medical officer, and two U.S. congressmen. *Id.* The FDA medical officer reviewed an application for thalidomide, a widely prescribed drug for morning sickness during pregnancy in Canadian, African, and European countries. *Id.* Upon persistent inquiry and review, it was revealed that thalidomide was connected to severe birth defects and thousands of children in Europe were born with missing, shortened, or flipper-like arms and legs. *Id.* When the Washington Post reported about FDA’s role in averting the thalidomide tragedy in the United States, and the Kefauver-Harris Amendments to FDCA gave FDA weight to demand that drug makers prove their products were safe and effective before receiving approval to market them in the United States. *Id.*

<sup>13</sup> *Id.*

<sup>14</sup> 21 U.S.C. § 355(d).

<sup>15</sup> *Id.*

<sup>16</sup> *Id.*

legislature also requires manufactures to obtain FDA approval prior to marketing a prescription drug in the United States.<sup>17</sup>

## II. HOW THE FDA APPROVES NEW DRUGS

The drug approval process begins before the FDA gets involved. During a new drug's early preclinical development, the sponsor (usually the manufacturer or potential marketer) has the responsibility of determining whether the product they are seeking to manufacture and market is reasonably safe for initial testing in humans.<sup>18</sup> When a product is identified as reasonably safe for further testing, the sponsor then focuses on collecting the data and information necessary to establish that the product will not expose humans to unreasonable risks when used in limited, early-stage clinical studies.<sup>19</sup> This is usually established through testing on animals.<sup>20</sup> FDA's role in the development of a new drug begins after the drug's sponsor has screened the new molecule for pharmacological activity and acute toxicity potential in animals and wants to test its diagnostic or therapeutic potential in humans.<sup>21</sup> At that point, the molecule changes in legal status under the Federal Food, Drug, and Cosmetic Act and becomes a new drug subject to specific requirements of the drug regulatory system.<sup>22</sup> There are four steps in the approval of new drugs for marketing in the United States.

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<sup>17</sup> FDCA, § 503(b)(1)

<sup>18</sup> FDA, "Approval and Development Process (Drugs)": <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalsApplications/InvestigationalNewDrugINDApplication/default.htm>; CRS Report R41705, *The National Institutes of Health (NIH): Organization, Funding, and Congressional Issues*, by Judith A. Johnson and Pamela W. Smith, provides that basic research is done in labs while clinical research involves a large amount of volunteers to test the new drug.

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

<sup>21</sup> *Id.*

<sup>22</sup> *Id.*

## **A. Investigational New Drug (IND) Application**

A manufacturer seeking to market a new drug must file an IND application with the FDA before clinical testing.<sup>23</sup> The IND must include information about preclinical data to assess whether the product is reasonably safe for clinical testing, which usually includes animal and pharmacology studies.<sup>24</sup> The IND must also include information about the composition and manufacturer of a drug in order for the FDA to determine whether the company can adequately produce and supply the drug consistently.<sup>25</sup> Lastly, the IND application must also contain detailed protocols for proposed clinical studies to assess whether the clinical trials could be subject to harm and that risk of harm will be explained to the clinical trial participants.<sup>26</sup> Once the IND is submitted, the sponsor must wait 30 calendar days before initiating any clinical trials.<sup>27</sup> During this time, FDA has an opportunity to review the IND for safety to assure that research subjects will not be subjected to unreasonable risk.<sup>28</sup>

## **B. Clinical Trials**

Clinical trials, also known as clinical studies, test potential new drugs in human volunteers to see whether they should be approved for wider use in the general population.<sup>29</sup> Clinical trials are done at hospitals and research centers around the country, and they are divided into three phases: Phase 1, phase 2, and phase 3.<sup>30</sup> Phase 1 trials usually involve a small number of healthy volunteers to try to determine dosing, how a drug is metabolized and excreted, and identify

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<sup>23</sup> FDA, “Investigational New Drug Application” (IND): <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalsApplications.htm>

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> FDA, “Inside Clinical Trials: Testing Medical Products in People; What Is a Clinical Trial?” Information for Consumers, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143531.htm>.

<sup>30</sup> *Id.*

acute side effects.<sup>31</sup> Phase 2 trials include more participants (about 100-300) who have the condition that the investigational new drug potentially could treat and researchers gather safety data and preliminary evidence of the drug's efficacy and develop research methods for future trials involving this new drug.<sup>32</sup> The investigational new drug only moves on to phase 3 if the phase 2 trials are indicative of the drug being effective and the risks are considered acceptable.<sup>33</sup> In phase 3 trials, the drug is studied in a larger number of people (approximately 1,000-3,000) infected with the disease that the drug seeks to cure.<sup>34</sup> This phase continues to test the product's effectiveness and monitors side effects.<sup>35</sup> The rationale behind this further testing is that as an increasing number of participants are tested over increased spans of time, the less common side effects are more likely to be revealed.<sup>36</sup>

### C. New Drug Application

After the clinical trials are completed, the manufacturer must then submit a New Drug Application (NDA) to FDA's Center for Drug Evaluation and Research (CDER).<sup>37</sup> The NDA contains clinical trial results, information about the manufacturing process and facilities, and a

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<sup>31</sup> Phase 2 and Phase 3 clinical trials generally have a control standard. What that means is that one group of volunteers are given the experimental new drug or treatment, while the control group is given either a standard treatment for the illness or an inactive pill has no treatment value (placebo). This control group provides a basis for comparing the effects of the investigation drugs as compared to the placebo or standard drug. *Id.*

<sup>32</sup> *Id.*

<sup>33</sup> *Id.*

<sup>34</sup> *Id.*

<sup>35</sup> Some treatments being studied can have unpleasant, or even serious, side effects. Often these are temporary and end when the treatment is stopped. Others, however, can be permanent. Some side effects appear during treatment, and others may not show up until after the study is over. The risks depend on the treatment being studied and the health of the people participating in the trial. *Id.*

