New Chemicals, Same Story: Clinical Trials and Bhopal's New Corporate Criminals

A report by the International Campaign for Justice in Bhopal

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Introduction:

On the 5th of August 2010 the Indian financial magazine LiveMint published an article reporting that the Indian regulatory agency the Drug Controller General of India (DCGI) was planning to conduct an audit into a clinical trial conducted at the Bhopal Memorial Hospital & Research Centre (BMHRC). It has emerged since then that the trial, conducted on Bhopal Gas victims who receive free care at the hospital was one of at least seven (and perhaps as many as 13) trials conducted on gas survivors since 2003. According to DCGI documentation, there have been 10 trial-related deaths in this time period. Gas survivors who depended on BMHRC, the only super-specialty hospital providing free care the gas exposed, were exploited by the trials, which diverted resources towards private interests. In addition to the basic ethical issue of conducting trials on a group with "reduced autonomy"[1], the trials do not appear to have gotten informed consent from participants, nor were participants compensated. Certain trials may also have violated Indian law, which until 2005 forbade concurrent Phase III trials of new drugs in India.

All of this would be bad enough at a regular hospital, but BMHRC's special history makes this one of the most egregious examples of ethical violations in clinical trials to date. Following the Bhopal Gas Disaster in 1984, Union Carbide had its 50.9% share in its Indian subsidiary (Union Carbide India Limited) frozen by the courts until such time as the legal proceedings around the case were concluded (which, to date, they are not). However, in 1994, a Justice in the Indian Court gave a ruling which briefly allowed Union Carbide to sell their shares in UCIL and remove them from India. These assets were converted into a trust, and Justice A.M. Ahmadi following his retirement became the chairman of this trust in 1998.

Conceived of illegally and led and guided by the same scoundrels who conspired to help Union Carbide abscond from justice in the Bhopal case (Union Carbide is still officially absconding from India in the Bhopal case), it is perhaps unsurprising that BMHRC became a hotbed of corruption and injustice that it is. From the beginning of its existence BMHRC has been accused of corruption, discrimination against gas survivors, exploiting resources meant for gas survivors in order to establish lucrative private practices, and failing to provide needed services. It was for this reason that, in the outrage after the announcement of the minimal criminal punishment for the Indian employees of Union Carbide in June 2010, BMHRC's outrageous status was acknowledged by the Supreme court, (the supreme court directed the taking over of BMHRC following an application by Bhopal Medical Hospital Trust that it be taken over.) who ordered it to be taken from the trust and given for administration to the Department of Atomic Energy (the DAE is still deciding what will be done with the hospital). Although part of BMHRC's mandate was to do research into the effects of gas exposure, a decade into its tenure it has yet to produce

any results on this. What it has done, in the tradition of its founders, is – whilst lining the pockets and CVs of a group of senior consultants - created a lawless shelter for the drug companies mentioned in the report below to conduct a series of clinical trials on a dependent population.

This factsheet looks closely at the names and reputations of the pharmaceutical and research companies who have chosen to test their drugs on Bhopal Gas survivors without either informed consent or compensation. Knowingly or unknowingly these corporations have now joined Union Carbide and Dow Chemical in infamy by using the people of Bhopal as chemical test subjects yet again. Yet as this report shows, most of these companies had already been caught in major ethical lapses related to drug trials or marketing. Although most of the outrage about the drug trials conducted on Bhopal victims has focused on the doctors who conducted, and profited handsomely from, the trials, they did not act alone.

Background and reputation of corporations involved in conducting clinical trials on Bhopal gas victims

Theravance:

Theravance is a relatively young pharmaceutical company, started in 1999 and based in San Francisco, CA, USA. However, already it has been embroiled in at least one case of publicized unethical trials in addition to the BMHRC case.

SFBC in Miami

Theravance was one of at least seven pharmaceutical companies involved in conducting trials through the Contract Research Organization (CRO) SFBC in Miami, Florida, between 2000-2005. SFBC was carrying out drug trials on "largely poor immigrants from Latin America."[i] Violations included:

- Participants not fully and properly informed about risks
- Informed consent was not verified
- Compensation was backloaded to the end of the trial to force participants who wanted to leave the trial to continue it.
- One of the IRBs was controlled by the wife of the SFBC president, a situation similar to what has occured at BMHRC, where the wife of one of the primary investigators was also the head of the hospital ethics commitee[ii]

Theravance Trial at BMHRC:

Theravance conducted a Phase III trial of Televancin at BMHRC between 2005 and 2008. Data with the DCGI caused them to audit this trial in 2010. Although media reports have said that 3 people died in this trial, the details are unknown. The DCGI has reported that, at minimum, the trial failed to compensate patients for their participation. According to material from the DCGI that is in the possession of LiveMint, this trial was led by BMHRC Dr. Pradeep Kumar Bhattacharya. 8 patients were screened for the trial, 7 were randomized into it. Of these 4 completed the trial and 3 patients died as a result.

