**Medical Whistleblower Advocacy Network**

Statement for consideration by the Human Rights Committee during the half-day general discussion in preparation for General Comment No. 36 - Article 6: Right to life of the International Covenant on Civil and Political Rights, at its 114th Session, Palais des Nations, Room XIX – 14 July 2015.

**Presented by**

**Dr. Janet Parker DVM**

Medical Whistleblower Advocacy Network greatly appreciates the opportunity to be able to provide our input to the Half Day of General Discussion commencing the Committee's process of developing its General Comment No. 36 on the "Right to Life" with regard to article 6 of the International Covenant on Civil and Political Rights (ICCPR).

This general comment offers the Committee an opportunity to more fully examine the right to life, including the consideration of the principles of equality and non-discrimination regarding persons within a medical context. Human Subjects of medical experimentation are placed at risk when investigating unconfirmed hypotheses about treatments. Research subjects can experience serious adverse health effects as a result of participation in trials including death, shortened life expectancy, or significant decrease in the quality of the person’s life. Patients/Human Subjects can also be placed at risk by patterns of investigative medical practices that are premature and based on an inadequate understanding of a new technique or new drug – or because of direct deceit or fraud by drug or medical device manufacturers about their products.

A person’s equal enjoyment of the right to life is clearly placed at risk by state’s failures to take positive measures to address human subject’s protections in biomedical research whether it takes place in a university or governmental agency setting or whether it takes place in a clinical therapeutic setting. The persons most vulnerable to exploitation as human subjects of medical research are those who are already marginalized and disadvantaged. Groups such as migrants, prisoners, Roma, children, people with disabilities, racial and ethnic minorities are more likely to be targeted by researchers. It is important to put in place international programs, policies and strategies to address global systemic violations of human subject’s protections.

At the end of the Second World War, at the Nuremberg Trials, 23 doctors including Dr. Joseph Mengele were placed before the international court for atrocities they committed under the guise and pretense of medical science. The Nazi doctors had conducted medical experiments on numerous prisoners – especially persons who were Jewish, Roma, other minorities and disabled children and adults.

The doctor-patient and doctor-human subject relationship is a relationship in which the doctor has great power and authority. In this imbalance of power, ethical violations of human rights occur - Including violations of the "Right to Life" with regard to article 6 of the International Covenant on Civil and Political Rights (ICCPR). In addition, the medical community uses the concept of privacy protections to prevent transparency and accountability for their actions. Unequal relationships exist between health researchers and their patients. But health practitioners rarely acknowledge this conflict of interest in their dual roles as health practitioners who are also doing research on their own patients. Vulnerable patients who are used as research subjects within a therapeutic doctor-patient relationship are not afforded the same level of protection as other research subjects, such as persons participating in university or governmental agency research project. A large number of subjects are poor, disabled, children, racial minorities and/or prisoners. These unwitting human subjects have been subjected to deliberate infection with deadly or debilitating diseases, exposed to biological or chemical weapons, exposed to radiation or radioactive chemical, given mind-altering chemicals or toxins. Subjects were told that they were receiving “medical treatment” and reassured by the doctor who they believed would be acting in their “best interest.”

Time and time again, since the original outcry against these atrocities, we are confronted with the reality that researchers, doctors and medical professionals have acted unethically and violated basic human rights of patients and human subjects. In spite of the Hippocratic Oath to “Do No Harm”, doctors and medical professionals have violated the human rights of vulnerable persons. The following are just a few examples:

**1932 -1972** U.S.A. - U.S. Public Health Service Tuskegee Study of Untreated Syphilis scientific researchers in Guatemala infected hundreds of mental patients with sexually transmitted diseases.

**1944-1945** Japan - Doctor Akira Makino performed surgery and amputations on condemned prisoners, mostly Moro Muslims, including women and children, while he was stationed on Mindano.

**1946-1948** Guatemala - U.S. Public Health Service study on syphilis where researchers enrolled people in studies that involved intentional exposure to STD’s without informing them of risks or seeking their consent.

**1945-1955** Sweden- The Vipeholm dental experiments patients of Vipeholm Mental Hospital

**1900 - 1930’s** U.S.A. - Indian Health Service doctors treated Native Americans for Trachoma, an infectious eye disease, by surgically removed the upper and lower eyelids of men, women and children. This was “a serious radical operation” called a tarsectomy and was done as a preventative measure on non-symptomatic individuals in several American Indian communities.