<sup>36</sup> *Id.* Note: Sometimes, Phase 4 trials are conducted after a product is already approved and on the market to find out more about the treatment's long-term risks, benefits, and optimal use, or to test the product in different populations of people, such as children. *Id.*

<sup>37</sup> New Drug Application (NDA)

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalsApplications/NewDrugApplicationNDA/default.htm>

description of the potential new product.<sup>38</sup> Since 1938, the FDA has required that each drug have an approved NDA before it can be marketed in the United States.<sup>39</sup> As the NDA is the medium through which drug sponsors petition the FDA to approve a new drug, the informational data gathered through the animal studies and human clinical trials become part of the NDA.<sup>40</sup> The goals of the NDA are to provide enough information to permit FDA reviewer to decide whether the drug is safe and effective for its proposed use and the benefits of the new drug outweighs the risks.<sup>41</sup> In addition, the reviewer also determines whether the labeling and packaging methods are appropriate and whether the methods used to manufacture the drugs are adequate to preserve the drug's quality, purity, and identity.<sup>42</sup>

In sum, for a new drug to be approved, the FDA must find “substantial evidence” of effectiveness from the data of adequate and well-controlled clinical trials.<sup>43</sup> Because the approval process requires the data from clinical studies, the potential new drugs have to be tested on humans in clinics before they are marketed in the United States.<sup>44</sup>

### **III. ETHICAL CONCERNS ABOUT TREATMENT OF TEST SUBJECTS**

Due to the large number of participants required for testing investigational new drugs, there is an obvious need for a large number of volunteers who will participate in the clinical testing of the investigational new drug. Western medicine has relied on human and animal experimentation since ancient times. It was by dissecting the bodies of criminals and the poor,

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<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

<sup>40</sup> *Id.*

<sup>41</sup> *Id.*

<sup>42</sup> *Id.*

<sup>43</sup> 21 U.S.C. § 355(d)

<sup>44</sup> *Id.*

for example, that Greek physicians discovered the nervous system in 300 B.C.<sup>45</sup> But it was only after the rigorous experimental design called the controlled clinical trial emerged in the 1940s and was codified into U.S. law in 1962, that the global hunt for experimental bodies began in earnest.<sup>46</sup> To their chagrin, pharmaceutical manufacturers have found Americans increasingly hesitant to participate in drug experiments because of skepticism about their safety.<sup>47</sup> This reluctant attitude of Americans is due to the ill reputation of pharmaceutical companies who are often maligned for putting profits before patients.<sup>48</sup> The well-publicized allegations of failures to warn of an investigational drug's harmful side effects is one of the many reasons that can be attributed to the negative image of the pharmaceutical companies.<sup>49</sup> Today, industry investigators can count on failing to find sufficient numbers of willing test subjects on time in four out five of their clinical trials.<sup>50</sup> Along with shortage of test subjects in America, pharmaceutical companies have another reason to be worried. Everyday a new drug remains locked in development, it bleeds companies of up to 1 million dollars in potential sales income.<sup>51</sup> This loss of money puts pressure on the pharmaceutical companies to put new drugs to the market at the earliest. Because of these concerns, pharmaceutical companies are reaching out to Contract Research Organizations (CROs).<sup>52</sup> CROs are independent contractors who perform clinical trials more

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<sup>45</sup> ROY PORTER, *THE GREATEST BENEFIT TO MANKIND: A MEDICAL HISTORY OF HUMANITY* 67 (1997).

<sup>46</sup> SONIA SHAH, *THE BODY HUNTERS: TESTING NEW DRUGS ON THE WORLD'S POOREST PATIENTS* 6, (2006).

<sup>47</sup> Shtilman, *Supra* note 1, at 432

<sup>48</sup> *Id.*

<sup>49</sup> *Id.* citing, Joel Slawotski, *International Product Liability Claims Under the Alien Tort Claims Act* 16 Tul. J. Int'l & Comp. L. 157, 168 (2007).

<sup>50</sup> SHAH, *Supra* note 46, at 5

<sup>51</sup> *Id.* citing Stan Barnard, "The Drug Drought: Primary Causes, Promising Solutions," Pharmaceutical Executive, November 2002, 7.

<sup>52</sup> Mary Pat Flaherty et al., *The Body Hunters: Testing Tidal Wave Hits Overseas*, Wash. Post, Dec. 18, 2000, at A1

quickly and are more aggressive in finding patients for the clinical trials.<sup>53</sup> CROs provide local expertise and recruit doctors who perform the clinical trials.<sup>54</sup> Many of these trials are being conducted in developing countries, including the rapidly evolving countries of Eastern Europe and the Russian Federation.<sup>55</sup> This swift move to foreign countries motivated by the pharmaceutical companies' desire to save money and find recruits more easily.<sup>56</sup> A pharmaceutical executive reported that a medical center in India charges approximately \$1500 to \$ 2000 per case report, which is less than one tenth the cost of second-tier center in the United States.<sup>57</sup> Also, there is a large pool of research participants in countries such and India and China, which helps accelerate recruitment.<sup>58</sup> In addition, foreign clinical trials are more attractive to the pharmaceutical companies because the regulatory barriers in those countries are less strict.<sup>59</sup>

There are also benefits of conducting trials in developing countries that include fostering positive relationships around clinical investigators globally and answering questions about the safety and efficacy of drugs that are of interest throughout the world.<sup>60</sup> Although there are a few benefits, the major concern of testing drugs overseas is the unethical treatment of human test subjects across the globe. Dr. Arthur Caplan, director of the Center for Bioethics at University of Pennsylvania's Perelman School of Medicine voiced some of these ethical concerns in his interview with PBS's News Hour. Dr. Caplan explained that along with it being cheaper to recruit participants for clinical research in developing countries, the citizens of these target poor

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<sup>53</sup> Emilie Reymond, CRO Supremacy in Clinical Research Raises Concerns: <http://www.outsourcing-pharma.com/Clinical-Development/CRO-supremacy-in-clinical-research-raises-concerns>.

<sup>54</sup> SHAH, *Supra* note 3, at 437.

