

# **Voiceless Victims:**

# **Wards of the Court**

**Medical Whistleblower Advocacy Network**

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## Voiceless Victims: Wards of the Court

### I. WHAT IS PSYCHIATRIC TORTURE?

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."

UN Special Rapporteur on Torture, Manfred Nowak stated in the Interim report A/63/150. 28. July 2008.

*"Torture, as the most serious violation of the human right to personal integrity and dignity, presupposes a situation of powerlessness, whereby the victim is under the total control of another person. Persons with disabilities often find themselves in such situations, for instance when they are deprived of their liberty in prisons or other places, or when they are under the control of their caregivers or legal guardians. In a given context, the particular disability of an individual may render him or her more likely to be in a dependent situation and make him or her an easier target of abuse. However, it is often circumstances external to the individual that render them "powerless" such as when one's exercise of decision-making and legal capacity is taken away by discriminatory laws or practices and given to others."*

UN Special Rapporteur on Torture, Manfred Nowak stated:

*"Medical treatments of an intrusive and irreversible nature, when they aim at correcting or alleviating a disability, may constitute torture and ill-treatment if enforced or administered without the free and informed consent of the person concerned." ... "The administration in detention and psychiatric institutions of drugs, including neuroleptics that cause trembling, shivering and contractions and make the subject apathetic and dull his or her intelligence, has been recognized as a form of torture." "The Special Rapporteur notes that forced and non-consensual administration of psychiatric drugs, and in particular of neuroleptics, for the treatment of a mental condition needs to be closely scrutinized. Depending on the circumstances of the case, the suffering inflicted and the effects upon the individual's health may constitute a form of torture or ill-treatment."*

SRT (2008) UN Special Rapporteur on Torture. Interim report A/63/150. 28. July 2008.

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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."<sup>1</sup>

## II. OFF-LABEL RESEARCH ON WARDS OF THE COURT

In the United States, according to 2012 Substance Abuse and Mental Health Services Administration (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.<sup>2</sup> There remains little accurate information of who is in guardianship and the quality and nature of their medical care. There are approximately 1.5 million active pending adult guardianship cases in the United States, according to the 2011 National Center for State Courts report Adult Guardianships: A "Best Guess" National Estimate and the Momentum for Reform. 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.<sup>3</sup>

List of issues:

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

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 disabled and the elderly especially the mentally ill.<sup>4</sup> 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.<sup>5 6 7</sup>

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

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federal institutions given psychiatric drugs for “off-label uses.”<sup>8</sup> 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.<sup>9</sup> 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).

In addition the use of medication with no real oversight of the process of diagnosis, means that patients often cannot 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.

Deceptive and coercive marketing practices by the pharmaceutical industry are common place.<sup>10</sup> 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 reality, pharmaceutical industry supported educational programs support coercive psychiatric drugging and the removal of civil rights of psychiatric patients, as well as life-long drugging with psychiatric drugs. These drugs are widely prescribed for unapproved uses, including other non-approved psychiatric conditions and insomnia, significantly boosting their sales. These off-label psychiatric 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.<sup>11</sup> Lives of some our most vulnerable citizens have been irreparably damaged and many have been lost to fatal adverse effects and even to suicide.<sup>12 13</sup>

Currently in all 50 states and in the District of Columbia, nurse practitioners prescribe these very dangerous mind altering substances. Authorized professionals include, psychiatric nurse practitioners, clinical nurse specialists, and certified nurse anesthetists, even certified nurse midwives. These nursing professionals are supposed to be supervised by medical doctors, but there is no actual oversight to make sure that this direct supervision actually occurs. So behind the closed doors of psychiatric hospitals, mental health clinics, and nursing homes, persons without the credentials of a doctor are prescribing these newly patented psychiatric drugs “off-label” with little restriction on wards of the court. It is routine for pharmaceutical marketing personnel to offer incentives to these prescribing professionals including kickbacks, free educational training, free samples of products and other gifts. Judges who make decisions about the medical care of the wards of the court, assume that these “qualified health care providers” are doing what is in “the best interest of the ward”.