Pfizer

Pfizer is a multi-national pharmaceutical behemoth. It is the leader in sales among all pharmaceutical companies, and it based in New York, where it was founded in 1849 as the Charles Pfizer and Company. In addition to a record of unethical drug trials, Pfizer was recently

fined $2.3 billion dollars for fraud in the marketing of drugs, the largest healthcare fraud settlement ever, and the largest single criminal penalty ever applied in the United States.[iii] This was the fourth time they had been brought up on fraud charges in the US since 2000. No wonder that they are willing to conduct clinical trials by any means necessary.

Trovafloxicin in Nigeria

This is an infamous case of unethical drug trials, which was profiled in the 2003 Brian Woods documentary *Dying for Drugs*. Pfizer arrived in Karo, Nigeria in 1996 two weeks into an outbreak of bacterial meningitis. They started treating adults and children with their experimental drug, even though Medicines Sans Frontiers was already there distributing the standard treatment free of charge. Ethical violations include, but are not limited to, the fact that Pfizer

- Did not get their protocol reviewed by an ethical review committee[iv]
- Did not inform subjects that they were participating in a trial[v]
- Did not get informed consent[vi]
- Forged approval documents necessary for the trial[vii]
- Tested the drug on children unnecessarily
- Tested a drug not being marketed in Europe because of severe side effects was tested on children without parental consent[viii]
- Out of 190 children enrolled in the trial, 11 died, 5 in the alternative treatment arm, and 6 in the standard treatment arm[ix]

Zoniporide in India

Pfizer has also already attracted negative international attention for another trial in India, one for perioperative cardiac events, which it conducted probably around 2000. In this case the Drugs Controller General of India (DCGI) appears to also have been complicit in the legal violations of this trial. They "approved Phase III trial of Pfizer's zoniporide while Phase II trials had not been completed in the USA and carcinogenic and reproductive studies on animals mandated by Indian law had not been completed." Little is known about this study.[x]

SFBC Miami Test Centre

Pfizer was also a sponsor of the controversial SFBC test center (see above, under Theravance)

Pfizer Trials at BMHRC:

Between 2006-2008 Pfizer conducted a Phase IV Gastrosurgery trial at BMHRC on the antibiotic formulation cefaperazone-sulbactam, a drug not currently approved for sale in the United States.

GlaxoSmithKline

GlaxoSmithKline (GSK) is a London-based pharmaceutical company - the world's largest after Pfizer and Johnson & Johnson. It evolved from merger of several companies that were founded as far back as 1843. In addition to its involvement in unethical drug trials, GSK also operates the notorious Huntington Life Sciences lab which conducts animal tested alleged by animal rights activists to be cruel and unnecessary, and has been the target of a PETA campaign since 1999. They have also been involved in scandals over suicides as a result of SSRI anti-depressants – their anti-depressant Paxil has been required to carry a 'black box' warning since 2004. In 2005 the AIDS Healthcare Foundation accused GSK of restricting the supply of anti-retroviral drugs to keep prices high.

"Standard treatment Interruption" (STI) of ART's in Africa (DART)

GSK was a sponsor of a controversial trial conducted between 2003-2006 in Uganda, Zimbabwe and Cote d'Ivoire, which compared continuous ART therapy to ART therapy with scheduled 12 week "interruptions". Although there was evidence from early on that both morbidity and mortality were higher in the STI arm, the trial did not discontinue it for three years up. Additional problems include:

- For many people, this was the only opportunity to get access to the drugs, therefore consent was impaired
- Post-trial access to drugs was not guaranteed, which discouraged patients from dropping out
- The obvious violation of the Helsinki declaration article 17, that the trial was not ceased even when an obvious risk to one arm of it was identified. [xi]

Hepatitis E Vaccine in Nepal

GSK sponsored a trial of Hep E vaccine between 2001-2003 in Kathmandu. They wanted to test the vaccine on patients, and then on Nepali soldiers, despite the fact that they did not plan to bring the drug to market. They promised to do so, and finally conducted the trial on the soldiers. However, despite the results of the trial being announced in 2007, GSK has not moved to bring out the vaccine.