<sup>55</sup> Ethical and Scientific Implications of Globalization of Clinical Research: [www.nejm.org/doi/full/10.1056/NEWJMs0803929](http://www.nejm.org/doi/full/10.1056/NEWJMs0803929)

<sup>56</sup> *Id.*

<sup>57</sup> *Id.*

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

<sup>60</sup> *Id.*

countries are not taking other medications that could interfere with the data in the new drug.<sup>61</sup> This is due to the population in these target countries being poor and generally not being able to afford medication for any ailments they might suffer.<sup>62</sup> Furthermore, there are ethical concerns about informed consent. Dr. Caplan expressed concern over whether the participants in these poor countries actually give informed consent or do they just sign up for anything because they trust doctors or they are in desperate need of money or medicine?<sup>63</sup> Another concern is the reliability of data from these poor nations. Data might not be reliable because the people might not take the pills as prescribed or they might be getting other side effects they might not report.<sup>64</sup>

These concerns come to life in foreign clinical centers in poor countries with large populations who cannot afford to go to a doctor or get proper medication. For instance, India, the most populous country in the world, has a large and diverse population.<sup>65</sup> India is a hotspot for clinical testing because it has an underprivileged and drug-naïve patient population who embrace the chance to participate in a clinical trial as a healthcare-windfall.<sup>66</sup> India's inadequate healthcare system, low costs for clinical trials, and corruption make India an attractive destination for clinical trials where pharmaceutical companies exploit the weaknesses of the poor citizen of these countries.<sup>67</sup> In addition, proper trial procedures may not be followed at these clinical testing centers. An example of such concerns came to life in the poor state of Madhya Pradesh in India. There, to put an end to the unethical treatment of the test subjects, local health

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<sup>61</sup> Miller, Talea. 'Explosive' Growth in Foreign Drug Testing Raises Ethical Questions.' [www.pbs.org/newshour/rundown/2011/08/sending-us-drug-research.htm](http://www.pbs.org/newshour/rundown/2011/08/sending-us-drug-research.htm)

<sup>62</sup> *Id.*

<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

<sup>65</sup> Samiran Nundy & Chandra m. Gulhati, *A New Colonialism Conducting Clinical Trials in India*, 325. *Eng. J. Med.* 1633, 1634 (2005).

<sup>66</sup> Shtilman, *Supra* note 1, at 440, citing, James Cekola, *Outsourcing Drug Investigations to India: A Comment on U.S., Indian and International Regulation of Clinical Trials in Cross-Border Pharmaceutical Research*, 28 *NW. J. INT'L L. & BUS.* 125, 126 (2007).

<sup>67</sup> *Id.*

activists filed formal complaints with the state and national human rights commissions, and the government controller.<sup>68</sup> As a result, the Indian government investigated practices at a certain public hospital where 73 clinical trials were performed on 3300 patients, including 1833 children, some of whom reported adverse affects and even died.<sup>69</sup> The investigation revealed that volunteers at that hospital did not give informed consent because the details were in English, among other shortcomings.<sup>70</sup> A World Health Organization representative to India acknowledged that there were concerns that vulnerable populations were exploited and informed consent processes were not followed in Madhya Pradesh.<sup>71</sup> Such exploitations occurred because doctors were paid heavily and given other benefits such as paid trips abroad to attend conferences.<sup>72</sup> These financial incentives motivated the doctors to cut corners and not follow the rules.<sup>73</sup> Another example of vulnerable populations being exploited at the hands of giant pharmaceutical companies is demonstrated in the case of *Abdullahi v. Pfizer, Inc.*<sup>74</sup> In that case, Pfizer, the world's largest pharmaceutical company conducted clinical trials in Nigeria to test its new antibiotic Trovan.<sup>75</sup> In the process of developing this new antibiotic, Pfizer seized the opportunity to perform clinical testing of this investigation new drug on a Nigerian population that had just suffered epidemics of meningitis, measles, and cholera.<sup>76</sup> Pfizer set up a medical treatment center in Nigeria.<sup>77</sup> Pfizer's new drug had only been tested on one child before the

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<sup>68</sup> World Report. Regulation Failing To Keep Up With India's Trials Boom. [www.thelancet.com](http://www.thelancet.com)

<sup>69</sup> *Id.*

<sup>70</sup> *Id.*

<sup>71</sup> *Id.*

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

<sup>74</sup> *Abdullahi v. Pfizer, Inc.*, No. 01 Civ. 8118, 2002 U.S. Dist. LEXIS 17436, at \*2-3 (S.D.N.Y. Sept. 16, 2002)

<sup>75</sup> *Id.* at 2

<sup>76</sup> *Id.*

<sup>77</sup> *Id.*

clinical trial in Nigeria.<sup>78</sup> Animal testing of Trovan had demonstrated that it might lead to side effects in children such as joint disease, abnormal cartilage growth and liver damage.<sup>79</sup> Although Pfizer sought permission from the parents of the children on whom the research would be done, few parents read or spoke English.<sup>80</sup> In addition, it was also alleged that Pfizer did not explain that the proposed treatment was only experimental and the subjects were allowed to refuse it.<sup>81</sup> Pfizer's medical team left Nigeria after the clinical trials and never followed up with the subjects about the complications they might have suffered.<sup>82</sup> As a result of the clinical trials, several Nigerian minor children died and many others suffered paralysis, deafness, and blindness as side effects of Trovan.<sup>83</sup> This case demonstrates that citizens in poor countries, especially those with no medical facilities fall prey to the pharmaceutical companies' clinical trials, mainly because informed consent procedures are not followed.

