Our democracy is dependent on the ability of the will of the people to affect the actions of our elected officials. Only when we know to whom elected officials are beholden, can we hold our elected officials accountable. We have an obligation to ensure that our legislation, administrative policies and practices are consistent with protections for Constitutional Rights and also Human Rights under International Human Rights Treaties. Because of Supreme Court decisions like Citizens United, many political spenders, such as the pharmaceutical industry are effectively allowed to hide their true identities and to greatly influence legislation and administrative policies. When we as a nation do not have transparency or accountability regarding political lobbying efforts of huge corporate interests, we cannot draft legislation that protects the human rights of patients to safe and effective health care. We can also not protect vulnerable patients from being human subjects of research without their informed consent, as medicine is a profit driven business and patients are very vulnerable and trusting of their medical providers.

Medical Whistleblower Advocacy Network is extremely concerned that the political power of the pharmaceutical industry has furthered a profit making agenda which has overshadowed the rights of patients and has led to the loss of human rights protections for vulnerable populations. The pursuit of the almighty dollar often overshadows corporate responsibility to the public. We ask you to please update and strengthen the FEC?s disclosure rules to protect our democracy.

The Pharmaceutical Industry lobby has mounted a sophisticated grassroots campaign to provide political support for its position on key issues that affect its profit making enterprise ? including expanded Medicare/Medicaid funding for off-label drugs. The industry has funded various groups to champion its positions, sponsored studies tilted to industry goals and hired public relations firms to spearhead campaigns to soften up public opinion and government policies.

The pharmaceutical industry gives millions to public advocacy non-profit organizations with a variety of missions, many of which then support the political agenda of the pharmaceutical firms. These non-profit organizations are under no legal obligation to reveal their donors, and thus provide an avenue for support for positions favorable to the industry.

The pharmaceutical industry's political agenda is profit making ? not provision of affordable, safe, health care for all. Deceptive marketing through contact with prescribing doctors and other medical professionals has expanded the off-label drug use in this country and has increased health care costs. Highly profitable and expensive patented medications are over-used and our population is over-medicated.

We need to hold elected officials accountable for the public health and safety and therefore we need to know who is giving them campaign contributions in order to influence their decisions. The pharmaceutical industry is currently influencing our elected officials so effectively that we are actually force drugging wards of the court with off-label psychiatric drugs that have no proven efficacy or safety. Pharmaceutical lobbying is hidden within so many countless NGO's that we have no idea which elected official is being influenced. This money from secret sources has led to wide spread corruption within the health care industry and has undermined the protections for human subjects, patients and has forced the US taxpayer to pay for expensive off-label drugs which are not only ineffective but in many cases dangerous.

Please update and strengthen the FEC?s disclosure rules to protect our democracy.

Comments provided by :
Parker DVM, Janet

Medical Whistleblower Advocacy Network

by

Dr. Janet Parker DVM

Written Comments for the Record

to the

Federal Election Commission

1/15/15

REG 2014-01 Earmarking, Affiliation, Joint Fundraising, Disclosure, and Other Issues (McCutcheon)

Our democracy is dependent on the ability of the will of the people to affect the actions of our elected officials. Only when we know to whom elected officials are beholden, can we hold our elected officials accountable. We have an obligation to ensure that our legislation, administrative policies and practices are consistent with protections for Constitutional Rights and also Human Rights under International Human Rights Treaties. Because of Supreme Court decisions like Citizens United, many political spenders, such as the pharmaceutical industry are effectively allowed to hide their true identities and to greatly influence legislation and administrative policies. When we as a nation do not have transparency or accountability regarding political lobbying efforts of huge corporate interests, we cannot draft legislation that protects the human rights of patients to safe and effective health care. We can also not protect vulnerable patients from being human subjects of research without their informed consent, as medicine is a profit driven business and patients are very vulnerable and trusting of their medical providers.

Medical Whistleblower Advocacy Network (MWAN) acts as a grassroots advocate for human rights for disabled persons and other individuals. MWAN provides information, referrals, and also direct human rights defender advocacy services. I am a participating human rights advocate to the 2nd cycle of the United Nations UPR Process reviewing the record of the United States of America.

Medical Whistleblower Advocacy Network is extremely concerned that the political power of the pharmaceutical industry has furthered a profit making agenda which has overshadowed the rights of patients and has led to the loss of human rights protections for vulnerable populations. The pursuit of the almighty dollar often overshadows corporate responsibility to the public. We ask you to please update and strengthen the FEC's disclosure rules to protect our democracy.

The Pharmaceutical Industry lobby has mounted a sophisticated grassroots campaign to provide political support for its position on key issues that affect its profit making enterprise – including expanded Medicare/Medicaid funding for off-label drugs. The industry has funded various groups to champion its positions, sponsored studies tilted to industry goals and hired public relations firms to spearhead campaigns to soften up public opinion and government policies.

The Pharmaceutical Research and Manufacturers of America spent $12,650,000 on lobbying in 2014 according to OpenSecrets.org. Pfizer Inc. spent $6,910,000, Amgen Inc. spent $6,590,00, Eli Lilly &

Co. spent $5,776,000 and Novartis AG spent $5,435,000 and this is only what they actually disclosed, not what they funneled through other 501 C 4 non-profit organizations. No health professional activity is safe from the $200 billion pharmaceutical industry financial and political influence. The largest growing portion of that market is now psychiatric medications which are highly profitable products but of dubious benefit. Pharmaceutical companies spend a majority of their funds in marketing rather than research and development. Financial and political power allows the pharmaceutical industry to push their legislative agenda through Congress, influence regulatory actions of the FDA, and to control research at academic medical centers. Public research institutions funded by tax dollars are doing the basic research for the drugs, but the actual clinical trials are funded privately by the drug companies. Off-label drug use clinical data is used to expand FDA approval to additional diagnoses. In order to make patented drugs look better than they really are, clinical research trials are rigged. Government granted exclusive marketing rights are extended for years by protective and aggressive industry lawyers. The pharmaceutical industry has found that clinical safety trials are costly to perform. Instead they have sifted their emphasis to political pressure on targeted government officials to sway public policy decision making and thus be able to use federal tax dollars to pay for “off-label” use of welfare recipients as their human subjects. Controlling the decisions of the medical proxy decision makers is therefore their focus rather than making sure that medications are approved by the FDA as safe and effective. Annually, the pharmaceuticals industry spends nearly twice as much on marketing as it spends on research and development. According to the Center for Public Integrity the pharmaceutical and health products industry has spent more than $800 million in federal lobbying and campaign donations at both federal and state levels in the past seven years. (PublicIntegrity.org) The Supreme Court Decision, Citizens United v. Federal Election Commission has now even further extended the pharmaceutical companies influence over policy makers through unbridled secret contributions to 501 c 4 organizations which then can lobby legislators on behalf of the pharmaceutical industry. Individual citizens of the U.S.A., especially persons with mental disabilities, cannot compete with equal lobbying actions to the pharmaceutical industry. Indeed, many with mental health diagnosis are actually stripped of their right to vote and even their right to petition their elected representatives for issues crucial to their human rights. Surrogate decision makers often controlled by the medical proxies make voting decisions for the wards and thus vote pro-pharmaceutical interventions. The human rights of wards of the court are lost in this political exercise of power.