**1950’s** U.S.A. - U.S. Air Force’s former Arctic Aeromedical Laboratory attempted to identify the role of the thyroid gland in human acclimatization to cold weather gave radioactive iodine (Iodine131) to Alaska Natives and Eskimos. Many of the Alaskan subjects were non-English-speaking individuals and children, who were unable to provide proper consent at the time.

**1950’s** United Kingdom - human experimentation at Porton Down and death of Ronald Maddison.

**1966** UK -British anesthesiologist Henry K. Beecher published 22 medical studies in which patients had been subjects with no expected benefit to the patient of the experiment including infusing patients with live cancer cells.

**1970’s** Zimbabwe - Depo-Provera was clinically tested on Zimbabwean women and then the women were pressured to use it once it was approved.

**1989-1991** U.S.A. - Los Angeles study of experimental and unlicensed Measles vaccinations on African American and Latino children.

**1996** Nigeria - Pfizer non-consensual administration of its experimental meningitis drug Trovan for meningitis in Kano. Pfizer eventually paid $75 million to settle claims that children were injured or killed by the drug Trovan.

**2008** Argentina - Santiago del Estero, seven babies died while taking part in trials for an experimental vaccine made by GlaxoSmithKline to prevent pneumonia and related diseases.

**1994** U.S.A. - The Medical University of South Carolina in Charleston was accused of enrolling poor black women into narcotic treatment research without their knowledge.

**1990 – 2005** U.S.A. - The US Department of Defense obtained a waiver that allowed it to force 8.9 million ground troops to accept inoculation with experimental anthrax vaccines.

**2001** U.S.A. - The Kennedy Krieger Institute in Baltimore encouraged black families to move into lead-contaminated housing as part of a study on lead levels in children.

**2003** U.S.A. - Northfield Laboratories set up a nationwide trial of its blood substitute PolyHeme. Which was randomly administered by ambulance crews to unconscious victims of car accidents, shootings and cardiac arrests. Because of a change in U.S. law in 1996, allowed non-consensual research on trauma victims on the pretext that they were unconscious and thus unable to give consent. It was later concluded that there were more deaths and heart attacks in the individuals who had received PolyHeme than those who had not. The blood substitute was therefore not licensed.

**Present** – U.S.A. and globally - Use of non-FDA approved psychiatric drugs “off-label” on wards of the court, elderly, foster children and school children, prisoners, and other minorities.

Medical research and the approval of prescription drugs is a global concern. Much of the research done by U.S. pharmaceutical companies is happening worldwide. Africa and other nations who are economically disadvantaged have been targeted by large international pharmaceutical companies to be sites of clinical testing. However, as human rights violations of corporations become known, people in the developing world are less willing to become guinea pigs – and for good reason. This fundamental distrust lies in the paradox of Hobson’s choice “Experimental medicine or no medicine at all”. Often the medical research offered does not fully protect human rights nor provide to those participating in the research the full benefits of the findings. This leads to another concern regarding the “Right to Life”. In that persons in the developing world are often denied innovative therapies and also important research developments regarding diseases and conditions important to their communities. Even within the U.S.A., there are impacts of the withholding of the potential benefits of research while at the same time exploiting those same vulnerable populations as research subjects. This leads to unequal access to treatment modalities as well as treatment that is not inclusive of the specific needs of those vulnerable populations.

Human subject research includes experiments and observational studies in basic biology, clinical medicine, nursing, psychology, and all other social sciences. There are various codes for the proper and responsible conduct of human experimentation in medical research, the best known of these codes are the Nuremberg Code of 1947,[[1]](#endnote-1) and the World Medical Organization’s Helsinki Declaration of 1964 (revised in 1975).[[2]](#endnote-2)

In the U.S.A. the Nuremberg Code and the related Declaration of Helsinki delineates what is considered ethical conduct for human subjects’ research and forms the basis for the US Code of Federal Regulations - Title 45 Volume 46 (The Common Rule). The Nuremberg Code’s influence on global human-rights law and medical ethics has been profound. Its basic requirement of informed consent, for example, has been universally accepted and is articulated in international law in Article 7 of the United Nations International Covenant on Civil and Political Rights (1966).