In contrast, if the clinical trials were conducted in the United States, the subjects would at least have a legal cause of action and standing to file a suit against the pharmaceutical companies for failing to give informed consent or any other wrongs. Most clinical trials are federally regulated with built-in safeguards to protect participants and the Office for Human Research Protections (OHRP) in the Department of Health and Human Services (HHS) leads the department's programs for the protection of human research participants and oversees human protection in HHS-funded research.<sup>84</sup> The FDA has authority over clinical trials for drugs and regulates studies that are HHS-funded (with joint oversight by the FDA and the OHRP), as well

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<sup>78</sup> *Id.*

<sup>79</sup> *Id.*

<sup>80</sup> *Id.*

<sup>81</sup> *Id.*

<sup>82</sup> *Id.*

<sup>83</sup> *Id.*

<sup>84</sup> FDA: <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143531.htm>

as studies that are solely funded by industry or by private parties.<sup>85</sup> Clinical trial procedures are reviewed by institutional review boards (IRBs) and they ensure that appropriate steps are taken to protect the rights and welfare of participants as subjects of research.<sup>86</sup> IRBs also review participant inclusion and exclusion requirements to be sure that appropriate people have been identified as eligible for the trial. Most importantly, the IRBs review the adequacy of the informed consent document to make sure that it includes all the elements required by law, and that it is at an appropriate reading level and understandable to study participants.<sup>87</sup> The informed consent is the most cogent of human subject protection and 21 C.F.R. § 50.25 requires researchers to explain eight factors to volunteers:

- (1) The purpose, extent and procedures of the trial;
- (2) Reasonably foreseeable risks;
- (3) Expected benefits;
- (4) Alternative procedures that may be advantageous to the patient;
- (5) Confidentiality of the trial's records;
- (6) Compensation for injuries;
- (7) A contact point for questions about the research; and
- (8) The voluntary character of participation.<sup>88</sup>

The federal law affords children even greater protections in research.<sup>89</sup> Generally, researchers must obtain parents' consent as well as the child's assent, and any research posing more than a

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<sup>85</sup> *Id.*

<sup>86</sup> *Id.*

<sup>87</sup> *Id.*

<sup>88</sup> 21 C.F.R. § 50.25

<sup>89</sup> 45 C.F.R. § 46.401. See generally Committee on Clinical Res. Involving Child., Inst. of Med. of the Nat'l Acad., *Ethical Conduct of Clinical Research Involving Children* (Marilyn J. Field & Richard E. Behrman eds., 2004)

minimal risk to the child subject must also directly benefit the child.<sup>90</sup> Hence, if Pfizer had conducted the clinical trials of Trovan in America, they would have to follow strict informed consent procedures. In addition, the plaintiffs would be very strongly protected by the federal law, especially the children, and would have a solid cause of action against Pfizer for any misdoings and disabling and life-threatening adverse effects of Trovan.

In addition to providing protection for clinical trial subjects in the United States, the FDA also conducts inspections of clinical trial sites to determine if the clinical investigators are conducting clinical studies in compliance with applicable statutory and regulatory requirements.<sup>91</sup> Clinical investigators who conduct FDA-regulated clinical investigations are required to permit FDA investigators to access, copy, and verify any records or reports made by the clinical investigator with regard to, among other records, the disposition of the investigational product and subjects' case histories.<sup>92</sup> The FDA investigator typically performs this oversight function through on-site inspections designed to document how the study was actually conducted at the clinical investigator's site.<sup>93</sup> The FDA conducts both announced and unannounced inspections of clinical investigator sites, typically under the following circumstances:

1. To verify the accuracy and reliability of data that has been submitted to the agency;
2. As a result of a complaint to the agency about the conduct of the study at a particular investigational site;
3. In response to sponsor concerns;
4. Upon termination of the clinical site;

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<sup>90</sup> *Id.*

<sup>91</sup> FDA: Regulatory Information:

<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126553.pdf>

<sup>92</sup> See 21 CFR 312.62(c)

<sup>93</sup> *Id.*

5. During ongoing clinical trials to provide real-time assessment of the investigator's conduct of the trial and protection of human subjects;

6. At the request of an FDA review division; and

7. Related to certain classes of investigational products that FDA has identified as products of special interest in its current work plan.<sup>94</sup> FDA's authority to inspect clinical testing centers in America also extends to clinical trials abroad.<sup>95</sup> Even if sponsors of clinical trials conducted outside the U.S. are not required to file an IND, sponsors submitting foreign clinical studies not conducted under an IND to FDA must comply with requirements in 21 CFR 312.120.<sup>96</sup> If a clinical investigator conducts a study under an IND outside of the U.S., the clinical investigator is subject to FDA regulations, including applicable provisions in 21 CFR parts 50, 56, and 312.<sup>97</sup> Although the FDA has guidelines for inspections at foreign clinical trials, the Department of Health and Human Services Office of Inspector General (OIG) released a report raising questions about the FDA's capacity to monitor the safety of clinical trials conducted in foreign countries.<sup>98</sup> The report found that eighty percent of approved marketing applications for drugs contained data from foreign clinical trials and over half of the clinical trial subjects were located outside the United States.<sup>99</sup> In addition, the report showed that FDA inspected clinical investigations at 1.2 percent of clinical trial sites for applications approved in the year 2008.<sup>100</sup> Furthermore, the FDA inspected clinical investigators at only 0.7 percent of foreign clinical

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<sup>94</sup> *Supra* note 90

<sup>95</sup> *Id.*

<sup>96</sup> *Id.*

<sup>97</sup> *Id.*

<sup>98</sup> Challenges to FDA's ability to Monitor and Inspect Foreign Clinical Trials.