The pharmaceutical industry gives millions to public advocacy non-profit organizations with a variety of missions, many of which then support the political agenda of the pharmaceutical firms. These non-profit organizations are under no legal obligation to reveal their donors, and thus provide an avenue for support for positions favorable to the industry. Some of the groups that receive the industry funds are independent, but many are just a front for the pharmaceutical lobby such as The Institute for Policy Innovation (IPI). IPI does not disclose its funders, but according to the Foundation Center – Eli Lilly and Company Foundation is among the group's supporters. The Eli Lilly Foundation is funded by Eli Lilly and has the mission of providing financial support for non-profit organizations. With the support of Eli Lilly funding the IPI has published reports opposing drug re-importation and price controls and defending the industry's lavish spending on advertising, especially the direct-to-consumer advertising. Other known pharmaceutical industry grassroots political lobbying groups are the Seniors Coalition and The United Seniors Association. The lobbying efforts by these so-called grassroots organizations can be very deceptive, such as the Consumer Alliance 2002 campaign against legislation that would have capped prices for prescription drugs. The Consumer Alliance faxed petitions to community leaders that warned the poor and disabled were in danger of losing access to affordable prescription drugs. It was revealed later by the Baltimore Sun, that Consumer Alliance was a front group used by

Bonner and Associates on behalf of PhRMA. PhRMA spent more than $60 million on television and newspaper ads through a group called Citizens for Better Medicare. Citizens for Better Medicare claimed to be a grassroots organization consisting of numerous organizations and more than 300,000 individual members and had a mission to get passage of the Medicare prescription drug benefit in 2003. This legislation has dramatically increased the amount of federal funding through Medicare to pay for off-label psychiatric prescription drugs.

Off-label use is using a drug for a use that it has not been scientifically proven to be safe or effective – in other words the drug has not met the requirements to be approved by the federal regulatory agency the Food and Drug Administration. The pharmaceutical industry politically pushed for legislation which would permit them to sell their patented drugs off-label (drugs without Food and Drug Administration approval for that use). There is no need for the pharmaceutical industry to pay for costly pharmaceutical clinical research trials when they can sell the drug off-label and get the US tax payer to pay for it even if it is not even FDA proven to be safe or effective. The drug companies promote these patented off-label drugs by deceptive direct-to-consumer and direct-to-doctor marketing efforts. The practice of marketing drugs for purposes not backed by science is called "off-label promotion." Off-label drug promotion undercuts expectations that drug safety and efficacy have been fully evaluated. The National Alliance for the Mentally Ill (NAMI) is a 501 C 3 which is funded by pharmaceutical companies such as Eli Lilly to provide educational materials to both doctors and patients touting the great benefits of the newly patented medications. Off-label promotion is illegal, but the pharmaceutical industry pays their attorneys well to fight the FDA in court and when they are finally criminally convicted the criminal penalties are not high enough to really prevent re-occurrence.

The pharmaceutical industry's political agenda is profit making – not provision of affordable, safe, health care for all. When the government becomes a third party payer for off-label drug use and the Medicare/Medicaid legislation mandates payment of any cost of psychiatric drugs then administrators cannot place reasonable cost-saving measures in place. When newer, more expensive drugs are used off-label, it increases health care costs. The pharmaceutical industry has effectively turned welfare recipients into human subjects for the testing of their patented drugs off-label and lobbied for the federal government Medicare program to pay for this off-label use. Deceptive marketing through contact with prescribing doctors and other medical professionals has expanded the off-label drug use in this country and has increased health care costs. Highly profitable and expensive patented medications are over-used and our population is over-medicated. Off-label drugs such as gabapentin for chronic pain and olanzapine (Zyprexa) for dementia have shown that off-label use has potentially very negative consequences. The highest rates of off-label use were for anticonvulsants (74%), antipsychotics (60%), and antibiotics (41%). 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. Atypical antipsychotics and antidepressants were particularly likely to be used off-label without strong evidence. (Radley DC, Finkelstein SN, Stafford RS. Off-label prescribing among office-based physicians. Arch Intern Med 2006;166: 1021-6.)

Getting informed consent from a patient is a process, not just a formality, and engaging in that process is of the essence of good medical care. But informed consent cannot happen when research data is suppressed and safety information is withheld from prescribing doctors and patients. Informed consent to use a medication 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 is an essential part of the standard of care in medicine. The involvement of human beings in such research is prohibited unless the subject or the subject's legally authorized representative has provided prior informed consent, with only very limited exceptions. A waiver of informed consent by the Institutional Review Board is supposed to be granted only in circumstances where the research presents no more than minimal risk to subjects, and the waiver will not adversely affect subjects' rights and welfare. Wards of the court have surrogate decision makers for both legal and medical decisions, thus wards are prevented even from effective appeal to the Judge or even to their US Congressmen/Congresswomen. Thus the pharmaceutical industry's influence on surrogate decision makers such as doctors can effectively control what medical care is given. In the U.S.A. the guardianship system offers few procedural protections, and has spawned a profit-driven professional guardianship industry that often enriches itself at the expense of society's most vulnerable members—the mentally ill.

We must support the right of federal regulatory agencies to do their job in researching what is safe and what is not. The Food and Drug Administration's restrictions on off-label promotion serve two substantial interests: ensuring that both doctors and consumers receive accurate, scientifically based information, and assuring that drugs have been proven safe and effective. Right now Jazz Pharmaceuticals is off-label marketing Xyrem which is the sodium salt of GHB – a well-known date rape drug. Xyrem is a Schedule III drug, but when diverted to illegal use it is a Schedule I DEA Controlled Substance. In the December 2012 case US v Caronia, the company appealed its conviction for off-label promotion claiming constitutional free speech. The ruling US v Caronia removes the liability for drug sales representatives which are left unsupervised 99 % of the time, yet control much of the industry's communication with physicians.

We need to hold elected officials accountable for the public health and safety and therefore we need to know who is giving them campaign contributions in order to influence their decisions. The pharmaceutical industry is currently influencing our elected officials so effectively that we are actually force drugging wards of the court with off-label psychiatric drugs that have no proven efficacy or safety. Pharmaceutical lobbying is hidden within so many countless NGO's that we have no idea which elected official is being influenced. This money from secret sources has led to wide spread corruption within the health care industry and has undermined the protections for human subjects, patients and has forced the US taxpayer to pay for expensive off-label drugs which are not only ineffective but in many cases dangerous.

Please update and strengthen the FEC's disclosure rules to protect our democracy.

Today the pharmaceutical industry has unprecedented ability to spread money to influence thinking, mental health practice, and policy making. We need to impose reasonable restrictions on those who can exercise such immense financial and political power.

For additional information please see my written statement for the record, The State of Civil and Human Rights in the United States, Senate Judiciary Subcommittee on the Constitution, Civil Rights and Human Rights, December 9, 2014 or visit my website:
http://MedicalWhistleblowerNetwork.Jigsy.com

United States of America

Shadow Report Submission to the United Nations

Convention against Torture and

Other Cruel, Inhuman or Degrading Treatment or Punishment (CAT)

53rd Session in Geneva on November 12 and 13, 2014

Geneva, Switzerland

Voiceless Victims: Wards of the Court

I. Drafted 9/22/14

II. Reporting Organization(s): Medical Whistleblower Advocacy Network

Contact Information: Dr. Janet Parker DVM, Executive Director

Email: MedicalWhistleblower@gmail.com Phone: +1-785-550-4945

http://medicalwhistleblowernetwork.jigsy.com/

1. Medical Whistleblower Advocacy Network (MWAN) acts as a grassroots advocate for human rights for disabled persons and other individuals within the U.S.A. and abroad. MWAN human rights cases often involve issues with medical implications, such as protection of mandated reporters, medical abuse, medical fraud, psychiatric abuse, prisoner mistreatment, sexual assault, domestic violence and stalking. MWAN provides information, referrals, and also direct human rights defender advocacy services. MWAN has allowed victims of human rights violations to directly tell their own stories, assisting them when necessary with their time lines, helping them access documents, and doing research and analysis of their situations. Some who experienced human rights violations chose to tell their stories in their own words on MWAN's internet radio program. MWAN also works with other NGO organizations to advocate for the rights of the disabled and promote the protection of human rights.