Lotronex in various countries

Lotronex, Glaxo Wellcome (now GSK) drug for the treatment of Irritable Bowel Syndrome, was withdrawn from the US market in November 2000 due to reports of serious complications and at least3 deaths. However, GSK continued to administer the drug to 7,500 study participants in other countries.[xii]

Lapatinib in India

This was a Phase IIb trial of "lapatinib monotherapy for chemotherapy naïve patients with advanced HER2 positive breast cancer" at three cancer centers in India. This was also a concurrent multi-phase trial conducted before 2005, contravening Indian regulations at the time. Besides the major problem that since advanced treatment for breast cancer is unaffordable for most Indians, and therefore consenting to the trial may be the only way to get treatment at all, the study had a number of other problems. Patients were also not guaranteed continuing treatment after the conclusion of the study.

- 7 percent of the patients reported serious adverse events
- Six women died in the study, one of which, the hepatic failure of a 73 year old woman, was attributed to the study drug.
- Patients were denied the "standard of care," which is treatment with trastuzumab for those patients who can afford it, in favor of the monotherapy demanded by the study.
- One of the study sites runs a charity program, and patients may have been recruited from it to participate in the study[xiii]

GlaxoSmithKline Trials at BMHRC:

Beginning in 2003 – and illegally, as phase concurrent Phase III trials were not allowed in India until 2005 - GSK collaborated with Sanofi-Aventis on a cardiology trial of Fondaprinux and Glucose insulin potassium infusion, known as Oasis-6. According to material from the DCGI that is in the possession of LiveMint, this trial was led by BMHRC Dr. Skand Kumar Trivedi. Suspiciously, of the 57 patients that were screened for the trial, all 57 were randomized into it, and all 57 completed it, which suggests that they may not have been asked for their consent. This trial resulted in 5 deaths according to DCGI.

Sanofi-Aventis

Sanofi-Aventis is the world's 4th largest drug company by sales. In a previous incarnation it was the company Rhone-Poulenc, founded by merger in 1928. Rhone-Poulenc was formerly a "pharmaceutical and chemical company" but it split in two in 1997, with Rhodia becoming the chemical company, and Sanofi-Aventis taking the pharmaceutical side. Rhodia still produces Aldicarb, a patent previously held by Union Carbide, and one of the chemicals being produced at the Bhopal factory site before the 1984 explosion, and which still contaminates drinking water and soil near the factory.

Rhone-Poulenc also independently added itself to the list of chemical corporations involved in environmental disaster through a 1993 controversy, in which a Brazilian judge ordered the closure of a Rhone Poulenc factory in Cubatao. RP had reported concealed large quantities of hexachlorobenze and pentachlorophenol contaminated soil at the plant. In 1992 a worker had died, and autopsy revealed high levels of HCH in his lungs.[xiv]

Cariporide trial in Argentina

In 1997 Hoechst Marion Roussel (Sanofi-Aventis since 1998) began a trial of a heart-surgery follow up drug in Buenas Aires. They did not get informed consent. At least 80 consent forms were later found to be forged. 13 patients died, and 3 were considered legally to be murders as they had been denied the standard of care. Key documentation disappeared. Sanofi-Aventis later decided not to bring the drug to market in the US as a result of the ensuing legal problems.[xv]

Sanofi-Aventis Trial at BMHRC:

Sanofi-Aventis collaborated with GSK on the Oasis-6 trial as reported above, but struck out as the lead sponsor (in collaboration with Bristol-Myer Squibb) for the Oasis-7 trial. Oasis -7 was a Phase III double-blind trial of high doses of the blood thinner clopidrogrel, begun in 2006.