<https://oig.hhs.gov/oei/reports/oei-01-08-00510.pdf>

<sup>99</sup> *Id.*

<sup>100</sup> *Id.*

sites.<sup>101</sup> Also, the report raised concerns that FDA could have been unaware of some ongoing early-phase clinical trials because sponsors conduct early-phase clinical trials outside the United State without obtaining INDs.<sup>102</sup> One of the reasons that the FDA rarely conducts inspections of foreign clinical sites is time.<sup>103</sup> According to the report, inspectors are generally allowed only 1 week, including travel time to conduct the inspections. Obtaining work visas and translators are also among the challenges faced by the FDA inspectors. Lastly, and most importantly, the FDA does not have sufficient funds to conduct the inspections overseas because inspections are expensive and may not always be cost effective.<sup>104</sup> With inspections costing about \$ 40,000 each and the additional challenges faced above, it really is difficult to physically perform investigations at foreign clinical sites.<sup>105</sup>

The report “highlights a very frightening and appalling situation,” said Representative Rosa DeLauro, Democrat from Connecticut. “By pursuing clinical trials in foreign countries with lower standards and where F.D.A. lacks oversight, the industry is seeking the path of least resistance toward lower costs and higher profits to the detriment of public health.” In addition to the monetary challenges, the agency has also had a very poor record-keeping system that recorded data submissions from drug makers that do not adhere to standardized formats.<sup>106</sup> From example, the F.D.A. was unable to provide Mr. Levinson’s investigators with detailed clinical trial data for 29 out of 129 of the approved applications in 2008.<sup>107</sup> For eight of the applications,

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<sup>101</sup> *Id.*

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

<sup>104</sup> *Id.*

<sup>105</sup> *Id.*

<sup>106</sup> *Id.*

<sup>107</sup> *Id.*

the agency could not locate any part of the application.<sup>108</sup> Daniel R. Levinson, the inspector general the Department of Health and Human Services who composed the report suggested that the agency should switch to an electronic database and demand that drug companies submit their data in an electronic format.<sup>109</sup> He wrote that, “As sponsors increase the number of foreign clinical trials in support of F.D.A. marketing applications, the agency’s current method of using inspections to ensure human subject protections and data validity is becoming increasingly strained.”<sup>110</sup> He also encouraged the FDA to develop more cooperative inspection agreements with foreign governments, inspect more clinical trials in more countries and tell companies to register their clinical trials before administering them.<sup>111</sup>

From a regulatory and an ethical standpoint, the risks associated with outsourcing clinical trials overseas that lack FDA oversight, pose threat to the safety and health of human test subjects.<sup>112</sup> Even though the clinical trials that are managed by the CROs for American pharmaceutical companies are subject to FDA regulations and inspections, these regulations can be circumvented more easily when trials are conducted overseas, exposing participants to health risks as new drugs are “speeded” to the market.<sup>113</sup> To add to the risk factors, governments who wish to attract drug companies to conduct drug trials within their borders have strong incentives to encourage lax national and local oversight of the research.<sup>114</sup> Furthermore, the FDA, pursuant to FDCA, allows companies to submit drugs for FDA approval even if the pharmaceutical

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<sup>108</sup> *Id.*

<sup>109</sup> *Id.*

<sup>110</sup> *Id.*

<sup>111</sup> *Id.*

<sup>112</sup> Shtilman, *Supra* note 1, at 425, citing Ken Gatter, *Fixing Cracks: A Discourse Norm to Repair the Crumbling Regulatory Structure Supporting Clinical Research and Protecting Human Subjects*, 73 UMKC L. Rev. 581, 618 (2005).

<sup>113</sup> *Id.* citing, Robert Gatter, *Conflicts of Interest in International Human Drug Research and the Insufficiency of International Protections*, 32 AM. J. L. & Med. 351, 351 (2006).

<sup>114</sup> *Id.*

company's trial data is based exclusively on the results of clinical trials that were conducted overseas as long as the foreign data is applicable to the U.S.'s medical practice and population, and the studies have been performed by recognizably competent clinical investigators.<sup>115</sup>

Therefore, because the regulatory bodies are often structured to monitor the quality of clinical trial data and the safety of drugs in their domestic markets,<sup>116</sup> the clinical trials abroad are bound by a very lenient FDA regulation. Moreover, other international regulations do not prove to be more help the injured plaintiffs either.

#### **IV. INTERNATIONAL REGULATIONS REGARDING RESEARCH ON HUMAN SUBJECTS**

As mentioned earlier, in *Abdullahi v. Pfizer*, several Nigerian minors died and a number of them suffered from paralysis, deafness, and blindness because of their treatment with Trovan.<sup>117</sup> In that case, many of the effected Nigerian minors and their guardians brought a class action suit against Pfizer.<sup>118</sup> They filed a claim for a violation of the law of nations under the Nuremberg Code (Code), the Declaration of Helsinki (Declaration), and the International Covenant on Civil and Political Rights (ICCPR), but did not win on the basis of either of them.<sup>119</sup> This part of the paper will examine the standards that the plaintiffs in *Abdullahi v. Pfizer* sued under, as well as the guidelines by the World Health Organization (WHO).

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<sup>115</sup> 21 C.F.R. § 314.106(b).

<sup>116</sup> Glickman SW, McHutchison JG, Peterson ED, Cairns CB, Harrington RA, Califf RM, Schulman KA, *Ethical and Scientific Implications of the Globalization of Clinical Research*. NEJM. 2009 Feb 19;360(8):816-2.

<sup>117</sup> *Abdullahi v. Pfizer, Inc.* 77 F. App'x 48, 5 (2d Cir. 2003).

<sup>118</sup> *Id.* at 6.

<sup>119</sup> *Id.*

### **A. The Nuremberg Code**

The Code presents ten principles to determine the boundaries of permissible medical experimentation on human subjects.<sup>120</sup> The Code says that informed consent is absolutely essential and goes on to list other principles that protect the welfare of the research subjects. However, the Code does not contain any language that would require the researchers to abide by it. The Code is a suggestion that can be adopted by countries and made into a mandatory law.

### **B. The Declaration of Helsinki**

The Declaration of Helsinki was issued in 1964 and provides guidance to physicians involved in medical research involving human test subjects.<sup>121</sup> In its principles, the Declaration advises physicians to protect the life, health, privacy and dignity of the human test subjects and use caution when conducting research.<sup>122</sup> In addition, the Declaration requires that informed consent should be documented and witnessed.<sup>123</sup> Furthermore, it also requires a balancing of interests and advises that research should only be conducted if the benefits outweigh the risks.<sup>124</sup> However, like the Nuremberg Code, the Declaration of Helsinki provides guidelines, but not specific rules.