III. Summary of Issues

- Right to Informed Consent
- Abuse and Neglect by Guardians
- Protection of Human Subjects
- Use of "off-label" Psychiatric Drugs

IV. Concluding Observations

2. In the United States, according to 2012 SAMHSA statistics there are an estimated 43.7 million adults aged 18 or older with mental illness. This represents 18.6% of all adults in the country.[1] The U.S.A. states clearly that "Under U.S. law, officials of all government agencies are prohibited from engaging in torture, at all times, and in all places." This would presume that vulnerable persons who are currently in court ordered guardianship would be protected from torture, cruel, inhuman or degrading treatment or punishment, but in reality there is little transparency or accountability for what actually happens to wards of the court – especially in mental health cases.[2]

3. Wards of the court have surrogate decision makers for both legal and medical decisions, thus wards are prevented even from effective appeal to the Judge or even to their US Congressmen/Congresswomen. The U.S.A. mental health guardianship system offers few procedural protections, and has spawned a profit-driven professional guardianship industry that often enriches itself at the expense of society's most vulnerable members—the mentally ill.[3] Yet despite numerous calls for reform, most states have done little to monitor professional guardians and prevent abuse and neglect. Secrecy, lack of transparency and lack of accountability makes a perfect environment for human rights violations of the mentally disabled.[4] [5] [6]

4. 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. 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." [7] 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.[8]

5. In addition the use of medication with no real oversight of the process of diagnosis, means that patients can often not question the use of these medications because surrogate decision makers have been assigned by the court to make all medical decisions. Wards in mental health care have often been stripped of their legal rights and thus cannot assert their objections to treatment decisions. Unbiased independent review of medical charts is almost non-existent. Patient human rights have been ignored and there is no direct process to bring guardianship abuse or doctor/proxy/decision maker abuse to the attention of the court.

6. Deceptive and coercive marketing practices by the pharmaceutical industry are common place.[9] The practice of marketing drugs for purposes not backed by science is called "off-label promotion." These 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.[10] Lives of some our most vulnerable citizens have been irreparably damaged and many have been lost to fatal adverse effects and even to suicide.[11] [12]

V. US Government Report

7. In its response to questions from the Human Rights Committee, the United States did not respond to the issue of mental health patients' *right to informed consent*, *abuse and neglect by guardians*, and the *use of "off-label" psychiatric drugs* because those issues were not specifically raised by the Committee. The United States of America agreed with the CAT Committee that … "the intentional infliction of mental pain or

suffering was appropriately included in the definition of torture to reflect the increasing and deplorable use by certain States of various psychological forms of torture and ill-treatment, such as mock executions, sensory deprivations, use of drugs, and confinement to mental hospitals." [13] And further stated that …" Psychological torture is redressable under the U.S. criminal laws."

8. The U.S.A. did respond to issue of *protection of human subjects* stating that the United States is under constraints in the government's power to use individuals in non-consensual experimentation, including non-consensual medical treatment and experimentation. Federal law also prohibits non-consensual clinical investigations of medical products on human subjects in the U.S.A., and in foreign clinical investigations when the data are to be used to support drug or device approvals. Control of pharmaceutical and device products is vested by statute in the Food and Drug Administration (FDA) within HHS.[14] The introduction of unapproved drugs and devices into interstate commerce is prohibited.

9. The Fourth, Fifth, Eighth, and Fourteenth Amendments to the Constitution, as well as federal statutes and agency rules, also restrict experimentation on prisoners. Specifically, the Fifth and Fourteenth Amendments proscribe deprivation of life, liberty or property without due process of law. [15] The Fourth Amendment proscribes unreasonable searches and seizures (including of a person's body), and the Eighth Amendment proscribes the infliction of cruel and unusual punishment. The Fifth and Fourteenth Amendment Due Process Clauses prohibit, inter alia, governmental action that "shocks the conscience," including acts of torture and cruel treatment, as well as punishing persons without first convicting them under appropriate standards. Torture is also absolutely prohibited by customary international law, and by U.S. domestic law, which prohibits acts of torture both inside and outside the United States, and at both the federal and state levels. It is unlawful for U.S. actors to commit an act of torture, under any circumstances, anywhere in the world.[16] [17]

10. The Civil Rights of Institutionalized Persons Act (CRIPA), 42 U.S.C. 1997 et seq., permits the Attorney General to institute civil lawsuits against state institutions regarding the civil rights of their residents, including the conditions of their confinement and use of excessive force. DOJ/CRD has utilized this statute to prosecute allegations of torture and cruel, inhuman, and degrading treatment or punishment.

11. Furthermore under the Detainee Treatment Act of 2005 (DTA), "No individual in the custody or under the physical control of the U.S. Government, regardless of nationality or physical location, shall be subject to cruel, inhuman, or degrading treatment or punishment." [18] Every U.S. official, wherever he or she may be, is also prohibited from engaging in acts that constitute cruel, inhuman or degrading treatment or punishment.

12. Under USA law, the Americans with Disabilities Act of 1990 (ADA) and the Rehabilitation Act of 1973 (Rehabilitation Act) restrict and regulate the use of solitary confinement for persons with disabilities. Title II of the ADA, 42 U.S.C. 12132, applies to state actors, while the Rehabilitation Act applies to federal facilities and facilities receiving funds from the federal government. Both statutes prohibit discrimination on the basis of disability instead require that persons with disabilities should be provided reasonable accommodation and modifications so that they can access services, programs, and activities, including mental health services.

13. Under 18 U.S.C. 242, individuals who acted under color of law may be prosecuted for willful deprivations of constitutional rights, such as the rights to be free from unreasonable seizure and from summary punishment or cruel and unusual punishment, and the right not to be deprived of liberty without due process of law.

VI. Legal Framework

CAT Articles 1, 2, 4, 5, 6, 7. 10, 11, 12, 13, 14, 15, 16, 22

VII. CAT Committee Comments

14. The Committee for the Prevention of Torture (CPT) has stated: "Patients should, as a matter of principle, be placed in a position to give their free and informed consent to treatment. The admission of a person to a psychiatric establishment on an involuntary basis should not be construed as authorizing treatment without his consent. It follows that every competent patient, whether voluntary or involuntary, should be given the opportunity to refuse treatment or any other medical intervention. Any derogation from this fundamental principle should be based upon law and only relate to clearly and strictly defined exceptional circumstances." [19]

VIII. Other UN Body Recommendations

15. The principle of Free, Prior and Informed Consent is an important human right which has been addressed in many international and domestic laws and practices. The U.S. is party to the Universal Declaration of Human Rights (UHDR), the International Covenant on Civil and Political Rights (ICCPR), the Convention against Torture (CAT), and the International Convention on the Elimination of Racial Discrimination (CERD), all of which must be applied without discrimination based on disability. The U.S. has signed but not yet ratified the Convention on the Rights of Persons with Disabilities (CRPD), as well as the Convention on the Rights of the Child (CRC) and the International Covenant on Economic, Social and Cultural Rights (ICESCR). The human rights of patients are also delineated in the Universal Declaration on Bioethics and Human Rights. [20]

16. The standards of the European Committee for the Prevention of Torture states that "consent to treatment can only be qualified as free and informed if it is based on full, accurate and comprehensible information about the patient's condition and the treatment proposed." Consequently, all patients should be provided systematically with relevant information about their condition and the treatment which it is proposed to prescribe for

them.” [21]

17. Guardianship keeps people in institutions and negates the right of people with disabilities to exercise legal capacity, an aspect of the right to recognition as persons before the law, in violation of UDHR Articles 2 and 6, and ICCPR Article 26, and in violation of CRPD Article 12.