Bristol-Myers Squibb

BMS is a New York based pharmaceutical firm, formed in a 1989 merger between Squibb (founded NY 1858) and Bristol-Myers (Founded NY 1878). Although BMS has not yet been the subject of any major scandals regarding unethical drug trials, it has been charged by the US Federal Trade Commission with anticompetitive practices, including working "to obstruct the entry of low-price generic competition for three of Bristol's widely-used pharmaceutical products."[xvi]

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[i] SOMO briefing paper on ethics in clinical trials , #1: Examples of unethical trials, February 2008 (updated), http://somo.nl/html/paginas/pdf/Examples_of_unethical_trials_nov_2006_NL.pdf, P. 7
[ii] SOMO p. 7
[iii] Pfizer Pays $2.3 Billion to Settle Marketing by Gardiner Harris, Published: September 2, 2009, New York Times
[iv] SOMO p. 12
[v] SOMO, p. 13
[vi] SOMO p. 13
[vii] A Bitter Pill: The risks of carrying out clinical trials in developing countries. The Wemos Foundation. Available from www.wemos.nl, p. 13
[viii] A Bitter Pill, p. 13
[ix] SOMO p. 12
[x] SOMO, p. 14
[xi] SOMO p. 4
[xii] SOMO p. 8
[xiii] Ethical concerns in clinical trials in India: an investigation, by Sandhya Srinivasan of the Centre for Studies in Ethics and Rights, Mumbai, India. Available from http://www.fairdrugs.org/uploads/files/Ethical_concerns_in_clinical_trials_in_India_An_investigation.pdf
[xiv] UN Economic and Social Council, Commission on Human Rights, 53rd Session, Item 5 of the provisional Agenda, #46 http://www.unhchr.ch/Huridocda/Huridoca.nsf/(Symbol)/E.CN.4.1997.19.En?Opendocument
[xv] SOMO p. 16

Bristol-Myers Squibb trial at BMHRC

Bristol-Myers Squibb collaborated with Sanofi-Aventis (above) on the Oasis -7 trial.

AstraZeneca

AstraZeneca is based in London, and has evolved by mergers from the original Astra AB, founded in 1913 in Sodertalje, Sweden, where it still has its R&D facilities. In addition to the major drug trial scandals that it is embroiled in, AstraZeneca has also come under scrutiny for manipulating drug trial data such that it favors a drug that it still holds a patent on above one for which the patent has expired. In a trial of its new drug Nexium against its old (patent expired) drug Prilosec, AstraZeneca allegedly gave trial subjects only a half dose of the Prilosec such that Nexium appeared superior. [xvii] They have also been accused of overmarketing Nexium directly to doctors.

Quetiapine (Seroquel) in India and elsewhere

Since it was first approved in 2004, Seroquel has accrued approval for several indications in treating mental illness, now including schizophrenia and bipolar disorder, although it now carries 'black box' warnings that it may cause "increased mortality in elderly patients with dementia related-psychosis" and suicidality. It has also accrued legal controversy. It is currently the subject of several class-action lawsuits in Canada, where lawyers contend that AstraZeneca knew about, but withheld information about health risks including "weight gain, increased risk of the onset of diabetes, hyperglycemia and blindness"[xviii] but failed to warn Health Canada as well as patients and doctors. American product-liability lawsuits also allege that Seroquel can cause diabetes.

Several quetiapine trials were conducted in India, and have caused controversy. Two placebo-controlled trials were conducted on patients with schizophrenia. The patients were "detoxed" of all the medications that they were on, and then were assigned either to the quetiapine wing, or the placebo wing of the trial. During the trial two patients died, one taking the drug who died of "unknown causes" and a patient in the placebo arm who committed suicide. AstraZeneca maintains that the suicide was "unrelated to treatment" despite suicide being a known risk of untreated schizophrenia. [xix] Problems with this study include the facts that

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[xvi] For Release: March 7, 2003 FTC Charges Bristol-Myers Squibb with Pattern of Abusing Government Processes to Stifle Generic Drug Competition http://www.ftc.gov/opa/2003/03/bms.shtm

[xvii] Grill, Markus and Hansen, Hans (2007): "*Vorsicht, Pharma! Wie die Industrie Ärzte manipuliert und Patienten täuscht.*" ('Caution, Pharma! How the industry manipulates physicians and deceives patients.') Published in the 16.08.2007 issue of *Stern* (Germany; *pp. 100-107*). Available as an e-paper here

[xviii] Seroquel Class Action http://www.kimorr.ca/FL-Seroquel.html

[xix] Ethical concerns, p. 46

- The trial may have been unnecessary, as it was just to test an extended release formula of something that was already approved in a quick release formula
- According to the Helsinki Declaration, placebo controlled studies should not be conducted if there is an established standard of treatment, but in this case very ill patients were removed from all medication and put on placebo
- It was not clear that consent was given, and it is not clear that the patients were able to give informed consent
- Two deaths resulted from this trial, and AstraZeneca has not made public information about these deaths, or whether the families received compensation.[xx]

SFBC Miami Test Centre

AstraZeneca was also a sponsor of the controversial SFBC test center (see above, under Theravance).