Informed consent is consent obtained freely, without threats or improper inducements, and after appropriate disclosure to the patient of adequate and understandable information in a form and language understood by the patient. Engaging in an informed-consent process between a clinical doctor and a patient should be an essential part of the standard of care in medicine. Informed consent is a process, not just a formality, and engaging in that process is of the essence of good medical care. Information must be provided to the patient in a timely manner and in accordance with the accepted standard of practice among members of the profession with similar training and experience. A health care professional may be legally liable if a patient does not give "informed consent" to a medical procedure and it results in harm to patient even if the procedure is properly performed.[[3]](#endnote-3)

Adequate informed-consent process is not just a risk management process, it is good medical practice. Informed consent should define risks and potential benefits, but also take into consideration alternative treatments. Informed consent is an agreement to do something or to allow something to happen, made with complete knowledge of all relevant facts, such as the risks involved. There is a general right for all human persons to be free of inhuman treatment and individuals also have the legal right to privacy under international human rights law.

International human rights case law supports the concept that individuals do have the legal right to decide whether a proposed medical treatment will be performed on them. The human right to decide one's own treatment does not disappear just because it is more convenient or financially more beneficial for the caregivers or for the family members of the individual to force treatment. This right to decide to refuse treatment is a human right we all enjoy. Mental health treatment under human rights law should be the same as other treatments in regards to consent to treatment. But it is a sad fact that this right has not necessarily been consistently protected and thus through our mental health systems extended to people with mental disabilities. Patients need to have the intellectual capacity to understand basic information about their diagnosis and proposed treatment. Correspondingly doctors have a responsibility to communicate the information in terms the patient can understand and to make efforts to be available to answer questions the patient may have.

Informed consent, with specific reliance on the Nuremberg Code, is also the basis of the International Ethical Guidelines for Biomedical Research Involving Human Subjects, the most recent guidelines promulgated by the World Health Organization and the Council for International Organizations of Medical Sciences (1993). The Nuremberg Code focuses on the human rights of research subjects, the Declaration of Helsinki focuses on the obligations of physician-investigators to research subjects, and the federal regulations emphasize the obligations of research institutions that receive federal funds.

In 1974, the U.S.A. signed a law empowering the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (hereafter called the National Commission or Commission) was charged by the U.S. Congress to identify the basic ethical principles that should underlie the conduct of research involving human subjects. In response to this charge, the National Commission published the Belmont Report in the Federal Register on 18 April 1979. The Belmont Report [[4]](#endnote-4) concerning the Ethical Principles and Guidelines for the protection of human subjects of research. The Belmont Report admits that research involving human subjects always inherently includes ethical issues and raises moral problems. The Belmont report delineates 3 major principles: Respect for persons, Beneficence and Justice. The Belmont report explains ethics in a manner which is understandable to a diverse group of professionals and is reflective of a common morality. It provides a strong protection regarding informed consent and also discusses justice and injustice in regards to vulnerable populations. Belmont was then adopted in its entirety as a policy statement by U.S. Department of Health, Education, and Welfare (DHEW) - now called the Department for Health and Human Services (DHHS). Its principles of respect for persons, beneficence, and justice are regarded as the three quintessential requirements for the ethical conduct of research involving human subjects by the National Institutes of Health (NIH) Office for Protection from Research Risks (OPRR). In the US, most research involving human participants funded by federal government agencies is subject to the Common Rule — a set of regulations delineating the requirements for review by an institutional review board. Similar rules apply to research regulated by the Food and Drug Administration (FDA). Although US institutions could decline to apply the Common Rule to research that does not receive federal funding, relatively few do so.

Yet the real promise of human subjects protections promised by the Belmont Report have not been fully realized in the U.S.A. In part, because although there was full discussion of the ethical principles involved, the US National Commission choose not to address the concerns regarding the practice of medical research within clinical therapeutic settings.

The true lessons of the past do need to be revisited. Take for example, the Tuskegee study which was highly publicized in at least 16 research articles which appeared in reputable medical journals, such as the Journal of the American Medical Association, the New England Journal of Medicine and the American Journal of Public Health. The Nuremberg Code had been adopted in 1947 and the ethical principle of informed consent was widely accepted by the medical community, yet the National Medical Association and its members remained silent to the abuse of human subjects at Tuskegee. In spite of the fact that this abuse of human subjects was not hidden from view and that the lessons from the Nuremberg trials should have been fresh in people’s minds – for 40 years no medical professional or medical association stood up to complain about the violations of the human rights of the human subjects. The white coat of silence that shields medical professionals meant that if anyone did object, they were certainly not going to make their concerns public. So during the Nazi era, doctors stood silent while atrocities occurred and then again years later, in the U.S.A., doctors were silent for 40 years about the abuses of the African American men in the Tuskegee syphilis trials. Racial bias against these poor black men made their abuse at the hands of the researchers almost unnoticed.