18. Often guardianship and the use of surrogate decision-makers is used to circumvent informed consent rather than making an honest attempt to discern the wishes of the person. To refuse to recognize the individual patient's human right to informed consent is contrary to the recognition of the legal capacity of persons with disabilities on an equal basis with others, as required by CRPD Article 12 and constitutes discrimination based on disability under UDHR Articles 2 and 6, and ICCPR Article 26. [22] [23]

19. Civil commitment laws create a separate regime of detention and involuntary treatment applicable only to persons with psychosocial disabilities that is discriminatory in purpose and effect, contrary to U.S. obligations under UDHR Articles 2, 3 and 5, ICCPR Articles 2, 7 and 9, and CAT Articles 2 and 16, as well as CRPD Articles 14, 17 and 25.

20. In situations of civil commitment and compulsory mental health treatment the U.S. Supreme Court recognizes infringements of the liberty interest (a Constitutional Right) but asserts that these infringements are justified by state interests.[24] [25] These practices pose a serious violation of mental and physical integrity by their close connection with disability-based discrimination, as analyzed by UN Special Rapporteur on Torture Manfred Nowak. [26]

21. Inadequate constitutional protections for persons with disabilities may constitute torture or ill-treatment, and violates U.S. obligations under UDHR Articles 2, 3 and 5, ICCPR Articles 2, 7 and 9, and CAT Articles 2 and 16, as well as CRPD Articles 4, 5, 15 and 17.

22. To refuse to recognize the individual patient's human right to informed consent, is

contrary to the recognition of the legal capacity of persons with disabilities on an equal basis with others, as required by CRPD Article 12 and constitutes discrimination based on disability under UDHR Articles 2 and 6, and ICCPR Article 26.

23. ECHR cases indicate that the guarantee of liberty is perhaps the most important human right in relation to the detention of mentally disordered people. [27] [28] [29]

IX. Recommended Questions

- What measures will the U.S.A. take to ensure the human rights protections for wards of the court?
- Why has the U.S. government not taken steps to curtail the wholesale use of "off-label" use of psychiatric medications in violation of the Common Rule?
- What will the federal government do to supervise the state courts guardianship system?

X. Suggested Recommendations for the U.S. government

- Ratify the CRPD, CRC and ICESCR without any reservations, understandings or declarations, and without further delay in order to be in compliance of international recognized standards regarding the human right of informed consent.

- Establish a federal database tracking system to facilitate tacking of complaints received by HHS, FDA or the DOJ regarding complaints of psychiatric abuse in psychiatric facilities, psychiatric nursing homes and in outpatient treatment.

- Establish a separate database used to record and process allegations of misconduct which have been lodged by the wards against their court assigned guardian or medical treatment team.

- Include persons with disabilities in the review policies at both the federal and state levels, to abolish all laws and mechanisms that restrict the legal capacity of any person (especially those with disabilities) and to create supportive measures for the exercise of

legal capacity that respect the will and preferences of the person.

- Evaluate all guardianship cases in the State Court system to see if they are in compliance with U.S. Department of Health, Education, and Welfare Codes for the conduct of social and behavioral research and consistent with the ethical code of conduct established by the American Psychological Association, published in 1973.

[1] Substance Abuse and Mental Health Services Administration, Results from the 2012 National Survey on Drug Use and Health: Mental Health Findings, NSDUH Series H-47, HHS Publication No. (SMA) 13-4805. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2013.

[2] Leonnig, Carol D., Lena H. Sun and Sarah Cohen. "Misplaced Trust: Special Report." The Washington Post (June 15-16, 2003).

[3] Fields, Robin, Evelyn Larrubia and Jack Leonard. "Guardians for Profit." Los Angeles Times (November 13-16, 2005).

[4] United States Government Accountability Office GAO Testimony Before the Special Committee on Aging, U.S. Senate, GUARDIANSHIPS, Little Progress in Ensuring Protection for Incapacitated Elderly People Statement of Barbara D. Bovbjerg, Director Education, Workforce, and Income Security, September 7, 2006, GAO-06- 1086T.

[5] Wood, Erica F. "State-Level Adult Guardianship Data: An Exploratory Survey," American Bar Association Commission on Law and Aging for the National Center on Elder Abuse, August 2006.

[6] Yeoman, Barry. "Stolen Lives." AARP: The Magazine (January-February 2004).

[7] Jones, Allen. (2004) "TMAP Critique," January 20, 2004, PschRights.org, http://psychrights.org/Drugs/AllenJonesTMAPJanuary20.pdf

[8] United States ex rel Law Project for Psychiatric Rights v. Matsutani, et al. US District Court, District of Alaska, Case No. 3:09-cv-0080-TMB.

[9] Jones, Allen, "Introduction to the documents on Big Pharma Corruption in Research & Clinical Trials," Revised January 20, 2004, The Law Project for Psychiatric Rights http://psychrights.org/

[10] Jackson, Grace E., MD, "What Doctors May Not Tell You About Psychiatric Drugs" Public Lecture, UCE Birmingham June 2004

[11] March 21, 2000 Report to the court by Dr. Loren R. Mosher M.D. regarding Eric Harris and Luvox use prior to the Columbine High School shooting, Scoteria Associates

[12] Jackson, Grace E. (2005) “Rethinking Psychiatric Drugs: A Guide for Informed Consent.” Bloomington, IN: Author House.

[13] ¶ 95 of the Initial Report U.S. Initial Report (CAT/C/28/Add.5, February 9, 2000) and in its Second Periodic Report (CAT/C/48/Add.3, June 29, 2005.

[14] 21 U.S.C. 355 (a) and 360 (k)

[15] United States Responses to Questions from the United Nations Human Rights Committee Concerning the Fourth Periodic Report of the United States on the International Covenant on Civil and Political Rights (ICCPR) Appendix 16: ¶¶ 187-189 of the U.S. Government's Fourth Periodic Report

[16] CAT/C/USA/CO/2 25 July 2006 Committee Against Torture, Thirty-sixth session, 1-19 May 2006, Consideration Of Reports Submitted By States Parties Under Article 19 Of The Convention, Conclusions and recommendations of the Committee against Torture, United States Of America

[17] United Nations Committee Against Torture, Convention Against Torture, Periodic Report Of The United States Of America, Paragraph 258

[18] Detainee Treatment Act of 2005 Pub. L. No. 109-163, 42 U.S.C. 2000dd

[19] CPT/Inf (98) 12 [EN] - Publication Date: 31 August 1998 para 41

[20] The Universal Declaration on Bioethics and Human Rights, adopted by acclamation October 2005 by the General Conference of UNESCO

[21] CPT Standards, 2002, CPT/inf/E (2002) 1, V. Involuntary placement in psychiatric establishments, para 41, Extract from the 8th General Report [CPT/Inf (98) 12]

[22] See also UDHR Articles 2, 3, 6 and 25, ICCPR Articles 7 and 26, CAT Articles 2 and 16, and CRPD Articles 12, 15, 17 and 25.

[23] See A/63/175, paragraphs 44 and 73-74.

[24] Addington v. Texas, 441 U.S. 418 (1979) (civil commitment)

[25] U.S. v. Sell, Riggins v. Nevada, 504 U.S. 97 (1992).

[26] See U.N. Doc. A/63/175 (2008), particularly paragraphs 40, 44, 47, 49, 50, 61-65, 73-74.