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<sup>120</sup> <http://ori.dhhs.gov/education/products/RCRintro/c03/b1c3.html>

<sup>121</sup> The Declaration of Helsinki. <http://www.fda.gov/ohrms/dockets/dockets/06d0331/06D-0331-EC20-Attach-1.pdf>

<sup>122</sup> *Id.*

<sup>123</sup> *Id.*

<sup>124</sup> *Id.*

### **C. International Covenant on Civil and Political Rights**

The ICCPR is the only legally binding international treaty concerning human experimentation.<sup>125</sup> The ICCPR comprises all of the traditional human rights as they are known from historic documents such as the First Ten Amendments to the Constitution of the United States (1789/1791) and the French *Déclaration des droits de l'homme et du citoyen* (1789).<sup>126</sup> Specifically, Article 7 requires informed consent, and prohibits torture and cruel or inhuman treatment or punishment.<sup>127</sup>

### **D. WHO-CIOMS Guidelines**

In 1982, the World Health Organization and Council for International Organization of Medical Sciences published the *Proposed International Ethical Guidelines for Biomedical Research Involving Human Subjects* (“Guidelines”).<sup>128</sup> The Guidelines were intended to serve as an example to nations who wanted to draft legislation on human research.<sup>129</sup> Specifically, guideline 4 requires individual informed consent for all biomedical research involving humans and the commentary to this guideline further explains what should be done with respect to the process, language, comprehension, documentation, and cultural considerations involved with informed consent.<sup>130</sup> Guidelines 5, 6, and 7 also relate to informed consent and discuss essential information for prospective research subjects, obligations of sponsors and investigators, and inducement to participate and propose a balancing of interests, favoring benefits over risks.<sup>131</sup>

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<sup>125</sup> Kristen Farrell, *Human Experimentation in Developing Countries: Improving International Practices by Identifying Vulnerable Populations and Allocating Fair Benefits*, 9 J. Health Care L. & Pol’y 136 (2006).

<sup>126</sup> International Covenant on Civil and Political Rights: <http://untreaty.un.org/cod/avl/ha/iccpr.html>

<sup>127</sup> *Id.*

<sup>128</sup> Farrell, *Supra* note 118, at 144

<sup>129</sup> *Id.*

<sup>130</sup> *Id.* at 145

<sup>131</sup> *Id.*

Although WHO advocates that the nations adopt its guidelines regarding research on human test subjects, the advisory guidelines have not proven sufficient to prevent violations and abuses in clinical research taking place in developing countries.<sup>132</sup>

#### **IV. THE SOLUTION**

As an increasing number of test subjects are enrolled in clinical drug trials all over the globe, researchers and doctors, many of whom are corrupt, are reporting failures in compliance with ethical standards because there is no positive law that governs ethical standards abroad.<sup>133</sup> Today, the greatest obstacle to ensuring health and safety of participants in overseas trials is largely due to the lack of regulation over the independent contractors that work for Western pharmaceutical manufacturers.<sup>134</sup> In addition, the FDA does not demand compliance with the U.S law where international test subjects are concerned.<sup>135</sup> The FDA advises applicants that “if the drug is manufactured outside of the U.S. or its territories, the trials sites are all outside the U.S., and the trial is not being conducted under an [investigational new drug application], then it would not be considered to be subject to section 505 of the [Food, Drug, and Cosmetic] Act or section 351 of the [Public Health Service] Act, and the clinical investigation would not be an “applicable drug clinical trials.””<sup>136</sup> In order to protect the human test subjects who are located outside the U.S. (who are not protected by the FDA), there have been proposals to stop the unethical treatment of human test subjects in international clinical trial investigations. One

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<sup>132</sup> Shtilman, *Supra* note 1, at 439.

<sup>133</sup> *Id.*

<sup>134</sup> *Supra* note 121 at 205.

<sup>135</sup> *Id.*; Nat’l. Inst. of Health, Elaboration of Definitions of Responsible Party and Applicable Clinical Trial, <http://prsinfo.clinialtrials.gov/ElaborationsOnDefinitions.pdf>.

<sup>136</sup> *Id.*

proposal seeks to allow the victims a cause of action by demonstrating the violation of one or more principles of the Nuremberg Code, a cause of action that would allow the victim to hold accountable the researcher conducting the drug trial as well as the pharmaceutical company sponsoring the trial and the CRO overseeing the researcher's activities.<sup>137</sup> However, this solution seems unviable because, although allowing a cause of action under the Nuremberg Code might give the injured plaintiffs some relief, this proposal is unlikely to stop the testing centers from continuing with their unethical practice of exploiting human subjects for several reasons. Firstly, the test subjects may not have enough knowledge about the laws and may never find out that there is any such cause of action that can grant them relief. Secondly, many of the test subjects in poor and populous countries such as India volunteer themselves at these research centers because of the need for money and medicine.<sup>138</sup> It is highly unlikely that such poor individuals will have the money or the resources to sue the big pharmaceutical companies. Thirdly, the corruption and the greed of local doctors will trump ethical treatment of human test subjects as many of the physicians conducting research for the pharmaceutical companies as well as the research institutions where the research takes place, have a financial interest in the studies because they are paid heavy sums for conducting and approving the trials.<sup>139</sup> Lastly, the cost developing new drugs in the United States has grown to near one billion dollars that include conducting preliminary research, clinical research on human test subjects, and fulfilling FDA requirements.<sup>140</sup> By transferring costly trials to countries with fewer regulatory hurdles<sup>141</sup>, a

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<sup>137</sup> *Id.* at 452.

<sup>138</sup> Kahn, *Supra* note 2.

<sup>139</sup> *Supra* note 67; Shtilman, *Supra* note 1, at 434, citing Robert Gatter, Conflicts of Interest in International Human Drug Research and the Insufficiency of International Protections, 32 *Am. J.L. Med.* 351, 351 (2006).