Concerns for the honesty and integrity of the medical profession are not new. But what is different is how complex the provision of medical care has become and the worldwide nature of today’s medical community. And thus how difficult it is for the average patient, a lay person, to understand whether they are getting safe and effective medical care. Even more difficult to comprehend, is the complex environment of medical research, which now often uses clinical doctors in their therapeutic settings to research the effects of newer drugs and treatments – often before these medications or procedures have been fully reviewed by the state’s regulatory agency (in the U.S.A. this is the F.D.A.).

There is a global distribution of pharmaceutical products. Medical research done in one nation will be used to obtain regulatory approval in another country. A drug approved for use in one country will rapidly acquire acceptance in other countries often through reciprocity. Thus if one nation has poor regulatory control over medical products or prescription medications, it will affect other nation states as well. A recent report of the US Department of Health and Human Services inspector general, indicated that “federal health officials did not know how many clinical trials were being conducted, audited fewer than 1 percent of the testing sites and, on the rare occasions when inspectors did appear, generally showed up long after the tests had been completed.” [[5]](#endnote-5) In the U.S.A. there is an increased use of prescription drugs “off-label” or without the approval for that use by the Food and Drug Administration (FDA). This essentially means that these drugs have not been proven by scientific evidence to be safe or effective. These “off-label” medications are quickly marketed in other countries “off-label” as well as in the U.S.A.

Deceptive and coercive marketing practices by the pharmaceutical industry are common place. The practice of marketing drugs for purposes not backed by science is called “off-label promotion.” In addition, the restrictions upon who can prescribe psychiatric drugs have been reduced, thus allowing persons with lesser medical credentials (such as nurses with prescription authority) to prescribe these mind altering drugs. The pharmaceutical industry has provided marketing and promotional educational training and materials for those wishing to gain prescription authority to prescribe these drugs. This training is biased to sell their product, not to maximize patient informed consent and medical safety for the public.

In the U.S.A., doctors routinely prescribe medications based on little evidence of their benefit. This is because there are high profit incentives to prescribe newly patented medications and many inducements offered by the pharmaceutical companies for doctor to prescribe their products. In an examination of off-label prescribing of 160 common drugs, off-label use was also found to account for 21% of all prescriptions, and most off-label drug uses (73%) were shown to have little or no scientific support. The highest rates of off-label use were for anticonvulsants (74%), antipsychotics (60%), and antibiotics (41%). Atypical antipsychotics and antidepressants were particularly likely to be used off-label without strong evidence. [[6]](#endnote-6) The very drugs which are most often prescribed off-label with little or no scientific support to indicate that the medication is truly beneficial to the patient, actually are the same drugs which commonly cause serious debilitating medical conditions and even death.

In the U.S.A. the rates of diagnosis of psychiatric disorders in children and the elderly has dramatically increased in recent years. Nearly 70 % of the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) task force members report having ties to the pharmaceutical industry. These drugs are widely prescribed for unapproved uses, including other non-approved conditions significantly boosting their sales. These prescription drugs do not live up to their marketing promises but instead have been known to cause serious, even fatal side-effects, particularly in children and the elderly. Lives of some our most vulnerable citizens have been irreparably damaged and many have been lost to fatal adverse effects and even to suicide.

All subjects or their representatives who consent to participate in medical research should be enabled 1) to freely choose whether or not to become enrolled, 2) to comprehend what is being told to them, and 3) to understand essential information about what the research entails, what their options are, and so on.

So when a doctor prescribes an “off-label” drug for a patient in a therapeutic setting but is a cooperating doctor in a research protocol to expand the use of that still not yet approved medication – how is that not medical research? If that physician received a kickback, or research funding, or free educational programs, is that physician still acting in the patient’s best interest? If that doctor removes the FDA mandated patient information insert from the medication bottle and instead gives the patient a glossy brochure printed by the pharmaceutical marketing agency – is that still getting true informed consent? If that doctor answers all the patient’s questions based on a script and training he got from the pharmaceutical sales representative – is he still actually doing medicine or acting as a marketing sales person himself? And if it is medical research, doesn’t the patient have the right to know that that medication was never found by scientific evidence to be safe or effective and that in reality the patient is actually a guinea pig for the pharmaceutical company’s research.