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There is no transparency about what happens behind those closed doors. Patients who are wards of the court are routinely switched from one psychiatric drug (one losing its patent protections) to another newly patented drug based on decisions regarding pharmaceutical company profit. Prescribing practitioners are paid to make these changes to a patient's drug therapy, even if the medication change causes severe distress to the patient and the drug being prescribed has not even met Food and Drug Administration (FDA) safety standards. Wards of the court have been switched onto psychiatric drugs for which there was an active FDA black box warning and even when the FDA was considering a recall of the patented drug. Wards of the court were instead switched to the dangerous drug in large numbers in order to counteract the FDA restrictions, maintain profit for the pharmaceutical company, and provide statistically numerous clinical cases for expanded FDA approval for additional uses.

Prescribing providers withhold critical evidence of adverse events from the Food and Drug Administration (FDA), thus interfering with the ability of the FDA to ensure patient and public safety. Judges are not educated by the Food and Drug Administration Regulators regarding what medications have black box warnings and what those warnings mean. Medical providers still switch wards of the court onto dangerous drugs in order to maximize profit, while at the same time claiming in court that the medication was still in the patient's best interest." Judges are not informed that the FDA had issued a medical safety alert and the need to watch carefully for medication switching. Wards of the court, had no informed consent and no right of refusal for this deliberate *color of official right* abuse of the court's power. This is medical experimentation using off-label drugs on wards of the court without informed consent. In addition, in the U.S.A. children in foster care are considered wards of the court and psychiatric medications are given to them without their informed consent.

In New Mexico, psychologists, who do not have medical training, and who have only completed a pharmaceutical industry training and certification program, are now permitted to prescribe these powerful psychotropic medications. Psychologists are trained to conduct psychological assessments and provide psychotherapy, not to provide medical treatment. 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. But right now in the U.S.A. persons without full medical training (certified nurse midwives, psychologists etc.) are routinely prescribing these drugs to wards of the court and getting paid kickbacks, bribes, and other incentives to do so.

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## III. CURRENT SITUATION

Mental health patients, those with a mental disability, foster children, prisoners and the elderly are very vulnerable to abuse and mistreatment. Survivor groups are forced to operate underground because of fear that their members will be victimized if their identities are revealed. This affects their ability to publicly advocate on behalf of their constituents and therefore further impedes access to justice.

Effective monitoring of complaints of torture, inhumane treatment and abuse is necessary to ensure accountability, yet there is no effective monitoring of guardianship cases and the treatment of wards of the court. Domestic mechanisms of accountability and redress, must be accessible, transparent and effective but in the U.S.A. the court system does not even know exactly how many persons are currently wards of the court and in guardianship. Wards of the court are clearly persons in detention who were deprived liberty by state action.

Medical Whistleblower Advocacy Network (MWAN) points out that the substituted decision makers, the “qualified health care providers,” are not chosen by the patient, but instead assigned to the patient by those in a position of power and authority. Medical practitioners sometimes treat persons with disabilities as objects of treatment rather than rights-holders and do not always seek their free and informed consent when it comes to treatments. These “qualified health care providers” are often directly chosen by those who are directly financially benefiting from the selected medical treatment and aligned with the abusers. The “qualified health care providers” are given quasi-governmental immunity for their health care decisions and protected under special insurance for medical malpractice liability.

In addition, since most current mental health treatment is considered the administration of psychiatric drugs, these “qualified health care providers” are often financially and politically protected by the pharmaceutical industry’s legal team and direct lobbying efforts to governmental officials including enforcement agencies. Qualified health care providers are often deceived by pharmaceutical marketing representatives into believing drug therapy is safer and more effective than it really is. Psychiatric drugs are often used off-label for uses that the FDA has not approved –essentially using the wards as scientific guinea pigs. The medical care by “qualified health care providers” is often profit driven, and is often done with little regard to human rights and civil liberties. The goal of such care is often coercion and control of the disabled person.

Wards of the court are forced into treatment against their wishes and without informed consent. Forced drugging can be considered a form of torture and yet it is widely practiced in the U.S.A. Psychiatric interventions can be enforced disappearances, often under the guise of emergency medical care where the victim is kept incognito from family and friends, while mental health staff force signatures on paperwork which effectively removes the right of others to legally intervene in what the medical establishment has planned.