[27] Winterwerp v Netherlands (1979) 2 EHRR 387

[28] Stanley Johnson v United Kingdom [1997] EHRLR 105-8

[29] Aerts v Belgium, ECHR Reports of Judgments and Decisions 1998

Medical Whistleblower Advocacy Network

Dr. Janet Parker DVM

Written Statement for the Record

The State of Civil and Human Rights in the United States

Hearing Before the Senate Judiciary Subcommittee on the

Constitution, Civil Rights, and Human Rights

December 9, 2014

Protection of Human Subjects: Human subject research includes experiments and observational studies in basic biology, clinical medicine, nursing, psychology, and all other social sciences. 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 Federal Policy for the Protection of Human Subjects or the "Common Rule" was codified in separate regulations by 15 Federal departments and agencies. The United States Department of Health and Human Services (HHS) regulations 45 CFR part 46 governs all federally-funded research in the United States. The United States Constitution should constrain the use of individuals in non-consensual experimentation, including non-consensual medical treatment and experimentation. Specifically, the Fifth and Fourteenth Amendments proscribe deprivation of life, liberty or property without due process of law. the Fourth Amendment proscribes unreasonable searches and seizures (including of a person's body), and the Eighth Amendment proscribes the infliction of cruel and unusual punishment. Federal law also prohibits non-consensual clinical investigations of medical products on human subjects in the U.S., and in foreign clinical investigations when the data are to be used to support drug or device approvals. Control of pharmaceutical and device products is vested by statute in the Food and Drug Administration (FDA) within HHS. The involvement of human beings in such research is prohibited unless the subject or the subject's legally authorized representative has provided prior informed consent, with only very limited exceptions. A waiver of informed consent by the Institutional Review Board is supposed to be granted only in circumstances where the research presents no more than minimal risk to subjects, and the waiver will not adversely affect subjects' rights and welfare. Human experiments have been performed in the United States which have been considered unethical, and were often performed illegally without the knowledge, consent, or informed consent of the test subjects. Vulnerable populations such as children, mentally disabled persons, prisoners, persons already suffering from disease or injury, financially disadvantaged, immigrants, or from a racial minority population were targeted for use by researchers. 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. Numerous court cases have been brought regarding psychiatric forced drugging and the lack of informed consent.

Informed Consent: 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. 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. Skepticism by the patient in such circumstances does not mean that the person does not have capacity to make treatment decisions. Even if the patient, due to their disability, cannot believe the doctor's diagnosis that doesn't mean that the patient does not have capacity to make treatment decisions. Essentially, people have the right to make treatment decisions under Principle 19 of the UN's "Principles for the Protection of Persons with Mental Illness." Because those with mental health disabilities are often detained, this then often automatically leads to forced treatment. This does not necessarily need to happen. It is not theoretically inconsistent with confining someone in a psychiatric facility, but still leaving them with the authority to decide treatment decisions. No treatment should be provided except in emergency situations until a determination of capacity has been made through a judicial hearing for treatment decisions. The hearing must be by an independent arbiter, and be judicial in character. In addition there must be a right of the patient to return for re-consideration of the situation at regular intervals. A hearing to determine incapacity is required. Persons, who are lacking capacity, are often institutionalized and over-medicated. These psychiatric medications may adversely affect the individual's quality of life and even shorten the person's life expectancy. 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.

Human Rights of Wards of the Court: Wards of the court have surrogate decision makers for both legal and medical decisions, thus wards are prevented even from effective appeal to the Judge or even to their US Congressmen/Congresswomen. In the U.S.A. the guardianship system offers few procedural protections, and has spawned a profit-driven professional guardianship industry that often enriches itself at the expense of society’s most vulnerable members—the mentally ill. A majority of jurisdictions do not require personal visits to the incapacitated individual. Financial resources are transferred to the guardians, thus leaving the individuals with diminished capacity, in complete dependency on the guardians’ decisions. According to a study in the Los Angeles Times, more than half of all guardianship petitions filed by professional guardians in Southern California between 1997 and 2003 were granted by the courts on an emergency basis. Of these emergency appointments, 56 percent were granted without notice to the proposed ward, 64 percent before an attorney was selected to represent the ward, and a stunning 92 percent before an otherwise mandatory court investigator’s report. The courts are being swamped with new applications for guardianship– many of them under the

guise of emergency guardianship, thus allowing medical proxy decision makers to make legal decisions about patients in many cases without notifying the patient or the patient's family. Emergency placements are prone to abuse by the professional guardianship industry and professional guardians making financial decisions for their own self-interest. Professional guardians know how to manipulate the medical and court system to use procedural loopholes of the emergency guardianship procedure to gain legal and financial control over the ward's rights and assets and total control over the ward's medical care. For profit "professional" guardians are allowed to be compensated from their wards' accounts for the services they provide, and many have seized the economic opportunity presented by the incapacity of others by making a business of acting as a guardian. They have cooperative business financial relationships with a variety of service providers such as doctors, hospitals, lawyers, courts and government agencies responsible for mental health care. By the time the family realizes what is happening legally behind closed doors, the legal process is already completed and guardianship has been granted by the court. Without ever talking to the patient or the family, Judges are making life changing decisions about these proposed wards. Thus the ward, who has the most to lose in these proceedings has often little or no input, in addition family members may not even be appraised of the court proceedings until after emergency guardianship has been already established – thus depowering them to act as advocates for their family member. A Los Angeles Times investigation similarly uncovered numerous instances of egregious abuse by guardians where evidence of abuse was already in the courts' own files. Nearly 75 percent of America's courts do not have a computerized data system to track guardianship cases and identify problems. Nearly 20 percent of courts do not require annual accounting of a ward's finances. Among courts that do collect such information, more than one third do not have an official who is designated to verify the content of the guardians' reports, and less than 20 percent verify every report. In more than 40 percent of courts, no one is assigned to visit individuals under guardianship to determine if they are being abused or financially exploited. Judges often out of expediency grant the guardian complete powers over a ward despite the principle of limited guardianship. It is important that the guardian stands for the human rights of the ward not for compliance with the hospital or doctors' wishes. Judges accept without question the written documents submitted by the medical proxy decision makers, without questioning their financial and sometimes pharmaceutical research related motives. Judges should instead make sure that they do true substantial judicial due diligence and insist that wards are transported to the court or that in some manner direct face-to-face communication is established with the Judge. Judges need to question whether a drug that is not approved by the FDA needs to be used on a ward of the court – especially in light of growing evidence of adverse effects, lack of evidence of efficacy and successful litigation against the drug manufacturer. Forcing wards of the court to take medications that are "off-label" – not approved for that use by the FDA, is tantamount to human experimentation on the vulnerable wards of the court. The ward has no legal ability to sue the pharmaceutical company for any harm he/she suffers even long-term disability, torture or even death result. Given that these drugs are expensive, have potentially severe side effects, and have limited evidence supporting their effectiveness off-label, they should perhaps be used with greater caution.

Human Rights of Children: Persons with mental health challenges still retain their human rights to informed choice in care, participation in family life and deserve respect for their human dignity. Children have fundamental human rights, even if they do have a mental disability. Parents have a fundamental right to decide what medical treatment is appropriate for their own children. Coerced mental health screening programs have no place in a free society, neither does coerced medication. Under universal screening programs, many children receive stigmatizing diagnoses that handicap them for the rest of their lives. The Medication Algorithms proposed by the pharmaceutical industry have

resulted in many thousands of children being medicated by expensive, ineffective, and often dangerous drugs. Children and young people have limited or no ability to make their own medical choices. Parents and guardians often are not given full information about treatment options. In the foster care system parents lose custody of their children and the children are not permitted to refuse treatment or have any meaningful input into the treatment they receive. Thus in the U.S.A we have a system of institutionalized injustice to minors entrusted to the Foster Care system. Coming from backgrounds of abuse and trauma, these emotionally vulnerable young people are exposed to physical, emotional, psychological and sexual abuse that often occurs in youth psychiatric facilities. Often these young people have committed no crime, but are detained against their will, and decisions about their care is made based on the type of health insurance they have (public or private), rather than their health needs. In the U.S. institutions are often overcrowded, poorly maintained. This is both unjust and discriminatory. Not surprisingly foster children exposed to such situations are unable to adjust to independent living when they reach adulthood and end up in large numbers in the U.S. prison system as adults. In addition, the pharmaceutical industry's successful marketing of drugs to this captive population of children has led to children as young as two years old given mood stabilizers and antipsychotics even before they are even able to speak. It is estimated that over 8 million children are drugged in the U.S.A. with 1,300 deaths due to this practice.