<sup>140</sup> Dennis M. Coyne, *International Pharmaceutical Mistrials: Existing Law for the Protection of Foreign Human Subjects and A Proposal for Reform*, 29 *B.U. Int'l L.J.* 427, 428 (2011)

pharmaceutical company can gain significant profits, which, when compared with the monetary damages they would have to pay for a claims by a few injured plaintiffs, might be significantly higher. Therefore, it might just be easier and less costly for the pharmaceutical companies to pay the plaintiffs their damages instead of delaying the testing of their investigational new drug, and thereby losing profits.

Rather than requiring the poor and injured plaintiffs in corrupt countries to take action to get any sort of monetary relief, a better solution would be to require the rich pharmaceutical companies to take action to ensure ethical treatment of human test subjects. Daniel R. Levinson, the inspector general the DHHS suggested that the FDA agency should switch to an electronic database and demand that drug companies submit their data in an electronic format.<sup>142</sup> Although his suggestion would not solve the problem of unethical treatment of human test subjects, it does suggest that the FDA switch to modern methods of data keeping and inspecting testing centers. Therefore, in order to solve the problem of unethical testing of human test subjects, my solution is that the FDA should be given authority to require video cameras at all domestic and foreign clinical research and testing centers. These cameras should be streaming live surveillance videos over the internet, so that testing can be recorded and monitored in real-time. One benefit of this would be that all activities of the clinical center would be recorded, if not constantly monitored by someone. This constant video monitoring would produce many beneficial outcomes. Perhaps these benefits can best be explained by comparing them to the benefits of video surveillance used in other highly reputed institutions. One example where video surveillance is used to ensure that ethical guidelines are being followed can be found at Seton Hall Law School, located in Newark, New Jersey. A recent mass email sent out to the law students during final exams period said that

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<sup>141</sup> *Id.*

<sup>142</sup> *Supra* note 128.

there would be no exam proctors in some rooms where the exams would be administered.<sup>143</sup> Instead, the school would use a virtual proctoring system that allows video and audio transmission and live communication between the students and the Registrar's office.<sup>144</sup> The emails further explained that the school opted to use the virtual proctoring system to ensure the academic integrity and allow students to alert the Registrar's Office in case of a problem during the exam without leaving the exam room.<sup>145</sup> In addition, the staff at the law school would also be able to remotely notify students when their exam time had ended.<sup>146</sup> Similarly, mandatory video surveillance at research testing centers will ensure the ethical treatment of research test subjects around the globe. Accordingly, the FDA should also be given authority to require that informed consent be given in front of the video cameras. This will make certain that informed consent is actually given, and it is given in the native language of the test subjects, and the test subjects only give consent after they are informed that the drug is not a cure but only an experimental drug that can possibly have adverse effects, sometimes even fatal. In a step ahead of the FDA, hospitals have begun their move towards remote video surveillance in the hospitals.

Many medical facilities and hospitals have already seen the benefits of video cameras in the workplace. A hospital in Alaska has implemented an upgrade to its CCU (Critical Care Unit), calling it an eICU (electronic Intensive Care Unit), and installed super high tech cameras on one side of seven rooms in the CCU.<sup>147</sup> Below the camera, there is a monitor and a big red alert push

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<sup>143</sup> Dean St-Romaine sent an email regarding exam procedures to the student. The email explaining that there were proctors for the students taking their exams in rooms 70-75 and the students would be monitored remotely.

<sup>144</sup> *Id.*

<sup>145</sup> *Id.*

<sup>146</sup> *Id.*

<sup>147</sup> <http://www.alaskajournal.com/Alaska-Journal-of-Commerce/AJOC-February-19-2012/Juneau-hospital-uses-video-to-keep-patients-local.htm>.

button that a nurse can push at any time.<sup>148</sup> Once the button is pushed, either a certified critical care nurse or physician from Providence Alaska Medical Center appears on the monitor.<sup>149</sup> The physician is available from 9 p.m. to 7 a.m., while other health care providers trained in intensive care are available 24 hours a day, seven days a week.<sup>150</sup> In a demonstration of how this high tech system works, the CCU director pushed the red button.<sup>151</sup> Almost instantly, a person appeared on the video screen and rotated the angle of the camera to see the people in the room.<sup>152</sup> Next, to show off of the superior features of the camera, a piece of paper was placed on the pillow of the bed across the room from the camera.<sup>153</sup> The person on the screen was able to read the contents of the paper.<sup>154</sup> The rooms at the hospital are also equipped with microphones so that any person from the hospital can communicate with anyone in the room.<sup>155</sup> In another instance, at another hospital in Florida, a doctor monitored a heavily bleeding patient through the video camera while working from a command center in a nearby office building.<sup>156</sup> The same doctor was remotely monitoring her and other patients in six intensive-care units in three different hospitals.<sup>157</sup> The monitoring system uses two-way video cameras, through which, the doctors in the command center can identify warning signs that a patient is taking a turn for the worse, advise bedside staff on giving medications and treatments, and point out potential errors or oversights.<sup>158</sup>

Accordingly, keeping the benefits of these hospitals receive from remote video

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<sup>148</sup> *Id.*

<sup>149</sup> *Id.*

<sup>150</sup> *Id.*

<sup>151</sup> *Id.*

<sup>152</sup> *Id.*

<sup>153</sup> *Id.*

<sup>154</sup> *Id.*

<sup>155</sup> *Id.*

<sup>156</sup> The Picture of Health: With critical-care specialists in short supply, remote monitoring offers a high-tech solution. <http://online.wsj.com/article/SB10001424052970204488304574428960127233136.html>

<sup>157</sup> *Id.*

<sup>158</sup> *Id.*

monitoring in mind, the FDA should be amended so that it becomes mandatory for manufacturers seeking approval of a new drug, to set up video cameras in the testing facility where they plan to test the drug. FDA inspectors who are qualified and authorized to conduct physical inspections of the testing centers can monitor that facility remotely. Some of the benefits that the FDA will obtain through this remote monitoring system can best explained by analyzing the list of benefits given by Safe-n-secure, a company that provides video surveillance in hospitals.<sup>159</sup> On their website, that company explains that video surveillance would benefit hospitals because it would:

1. Increase the overall security and safety of the hospital administration and the patients as the security cameras help in preventing crimes and breaks in and also allow operators to watch for troubled patients who may wander out of their rooms at night;
2. Improve worker productivity because the presences of surveillance cameras on the premises can improve communication between hospital departments or buildings, allowing for heightened productivity;
3. Prevent dishonest claims in instances where patients or visitors make false claims of injuring themselves on hospital property. Visual evidence from the facility's security cameras can prove that these claims are unwarranted and in turn, save the hospital from pricey lawsuits;
5. Allow for continuous real-time monitoring so that authorized hospital employees can monitor critical areas continuously, in real time, from their personal computers.
6. Allow for Digital store, which would enable the user to store recorded footage digitally on network servers where the surveillance video is easily accessible to authorized users, and offers improved searching capabilities;

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<sup>159</sup> Video Surveillance for Hospitals and Medical Facilities: Benefits of Hospital Video Surveillance. [http://www.safe-n-secureinc.com/Docs/Video\\_Surveillance\\_at\\_Hospital.pdf](http://www.safe-n-secureinc.com/Docs/Video_Surveillance_at_Hospital.pdf)

7. Have visual evidence for investigations as video cameras can provide invaluable visual evidence for investigations of criminal activity and other specific events that have taken place at the healthcare facilities.<sup>160</sup>

Accordingly, the benefits of remote video monitoring will also be similar. Firstly, the video surveillance will most likely decrease the chances of unethical treatment as informed consent procedures will be recorded to see if they are performed correctly. Secondly, it will mostly likely increase the efficiency of the staff at the testing centers and serve as a crime-prevention medium. The presence of video cameras as testing centers can deter some of the illegal activities happening at the testing centers and deter the staff at the testing centers from treating the test subjects unethically. Video surveillance is used in other industries for crime prevention purposes. The private sector began using Close Circuit Television (CCTV) surveillance in banks in the early 1960s, as mandated by federal law, and later in commercial buildings.<sup>161</sup> By the 1970s, CCTV surveillance was also in use in hospitals, all-night convenience stores, art galleries, and in many other commercial locations.<sup>162</sup> Borrowing from these industries, the regulations should be changed so that FDA is given the power to demand the pharmaceutical companies to install video cameras as research testing centers. Through this mechanism, the FDA will be equipped with the necessary resources to stop the inhumane treatment of human test subjects around the globe. Thirdly, video surveillance will also provide the FDA with the proof and ability to sanction drug companies that manufacture drugs in case of reports of adverse effects of the drug. One possible explanation for the FDA's inability to change pharmaceutical companies' conduct in developing overseas studies is a lack of severe sanctions when

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<sup>160</sup> *Id.*

<sup>161</sup> Public Video Surveillance: Is It An Effective Crime Prevention Tool?  
<http://www.library.ca.gov/crb/97/05/crb97-005.html#usage>

<sup>162</sup> *Id.*

researchers exploit foreign subjects.<sup>163</sup> This problem would be easily resolved if the evidence needed to sanction is readily available through the recorded footage from the drug testing centers. Fourthly, to help protect the rights and welfare of volunteers and verify the quality and integrity of data submitted for review, the FDA performs inspections of clinical trial study sites and anyone involved in the research.<sup>164</sup> However, because of the FDA's limited funding, the inspections rarely take place in domestic clinical testing centers, and almost never in foreign clinical testing centers. To resolve this problem, the FDA should require the same inspectors who are responsible for physical inspections of clinical testing centers, to audit the videotapes to make sure that safety procedures are followed. Auditing a large quantity of video footage of the entirety of the trial at numerous locations around the world would be time consuming and not very productive. Hence, the pharmaceutical companies should be asked to perform the most important procedure informed consent procedures at the beginning of the trial, in front of the cameras. The nexus of informed consent is that it be done in the test subject's native language if they do not understand English. The remote monitoring would encourage the researchers that the backbone of ethical guidelines, the informed consent procedure, is performed properly and efficiently. In addition, the video footage can also be consulted if there is an issue about the informed consent procedures not being followed properly. In the case of *Abdullahi v. Pfizer*, the plaintiffs claimed that they had suffered because the informed consent procedures were given in English, and not in their native language of the test subjects.<sup>165</sup> The video surveillance would prevent these type of abuses regarding informed consent from taking place. Critics of my solution are likely to bring up privacy issues regarding the video surveillance at testing centers.

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<sup>163</sup> See Samantha Evans, *The Globalization of Drug Testing: Enforcing Informed Consent Through the Alien Tort Claims Act*, 19 TEMP. INT'L & COMP. L. J. 477, 505 (2005).

<sup>164</sup> *Id.*

<sup>165</sup> *Abdullahi*, *Supra* note 114, at 5.

One answer is that video surveillance is already in place in America and many other countries to ensure the safety of its citizens, even if it may not ask for their consent. But still, as a solution for this problem, the FDA can require informed consent procedures to include a consent that the test subjects agree to being video taped and recorded at the testing center. This consent to video recording and surveillance will spare the FDA from solving problems arising from privacy issues.

## **VI. CONCLUSION**

Despite the privacy concerns that may arise in some rare instances, remote video surveillance of research testing centers will provide a viable solution to the problem of unethical treatment of research test subjects around the world. This is because other solutions that have been presented to solve the problem of the unethical treatment of test subjects, places upon them the burden to know the existing law, and taking affirmative actions to remedy any damages they might have suffered. In contrast, my solution is better because it elevates the responsibility of providing ethical treatment to research test subjects around the globe. In addition, it solves the monetary problem of the FDA inspectors who are unable to conduct inspections of testing centers in America and in foreign countries because of the lack of funding. My solution places the monetary burden of installing video cameras on the rich pharmaceutical companies, and allows the FDA inspectors to inspect the centers remotely from anywhere they desire, without bearing a heavy financial burden. Therefore, the FDA should be amended such that pharmaceutical

companies are required to place video cameras at testing centers where they would conduct their new drug trials.