AstraZeneca Trials at BMHRC:

Beginning in 2006 AstraZeneca conducted a Phase III double-blind cardiology study at BMHRC, comparing the drugs clopidogrel and ticagalor for efficacy and safety. This trial is known as PLATO.

Schering-Plough (bought Merck & Co in 2009, and then renamed itself Merck & Co.)

Schering-Plough, now called Merck & Co, is the 7th largest pharmaceutical company in the world. It is headquartered in Whitehouse Station, New Jersey, USA. Although it attracted some controversy in 1999 over adapting and unblinding its HIV and Hepatitis C trials based on emerging scientific findings, it has largely stayed out of the spotlight.

SFBC Miami Test Centre

Schering-Plough was also a sponsor of the controversial SFBC test center (see above, under Theravance).

Schering-Plough Trial at BMHRC:

Beginning in 2006 at least one (but likely 3 connected but distinct) Phase III placebo-controlled studies on the asthma drug mometasone furoate were conducted by Schering-Plough at BMHRC. These trials were conducted on the ground by Quintiles CRO, referenced below.

Wyeth (Bought by Pfizer in 2009)

[xx] Ethical Concerns, 36, iii,

Wyeth, founded in 1860 in Philadelphia, was absorbed into Pfizer on October 15th, 2009. The merger was likely welcome, as Wyeth was engaged in a number of scandals at the time. In 2004 the diet drug popularly known as Fen-Phen was taken off the market for causing heart problems, problems that it is alleged Wyeth knew about previously (the Wyeth portion of the drug was fenfluramine, which was established to be causing the vascular damage). More than 50,000 product liability suits were filed in the United States.[xxi] A suit was also filed against Wyeth in 2005 alleging that they were pushing their drug Rapamune off-label to mainly African-American transplant patients.[xxii]

However, the primary example of unethical behavior by Wyeth is the case of their profitable business in female Hormone Replacement Therapy, or HRT. Wyeth's flagship product from 1943-2002 was an estrogen replacement drug called Premarin. Hormone replacement therapy was touted as the fountain of youth, and was prescribed for women undergoing menopause, because the symptoms of menopause are linked to reduction of female sex hormones in the body. This was standard practice until the shocking results of the placebo controlled Women's Health Initiative Study were released after the study was shut down in 2002, which found that women in the treatment arm were suffering "statistically significant increases in rates of breast cancer, coronary heart disease, strokes and pulmonary emboli. The study also found statistically significant decreases in rates of hip fracture and colorectal cancer."

Not only was HRT very dangerous, but Wyeth had systematically been manipulating the medical consensus for years. In September 2010, the journal PLoS, with the New York Times, forced Wyeth to release in court 1500 documents detailing how they had hired ghostwriters to plant articles in favor of HRT in prominent medical journals – over 50 peer-reviewed articles promoting "unproven and unlicensed benefits of Wyeth's HRT drug, undermin[ing] its competitors, and downplay[ing] its harms."[xxiii]

Wyeth is currently the subject of a number of lawsuits regarding HRT drugs. In addition, it was implicated in a 2002 scandal in Europe, where it was found to have illegally sold its sugary waste-water (leftover from coating hormone pills) to a firm Bioland, who sold it as sugar to soft-drink makers and animal feed-producers, resulting in hormone contamination and animal infertility.[xxiv]

[xxi] Fen-Phen Case Lawyers Say They'll Reject Wyeth Offer
By STEPHANIE SAUL
Published: February 17, 2005 http://query.nytimes.com/gst/fullpage.html?res=9505E7D6133AF934A25751C0A9639C8B63

[xxii] Wyeth Marketing Targeted Blacks Illegally: Lawsuit By Ed Silverman // May 24th, 2010 http://www.pharmalot.com/2010/05/wyeth-targeted-blacks-with-illegal-marketing-lawsuit/?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed:+Pharmalot+(Pharmalot)

[xxiii] Medical ghostwriters who build a brand: There are no rules against this, just traditions, good faith, and leaky regulations, by Ben Goldac, http://www.guardian.co.uk/commentisfree/2010/sep/18/bad-science-medical-ghostwriters

[xxiv] Hormone food scandal rocks Europe, 16 July 2002 by Debora MacKenzie http://www.newscientist.com/article/dn2551

Wyeth Trial at BMHRC:

Beginning in 2005 Wyeth conducted a Phase IV gastro-surgery study at BMHRC comparing tigycycline, ceftriaxone sodium and metranidazole in hospital patients with complicated intra-abdominal infections. This study was run by BMHRC Dr. Subodh Varshney. According to DCGI documents with LiveMint, 36 patients were screened for this trial at BMHRC, 34 were randomized, 30 completed, and 2 died during the study.