Human Rights of Minorities: Experts admit that mental health diagnoses are inherently subjective. Even according to the 1999 "Mental Health: A Report of the Surgeon General," there are serious conflicts even in the medical literature about the definitions of mental health and mental illness. These very definitions are rooted in subjective value judgments that vary across cultures and are subject to bias and prejudice. Mental illness is based on behaviors observed by others and subjective reporting, while physical illness is able to be objectively measured by verifiable physical signs. Because of inherent subjectivity and lack of objective verification, it's all too easy for a psychiatrist to label disagreement with political and/or social beliefs to be a mental disorder. Thus mental illness is commonly diagnosed in minority groups with greater frequency– possibly because of personal bias and cultural differences. But it is also evident that minorities have less access to, and availability of, mental health services. There is an inequality in the U.S.A., racial and ethnic minorities collectively experience a greater disability burden from mental illness than do whites. Minorities receive less care and poorer quality of care. Drug-metabolizing enzymes found primarily in the liver (CYP450) are a major determinant of therapeutic drug response. There are well - established differences between Caucasians, Black populations and Asians in regards to how they metabolize neuroleptic drugs. African Americans and Asians have slower metabolic rates compared with Caucasians. Common clinical practice, supported by controlled clinical studies has led to a reduction in dosage recommendations for many antidepressants and neuroleptics for these ethnic groups. (Bradford & Kirlin 1998)

Human Rights of Veterans: The Veterans Administration was paying for medication "off-label" that was not effective or safe. Although Risperdal® (risperidone), which is a second generation anti-psychotic drug, is approved to treat severe mental conditions such as schizophrenia and bipolar disorder, the US Veterans Administration doctors were prescribing the drug "off-label" to treat Post Traumatic Stress Disorder or PTSD. But a study by Veterans Administration researchers published in the Journal of the American Medical Association concluded, "Treatment with risperidone compared with placebo did not reduce PTSD symptoms."

Effects of Psychiatric Medications: Psychiatric medications have unpleasant and sometime irreversible side effects that make them extremely undesirable to patients. These side effects include: vomiting, erectile dysfunction, difficulty concentrating, anxiety, dry mouth or excessive salivation,

depression, feeling tired all the time, sleep disturbances or nerve damage. Patients can have coherent and valid reasons for refusing medication. Many patients have rational reasons for rejecting treatment and concerns about the severe and potentially life-threatening side effects of psychotropic medications. Serious side effects include tardive dyskinesia, neurololeptic malignant syndrome, and akathisia. In addition chronic use of these medications can lead to Parkinson's disease symptoms, chronic psychosis, as well as early death. Many patients wish to discontinue their medication and need competent medical help to do so.

According to the National Institute of Neurological Disorders and Strokes of the National Institutes of Health, antipsychotic drugs can cause neuroleptic malignant syndrome, a life-threatening neurological disorder. Additionally, the National Institutes for Mental Health ("NIMH") has found that long-term use of antipsychotic medications can cause tardive dyskinesia, a potentially incurable and disfiguring condition that causes muscle movements a person cannot control. For long-term psychiatric patients the chance of contracting tardive dyskinesia from psychotropic drugs is approximately one in four. The published rate for tardive dyskinesia among people who stay on the older drugs is approximately 3-5% per year - if you stay on these medications, for ten years, the risk of developing TD is 50%. (Dr. Grace E. Jackson MD 'What Doctors May Not Tell You About Psychiatric Drugs' Public Lecture, UCE Birmingham June 2004)

One of the most common side effects of antipsychotic drugs is a condition known as ***akathisia***, which is marked by uncontrollable physical restlessness and agitation and by interminable pacing, shaking of arms and legs, foot bouncing, and anxiety or panic. When this side effect occurs it is often mistaken for symptoms of mental illness itself. Then even more antipsychotic medication is administered due to a psychiatrist's erroneous perception that the signs of akathisia are actually symptoms of disease, with increased medication the patient's agitation and panic therefore increase. The opposite type of side effect is ***akinesia***, which is typified by drowsiness and the need to sleep a great deal. This effect is appreciated by those wishing to chemically restrain patients and prevent their moving around or demanding care in the middle of the night. This also allows caretakers to ignore patient's various medical problems and use ever increasing amounts of drugs to achieve the desired ends. This is not treatment of the underlying disease but instead forced drugging for the convenience of the caretakers. In addition, polypharmacy, which is the prescribing for a single person of more than one drug of the same chemical class (such as anti-psychotics), is widely practiced despite little empirical support, and can result in serious adverse reactions and intensified side effects and can lead to early death. Persons, who are lacking capacity, are often institutionalized and over-medicated. This not only adversely affects the individual's quality of life and but can even shorten the person's life expectancy. There is a lot of research that indicates that there is decreased life expectancy for persons taking neuroleptic medication. One study by Joukamaa published in the British Journal of Psychiatry in 2006 followed 99 people diagnosed schizophrenic for 17 years. The study found that if the person received even one neuroleptic drug there was an increased risk of dying by 3 fold (35% died). If given 3 neuroleptic drugs that increased the risk of dying in 17 years by 7 fold (57% died). Thus it is important that over-medication minimized for all mental health patients.

Off-Label Use of Psychiatric Drugs: Once a drug has been approved by the Food and Drug Administration (FDA), clinicians are free to prescribe it as they see fit. Because there often is not the same level of high -quality clinical research demonstrating the safety and efficacy of these drugs for non–FDA-approved indications, the benefits of such off-label use are usually unclear. "Off-label" use of anti-psychotic medications is common, particularly among the elderly and children/adolescents. In the United States, the medical community is focused on profits and market forces have resulted in

psychiatric medications prescribed for patients who are dependent in some way to the social welfare system. Psychiatric medications for schizophrenia alone cost the US taxpayer 3.5 million dollars a day. Pharmaceutical companies have spent huge amounts of money to lobby the US Congress for legislation that will minimize their legal risk and maximize their profits. The medical professionals, doctors, nurses, hospital social workers, pharmacists, and therapists are all financially dependent on the profit making aspect of medicine for their economic livelihood. This has resulted in a high rate of prescription of psychiatric medications for "off-label" use in the absence of good evidence of effectiveness. Once a drug has been approved by the FDA, clinicians are free to prescribe it as they see fit. Because there often is not the same level of high-quality clinical research demonstrating the safety and efficacy of these drugs for non–FDA-approved indications, the benefits of such off-label use are usually unclear. Given that these drugs are expensive and have serious side effects (Including: weight gain, diabetes mellitus, tardive dyskinesia, and extrapyramidal symptoms), their off-label use may represent significant risk and cost with undemonstrated clinical benefit. “Off-label” use of anti-psychotic medications is common, particularly among the elderly and children/adolescents. Medicaid is the primary payer for patients with schizophrenia in the United States, with over a third of individuals with schizophrenia receiving their care through state Medicaid programs. The cost of anti-psychotic medications has been rapidly escalating and now makes up a considerable share of Medicaid prescription drug programs. The public financing for anti-psychotic medications has been roughly equally divided between Medicaid and Medicare. It is estimated that Medicaid currently pays for more than 70% of all the antipsychotic prescriptions in the United States. In 2008, Medicaid spent $3.6 billion on antipsychotic medications, up from $1.65 billion in 1999, according to Mathematica Policy Research, which analyzes Medicaid data for HHS. Medicaid spends more on antipsychotics than on any other class of drugs. In one study of data from the Medicaid programs of 42 states from 2003 they found a considerable degree of off-label use of these drugs, with 57.6% of patients who were given anti-psychotic medications having no visit with a diagnosis of either schizophrenia or bipolar disorder during the year. (Leslie 2012) The FDA initiated regulatory actions to address reports of increased suicide rates on these psychiatric medications. One of these actions was to require a black box warning label for the new anti-depressants that warned of increased risk for violent tendencies, including suicide, caused by these medications.