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## IV. REVIEW OF HUMAN RIGHTS INVOLVED

### PROTECTION OF HUMAN SUBJECTS

The Nuremberg Code and the related Declaration of Helsinki<sup>14</sup> delineates what is considered ethical conduct for human subjects' research<sup>15</sup> and forms the basis for the US Code of Federal Regulations - Title 45 Volume 46 (The Common Rule). The United States Department of Health and Human Services (HHS) regulations 45 CFR part 46<sup>16</sup> 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.<sup>17</sup> 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.<sup>18</sup>

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,<sup>19</sup> the Helsinki Declaration of 1964 (revised in 1975),<sup>20</sup> and the 1971 Guidelines<sup>21</sup> (codified into Federal Regulations in 1974) issued by the U.S. Department of Health, Education. The Belmont Report<sup>22</sup> was written concerning the Ethical Principles and Guidelines for the protection of human subjects of research. 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.<sup>23</sup> The right to informed consent is delineated in the federal regulation Protection of Human Subjects, 45 CFR 46 also known as the Common Rule under the authority granted by the U.S. Department of Health and Human Services. There are also Welfare Codes for the conduct of social and behavioral research such as that published by the American Psychological Association in 1973.

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



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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.<sup>24</sup> 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.<sup>25 26</sup>  
27 28 29

## INFORMED CONSENT

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. 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. 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. 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

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.<sup>30 31</sup> 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.<sup>32</sup>

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.<sup>33</sup>

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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.

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.<sup>34</sup> 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.

Food and Drug Administration officials appear to be rubber-stamping approval of unsafe toxic drugs that increase risk of death and debilitating, irreversible adverse effects. One of the causes of this is FDA's increased financial dependence on user fees in order to finance its regulatory

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functions. This dramatically changed the FDA's mission from protecting the American public to instead supporting increasing marketing potential and pharmaceutical corporate profits.

### V. LACK OF EFFECTIVE, INDEPENDENT AND IMPARTIAL INVESTIGATIONS

MWAN was unable to identify any federal monitoring of complaints by wards of the court, regarding alleged incidents of torture, cruel, inhumane, and degrading treatment and psychiatric abuse. Instead individual complaints and those against private institutions or governmental subcontractors are handled at the state or local level.

#### THE HUMAN RIGHTS AND SPECIAL PROSECUTIONS SECTION (HRSP)

The Human Rights and Special Prosecutions Section (HRSP)<sup>35</sup> is a component of the Criminal Division of the U.S. Department of Justice (DOJ). HRSP's responsibilities including enforcing federal criminal laws relating to:

- Serious human rights violations such as torture, genocide, war crimes and use of child soldiers
- Immigration related offenses, particularly those involving human rights violators or smuggling networks connected with national security or transnational organized crime
- International violent crimes, particularly those involving U.S. government employees and contractors overseas.

HRSP prosecutes cases in partnership with the United States Attorneys' Offices. HRSP does not investigate instances of domestic torture and does not investigate individual cases of alleged abuse and mistreatment of wards of the court or prisoners residing in the U.S.A.

#### THE CIVIL RIGHTS OF INSTITUTIONALIZED PERSONS ACT (CRIPA)

MWAN is not aware of any cases of alleged psychiatric torture or forced drugging or involuntary electroshock treatment that were litigated under CRIPA. CRIPA does not investigate individual allegations of torture, cruel, inhumane and degrading treatment. In 2014 DOJ Disability Rights Cases (CRIPA) that are published on their website involved primarily cases of community integration or disability access under Title II of ADA. The emphasis is the rights of individuals with disabilities to receive services in their communities, rather than in institutions.<sup>36</sup>

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## CRIPA DOES NOT INVESTIGATE PRIVATE FACILITIES

Many U.S. facilities that house and provide medical treatment to wards of the court are private facilities or run by government sub-contractors.