Research can be disguised as “treatment,” but instead actually be a harmful or deadly experiment done without the patient’s knowledge or informed consent to treatment. In the U.S.A. many medical institutions are allowed to include wards of the State in research that presents greater than minimal risk to the subject with no prospect of direct benefit for the research subject. Forcing wards of the court to take medications that are “off-label” (not approved for that use by the Food and Drug Administration), is tantamount to human experimentation on the vulnerable wards of the court. Such violations of human subject provisions are routine with many patients in locked state and federal institutions given psychiatric drugs for “off-label uses.” Problems of patient abuse occur including: excessive dosing for purposes of chemical restraint, poly-pharmacy with multiple medications, lack of informed consent and the use of medication with little or no direct doctor/patient contact. According to the drug data firm IMS Health, the 2009 worldwide sales of antipsychotic drugs was $23.25 billion, and the largest market for these products is in the U.S.A. Antipsychotics (neuroleptics) are a controversial class of drugs, examples include: Risperdal (approved in 1993), Zyprexa (1994), Seroquel (1997), Abilify (2002), and Saphris (2009).

All psychotropic medications have the potential to induce serious adverse effects and these psychiatric drugs are not of small risk because they cause massive changes in the way the brain functions. Long term studies have indicated that there are severe debilitating and sometimes fatal effects of these drugs. Possible negative effects are minimized or not even discussed at all. There are risks of long term psychological harm, physical harm, social harm and economic harm. Many of these drugs cause symptoms that can themselves be construed as mental illness. The probability of developing Parkinson’s like symptoms is also great. These powerful mind-altering psychotropic medications do cause potentially disabling and life-threatening side effects such as: suicide and violence toward others, increased risks of stroke, cardiovascular disease, metabolic syndrome, diabetes, acute closed angle glaucoma, seizures, fainting, and decreased infection-fighting white blood cells. One adverse effect of these medications is neuroleptic malignant syndrome (NMS), a drug induced, toxic, potentially fatal condition resulting in renal failure (10% to 38% of NMS patients die). Early recognition and immediate emergency medical treatment of NMS is necessary to prevent death. It is estimated that that over 50% of individuals with mental illnesses who are prescribed psychotropic drugs also have other serious medical conditions requiring other medications. It takes medical expertise and experience to properly prescribe and monitor these complex medical interactions. Side effects of these drugs include somnolence, obesity, and impaired cognition. These psychiatric medications may adversely affect the individual's quality of life and even shorten the person's life expectancy.[[7]](#endnote-7) Thus it is important that over-medication minimized, the views of the patient are considered and the quality of life issues explored. So an effective means of reviewing the treatment plans is important.

So can we really trust doctors to do what is always in their patient’s best interest? Clearly the history of violations of the rights of human subjects would teach us that we cannot and therefore some supervision and ethical guidance is necessary. Yet how do we know whether physicians and medical professionals are abusing their power in their private relationships with their patients and using the therapeutic relationship to coerce patients to submit to medical research?

In the U.S.A. the authors of the Belmont Report were aware that monitoring a doctor’s actions within the therapeutic relationship with his patient would be very difficult. The US Federal Regulations governing scientific research and the protection of human subjects does not address many of the difficult ethical questions and the kinds of situations that now occur. The Belmont Report can be used to supplement and augment the US Federal Regulations in order to provide a source of additional ethical guidance for essential protections for human subjects. In addition the US Food and Drug Administration could embrace both the Belmont Report and the Nuremberg Code.

The protection of Human Subjects in biomedical research is clearly a matter of life or death and relates to Article 6: Right to life of the International Covenant on Civil and Political Rights.

Dr. Janet Parker DVM

MedicalWhistleblower@gmail.com

1. Nuremberg Code Directives for Human Experimentation [↑](#endnote-ref-1)
2. World Medical Association Declaration Of Helsinki [↑](#endnote-ref-2)
3. *Meador v. Stahler and Gheridian* (Middlesex Superior Court C.A. No. 88-6450, Mass. 1993) [↑](#endnote-ref-3)
4. The Belmont Report Ethical Principles and Guidelines for the Protection of Human Subjects of Research [↑](#endnote-ref-4)
5. Harris G. Report assails FDA oversight of clinical trials. New York Times 28 Sept 2007. [www.nytimes.com/2004/11/19/business/19fda.html](http://www.nytimes.com/2004/11/19/business/19fda.html) [↑](#endnote-ref-5)
6. Radley DC, Finkelstein SN, Stafford RS. (2006) “Off-label prescribing among office-based physicians.” Arch Intern Med 2006;166: 1021-6. [↑](#endnote-ref-6)
7. Jackson, G.R., (2005). Rethinking psychiatric drugs: A guide to informed consent. Bloomington, IN: Author House [↑](#endnote-ref-7)