Off-Label Promotion/Deceptive Marketing of Psychiatric Drugs: The practice of marketing drugs for purposes not backed by science is called “off-label promotion.” The Food and Drug Administration which regulates prescription drugs and has not adequately regulated the “off-label” promotion of Risperdal by Johnson & Johnson Pharmaceutical Co. and its Janssen subsidiary. The FDA was aware of grave concerns regarding its safety and clear indication that it is not effective for the conditions it is prescribed for. Johnson & Johnson-Janssen's “off-label” promotion of Risperdal through Teen Screen was targeted to young adolescent boys. Johnson & Johnson's subsidiary-Janssen strategically marketed Risperdal-a drug designated for narrow use in the treatment of schizophrenia, into a $34 billion dollar profit making drug, with a 97% profit rate. (Applbaum 2012) This antipsychotic drug, Risperdal cost 40-50 times as much as the first generation antipsychotics. Risperdal is a second generation antipsychotic (SGA). Their marketing strategy caused the drug to be used preferentially to older generic versions of antipsychotic medications (FGA-first generation antipsychotics). Doctors are encouraged or pressured to treat their patients with the newest, most expensive drugs and they are discouraged from using the cheaper generic medications. The newer drugs often did not have extensive clinical trials before their “off-label” use, therefore the full dangers of the medication and possible adverse side effects were often unknown or not reported. Research studies delineating concerns for the newer drugs’ safety and efficacy were suppressed. The Food and

Drug Administration sent warning letters sent to Janssen which questioned the company's marketing claims that its drug was superior to first generation antipsychotics or safer. Instead the pharmaceutical industry bypassed governmental safeguards and medical review by using political pressure on select governmental officials. When oral Risperdal was headed to be off patent and generic forms of it would have become available. Jansen promoted its long-acting version of Risperdal–Consta injectable to be recommended in the Texas Medical Algorithm Project (TMAP). (Rosenheck et al 2011) Marketing of Consta was focused on hospital inpatients because it is rare for stable patients to be switched to a different drug once they are discharged from the hospital. Patients were switched while still in the hospital to the still patented injectable Risperdal while still in the hospital before discharge. The pharmaceutical industry spent and continues to spend millions on lobbying Congress to effect changes in legislation favorable to the pharmaceutical industry's bottom line including changes in the Medicaid Act 2003. These changes allowed the federal government to pay through Medicaid for psychiatric drugs used for "off-label" (extra -label) uses. What may appear as a consensus of medical approval is a carefully planned marketing effort to influence medical decisions on mental health care. Among the many marketing strategies used by the pharmaceutical industry are: 1) One-to-one detail marketing to doctors and professionals 2) Continuing education seminars and sponsorship 3) Pharmacy specific advocacy groups 4) Ghost-writing of "scientific" articles and dissemination of unsupported "medication algorithms" 5) Direct-to-consumer advertising 6) Intense legislative lobbying 7) Suppression of research findings through control of research findings and research grantees 8) Illegal marketing of psychotropic drugs for off-label purposes 9) Bribing state officials with cash payments to add atypical antipsychotics on Medicaid formularies. The National Alliance on Mental Illness (NAMI) provides pharmaceutical grassroots political support and distributes pharmaceutical educational materials used to support and expand off-label use of patented psychiatric drugs.

The New Freedom Commission on Mental Health: The controversial New Freedom Commission on Mental Health was established by the 43rd U.S.A. President, George W. Bush, with Executive Order 13263 of April 29, 2002. The Commission was established to conduct a comprehensive study of the U.S. A. mental health service delivery system and make recommendations based on its findings. The Commission issued its report on July 22, 2003. President Bush has instructed 25 federal agencies to develop a plan to implement the Commission's recommendations. In 2004, Congress appropriated $20 million to finance the recommendations of this New Freedom Commission on Mental Health. Congress also passed the Garrett Lee Smith Memorial Act that included $7 million for suicide screening and tens of millions more for Substance Abuse and Mental Health Services Administration and its Center for Mental Health Services. The No Child Left Behind Act already included $5 million for Mental Health Integration. This was a part of a federal plan to subject all children to mental health screening in school and during routine physical exams. This was an effort to force millions of kids to undergo psychiatric screening whether their parents' consent or not. The New Freedom Commission on Mental Health recommended increased use of pharmaceutical interventions despite the Food and Drug Administration (FDA) objections.

Texas Medication Algorithm Project (TMAP): The Texas Medication Algorithm Project or TMAP was described as a thinly veiled proxy for the pharmaceutical industry, which pursued profits by recommending more psychotropic medication interventions. TMAP had been created in 1995 while President Bush was governor of Texas. It formed as an alliance of individuals from the University of Texas, the pharmaceutical industry, and the mental health and corrections systems of Texas. The New Freedom Commission on Mental Health used TMAP as a blueprint and began to recommend screening of American adults for untreated mental illnesses and children for emotional disturbances. The commission, using the Texas Medication Algorithm Project (TMAP) as a blueprint, subsequently

recommended screening of American adults for possible mental illnesses, and children for emotional disturbances. The primary purpose was to recommend implementation of TMAP based algorithms on a nationwide basis. The strategy behind the commission was developed by the pharmaceutical industry, and the goal was to identify all those with suspected disabilities who could then be provided the newer psychoactive drugs. The pharmaceutical industry's marketing concept behind Texas Medication Algorithm Project (TMAP) was to standardize treatment through the imposition of a strict algorithm. Mental health care has evolved into a revolving door between state mental hospitals and prisons, where patients flow through these facilities and leave with prescriptions for the medications they were treated with while institutionalized. Most of these patients will rely on Medicaid or Medicare to pay for the drugs. Forcing prisons and state mental hospitals and other community mental health centers to prescribe medications based on a pharmaceutical industry marketing model permits "patient recruitment and retention" in pharmaceutical industry terms. This has been translated to clinical marketing terms emphasizing client compliance to the treatment regime and adherence to a particular drug.

Financially responsible governmental policy regulators and governmental agencies attempted to put in place cost containment measures which were meant to limit the escalating seemingly unlimited cost of psychiatric medications now borne by the US taxpayer. State legislatures started drafting measures that would permit them to regulate prescription drug prices for state employees, Medicaid recipients, and the uninsured. Like managed care plans, they were creating formularies of preferred drugs. One such cost containment measure was the requirement that a "consumer" can only receive a specific service or treatment if the service/medication is first screened and approved by the paying insurance company. The Medication Algorithm Project (MAP) was instituted, so that "prior authorization" requirements by Medicaid would not prevent customers from buying expensive newer psychiatric medications that had just been patented In 1995, as part of a marketing strategy, the pharmaceutical industry started to push for Medication Algorithm Project guidelines that would dictate what medications would be prescribed. The Texas Medication Algorithm Project (TMAP) is a decision-tree medical algorithm that gives guidelines for what medications to prescribe. Political pressure was applied on state decision makers to have these guidelines implemented within state of Texas Mental Health and Mental Retardation guidelines which would thus make it difficult for state Medicaid auditors to make decisions outside these guidelines. With state issued guidelines, doctors didn't need to worry about choosing which medication is most effective, but instead just go by the MAP chart. Pharmaceutical industry representatives suggested which drugs should be the first, second, third, choice. All the doctor needs to do is prescribe the drugs in that order, if the first doesn't work, the doctor prescribes the second on the list. Doctor's don't need to research the newer drugs and determine what is best for a particular patient - they just prescribe according to the list recommended by the state agency MAP chart. The legal malpractice risk of making a wrong choice is then transferred to the state agency which has legal immunity and thus the choices are already made by pharmaceutical industry representatives. If an adverse event happens (i.e. suicide or murder) the doctor can legally fall back on the fact that the state agency recommended his prescription choice. This has also opened the door to prescription authority extended to physician assistants and nurse practitioners, who do not have the same extensive medical training that is required for an M.D. The use of a Medication Algorithm meant that the legal risk of a malpractice claim was lowered to almost nil, shifting legal responsibility to the state which has legal immunity. This meant decreased malpractice insurance costs for these less qualified medical practitioners. The drug companies involved in financing and/or directly creating and marketing TMAP include: Janssen Pharmaceutica, Johnson & Johnson, Eli Lilly, and Austrazeneca, Pfizer, Novartis, Janssen-Ortho-McNeil, GlaxoSmithKline, Abbott, Bristol Myers Squibb, Wyeth-