Eisai

Eisai is a Japanese pharmaceutical company, founded in 1941 and headquartered in Tokyo, Japan. In 1999 Eisai paid a fine of $40 million US dollars for conspiring to fix the price of Vitamin E. Eisai is planning a major expansion into India.[xxv]

Eisai Trial at BMHRC:

Although BMHRC denies conducting any trials after 2008, the US government website www.clinicaltrials.gov identifies a site called " Bhopal, Madhya Pradesh, India, 462038" for a Phase III trial beginning in April 2008 of rabeprazole and esomeprazole in the treatment of GERD. As BMHRC is somewhat outside the city of Bhopal, it does not share a zip code with other major hospitals. It is likely therefore that the site of this trial was BMHRC.

Tranzyme (in a partnership with Bristol-Myers Squibb since 2009)

Tranzyme is a small pharmaceutical company based in Durham, North Carolina, USA.

Tranzyme Trial at BMHRC:

Although documentation from BMHRC make no reference to a trial by Tranzyme, they do reference a Pfizer trial of TZP-101, a Tranzyme product that is also being tested for complex abdominal infections.

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Targacept (formerly a part of R.J.Reynolds Tobacco Company)

Targacept is a small pharmaceutical company based in Winston-Salem, North Carolina, USA. In 2000 they were spun off from RJ Reynolds. They had been doing research into to the biology of nicotine, and discovered "neuronal nicotine receptors." Targacept is developing drugs that target these receptors. Currently they are developing drugs for depression, schizophrenia, Alzheimer's, asthma, diabetes, Parkinson's, and pain/addiction/obesity.

[xxv] Eisai bets big on India, by BV MAHALAKSHMI Posted: Thursday, Dec 24, 2009 http://www.financialexpress.com/news/eisai-bets-big-on-india/558386/

Targacept Trial at BMHRC:

Although BMHRC denies conducting any clinical trials after 2008, according to the US government database www.clinicaltrials.gov, beginning in 2008 and concluding in 2010, Targacept conducted an anti-depressant trial of citalopram plus add-on of its new anti-depressant TC-5214 at BMHRC.

Quintiles

Quintiles is a Contract Research Organization (CRO), that provides trial services to corporations. It was founded in 1974 in North Carolina. It began operating in India in September of 1997 as Quintiles Spectral Limited. Quintiles, as is the case with many CRO's, has been implicated in many violations of ethics in clinical trials. Some Indian examples:

Risperidone in India

Quintiles was in charge of running the Johnson & Johnson Company's clinical trial on the anti-psychotic drug risperidone in India in 2001. The Indian trial was one of three trials that were instrumental in convincing the FDA to approve risperidone for the treatment of acute mania. As in the Seroquel trial, this trial was placebo controlled, so patients in the placebo arm were denied treatment for a serious condition. Besides the above mentioned, criticisms of this trial include the facts that:

- Patients with acute illness were denied the standard treatment of haloperidol, in violation of the Declaration of Helsinki's ban on placebo controlled studies unless there is no standard of care
- More than 210 of the 290 trial enrollees were from government hospitals
- Patients in India had more severe mania than patients in other trials, and are unlikely to have been able to give real informed consent
- Trial may not have been necessary to approve the drug for the Indian market[xxvi]

Quetiapine for acutely ill patients with schizophrenia

Quintiles conducted this placebo-controlled study of the AstraZeneca drug Seroquel between 2004-2005. The same criticisms about placebo use and informed consent apply here as above. In addition, there was a death during the trial of a 42 year old man that Quintiles maintains was not study-related.[xxvii]

Quietiapine for maintenance in schizophrenia

[xxvi] Ethical Concerns, p. 33-34
[xxvii] Ethical concerns, p. 37

Quintiles also conducted for AstraZeneca the earlier mentioned study, in which a man in the placebo arm of the study committed suicide.

Quintiles Trials at BMHRC:

Quintiles conducted at minimum the Schering-Plough mometasone asthma trials at BMHRC, and may have also conducted others.