Ayerst Forrest Laboratories and U.S. Pharmacopeia. The pharmaceutical industry repressed clinical research information about adverse events, while paying university professors and other respected medical professionals to ghost write articles favorable to their products. Doctors can be unduly swayed by pharmaceutical company promotional messages which are spread through supposedly neutral continuing educational events and written material. The Texas Medication Algorithm Project (TMAP) was supported by state governmental authorities and has been imported to other states such as Pennsylvania and TMAP currently impacts mental health care in at least 17 states. (Healy 2006, 2008) Doctors stopped using their discretionary options and instead started to prescribe according to the MAP chart because of legal ramifications of not practicing the "standard of care." The Medication Algorithm Project (MAP) was created by the pharmaceutical industry leaders as a marketing tool with little valid scientific research to back MAP recommendations. In reality, the FDA was pressured to overlook clear dangers of medications in the MAP model and to continue to allow drugs to be sold to vulnerable patients with serious and even fatal adverse effects. Research into the dangers of the increased use of psychiatric medications recommended by the MAP has been suppressed.

Allan Jones was the former investigator in the Commonwealth of Pennsylvania Office of Inspector General (OIG), Bureau of Special Investigations. As a human rights defender and medical whistleblower, Alan Jones, investigated for the Office of Inspector General of FDA. He delivered a scathing report on the fraudulent behavior of the pharmaceutical industry and its political control over both legislation and regulatory functions. OIG Investigator Allen Jones' report indicated that key administrative governmental regulatory employees in Pennsylvania were closely aligned to drug manufacturers. These officials working in cooperation with pharmaceutical industry insiders manipulated the regulatory agencies to turn a blind eye to the excessive profits of the pharmaceutical companies and to permit wholesale marketing at taxpayers' expense of psychotropic drugs. (Jones, Allen, "Introduction to the documents on Big Pharma Corruption in Research & Clinical Trials," Revised January 20, 2004 http://psychrights.org/)

In addition to pressuring medical professionals to prescribe these medications, the pharmaceutical industry has put a great pressure and influence on the American Psychiatric Association Task Force which writes the Diagnostic and Statistical Manual of Mental Disorders (DSM), the manual of mental health diagnoses. These changes in the DSM will increase the number of persons diagnosed with mental illness. (Carey 2012) The new manual the DSM V that is just now coming out has been written with the strategic marketing pharmaceutical industry objectives in mind. Therapists and clinicians use the DSM IV to do their billing codes, and thus their ability to get paid is based on how they comply with the diagnostic guidelines in the DSM IV. Allen Frances, MD, who chaired the DSM–IV Task Force, voiced considerable concern for the implications of the new edition. The newer version of the diagnostic manual, the DSM V is now being boycotted in protest by many mental health stakeholders, psychiatrists, clinical psychologists, therapists and psychiatric social workers. (Carney J 2012)

Adverse Effects of Neuroleptic/Anti-psychotic Medications: These neuroleptic and anti-psychotic medications can have profound negative effects including what could be called "inner torment" or what is called clinically akathisia. ***Akathisia*** is one of the most common side effects of antipsychotic drugs and causes uncontrollable physical restlessness and agitation and by pacing, shaking of arms and legs, foot bouncing, and anxiety or panic. When this side effect occurs it is often mistaken for symptoms of mental illness itself and then the psychiatrist's erroneous assumption will lead to even more anti-psychotic medication being administered. With the subsequent increased dosage, the patient's agitation and panic therefore increase, leading to a terrible feeling of inescapable physical and mental turmoil, this sometimes leads to acts of violence. When patients are confronted with such feelings of

restlessness, agitation, and incoherent thoughts caused by the psychiatric medications they often have racing thoughts of violence even suicide. This is why these medications carry a Food and Drug Administration black box warning label stating that they can cause violent thoughts, actions and even suicide. Neuroleptic adverse reactions are related to behavioral changes such as akathisia. In the late 1970's, akathisia was formally recognized and known to be a predisposing factor to violence. (Keckich 1978) These neuroleptic medications are highly addictive and the brain becomes dependent on them for normal functioning and thus withdrawal can have serious symptoms including irritability and agitation. Thus suddenly going off these medications can make patients extremely emotional, agitated, less inhibited, suicidal and even violent. During a patient's withdrawal period, any perceived untoward disrespectful attitudes or verbal communications can trigger violence. Neuroleptic Induced Akathisia (NIA) can lead to violence, including mass murder, as was seen in the Columbine Shooting, when Eric Harris while on Luvox murdered his classmates.

Political Pressure to Influence Legislation: No mental health profession and no professional activity is safe from the $200 billion pharmaceutical industry financial and political influence. The largest growing portion of that market is now psychiatric medications which are highly profitable products but of dubious benefit. Pharmaceutical companies spend a majority of their funds in marketing rather than research and development. Financial and political power allows the pharmaceutical industry to push their legislative agenda through Congress, influence regulatory actions of the FDA, and to control research at academic medical centers. Public research institutions funded by tax dollars are doing the basic research for the drugs, but the actual clinical trials are funded privately by the drug companies. Off-label drug use clinical data is used to expand FDA approval to additional diagnoses. In order to make patented drugs look better than they really are clinical research trials are rigged. Government granted exclusive marketing rights are extended for years by protective and aggressive industry lawyers. They also flood the market with copycat drugs of the same general class of drugs that cost a lot more than the drugs they mimic, but really are no more effective. The pharmaceutical industry has found that clinical safety trials are costly to perform. Instead they have sifted their emphasis to political pressure on targeted government officials to sway public policy decision making and thus be able to use federal tax dollars to pay for “off-label” use of welfare recipients as their human subjects. Controlling the decisions of the medical proxy decision makers is therefore their focus rather than making sure that medications are approved by the FDA as safe and effective. The pursuit of the almighty dollar often overshadows corporate responsibility to the public. Annually, the pharmaceuticals industry spends nearly twice as much on marketing as it spends on research and development. According to the Center for Public Integrity the pharmaceutical and health products industry has spent more than $800 million in federal lobbying and campaign donations at both federal and state levels in the past seven years. (PublicIntegrity.org) The Supreme Court Decision, Citizens United v. Federal Election Commission has now even further extended the pharmaceutical companies influence over policy makers through unbridled secret contributions to 501 c 4 organizations which then can lobby legislators on behalf of the pharmaceutical industry. Individual citizens of the U.S.A., especially persons with mental disabilities, cannot compete with equal lobbying actions to the pharmaceutical industry. Indeed, many with mental health diagnosis are actually stripped of their right to vote and even their right to petition their elected representatives for issues crucial to their human rights. Surrogate decision makers often controlled by the medical proxies make voting decisions for the wards and thus vote pro-pharmaceutical interventions. The human rights of wards are lost in this political exercise of power. Today the pharmaceutical industry has unprecedented ability to spread money to influence thinking, mental health practice, and policy making. We need to impose reasonable restrictions on those who can exercise such immense financial and political power.