## CRIPA DOES NOT INVESTIGATE INDIVIDUAL COMPLAINTS OF ABUSE AND MISTREATMENT

Although even one incidence of individual torture would constitute a violation of CAT, the DOJ does not represent individuals or address specific individual cases. CRIPA investigators are not trained to do Istanbul Protocol torture evaluations. The DOJ only investigates institutional, systemic problems and file lawsuits against facilities as a whole. There have been relatively few investigations and even less prosecutions of human rights violations of individual persons who are abused within psychiatric facilities and in outpatient treatment. This lack of prosecution does not mean that human rights abuses do not occur. The most serious human rights abuses occur behind closed doors and in secret.

## UNDER-REPORTING OF ABUSE

The isolated nature of institutions and the vulnerability of their residents combine to create environments ripe for abuse. In 2002 one and a half million Americans resided in 17,000 nursing homes, and 30 percent of those facilities had been cited for harming residents or placing them at risk of serious injury or death.<sup>37</sup> Studies suggest that 80 percent to 85 percent of abuse in institutions goes unreported.<sup>38</sup>

Abuse typically occurs behind closed doors. Residents and family members are often reluctant to report abuse for fear of reprisal. Many victims have no prior experience with the legal system and do not know how to proceed to defend their rights. In some cases, disabilities may interfere with residents' ability to ask for help or may lead caregivers to dismiss what residents say. Some persons with disabilities must rely on others to recognize that they are being abused and to take appropriate action to notify investigators from responsible agencies. Yet few family members, friends, and providers are adequately trained to recognize signs of abuse in individuals with developmental disabilities or mental disabilities and adequately assist victims to access the criminal justice and/or social service system.

Even if they want to report or stop the abuse, some individuals may not be able to formulate and execute a plan of response. Some victims may not be able to physically escape from an abusive environment. Other victims may not be able to travel to a police station to file a report. The insensitive attitudes of investigating officers may deter victims from coming forward or prevent them from pursuing a case. Communication difficulties frequently leads to frustration when officers taking the report cannot understand the victim.

Regardless of the type of disability or whether the abuse is emotional, physical, or sexual, people who provide care and support to individuals with disabilities are often the same people who victimize them – people the victims know and trust.<sup>39</sup> (Petersilia et al., 2001)

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## INTIMIDATION OF VICTIMS

Protection and security measures for victims is often inadequate and the abusers and their collaborators are routinely in charge of the victim's care. The perpetrators of abuse within a psychiatric institution are often doctors and medical professionals – persons that the patient is supposed to trust. The act of abuse is a betrayal of that trust. The relationship of confidentiality between them makes proceeding with a complaint even more difficult. Victims also suffer loss of personal medical privacy in order to receive any consideration of redress or reparations for harm.

Victims are re-traumatized through the process by being forced to recant over and over the circumstances of their abuse. The boomerang effect of making a complaint means that the victim finds himself penalized with more coercive and abusive measures against him/her for coming forward. For victims of psychiatric abuse, most of whom have been stripped of their legal rights and placed in financial conservatorship by the court, these are insurmountable obstacles to finding justice. So most victims suffer in silence.

Physicians for Human Rights has stated that patient autonomy should be respected and informed refusal from competent patients honored. Physicians treating patients must retain clinical autonomy which is essential to the establishment of trust, and clinical intervention should not be directed by non-clinical personnel in the chain of command. The physician's primary obligation “to do no harm” to the patient is honored. Medical intervention should never be used as punishment.<sup>40</sup>

## DIFFICULTY PROVING PSYCHIATRIC TORTURE ALLEGATIONS

Medical Whistleblower Advocacy Network (MWAN) found that organizations tasked with investigation of complaints routinely discounted any complaint that did not show long term physical harm to the patient. Psychiatric, emotional, psychological mistreatment was routinely ignored and rarely documented. Patients are presumed to be mentally ill and thus their perceptions of mental harm were discounted. This is in spite of mounting evidence that physical torture – although it leaves identifiable scars is not more damaging than psychological torture. Psychological torture can leave lifelong emotional scars and often victims never fully recover.<sup>41</sup>

U.S. investigators of alleged cases of psychiatric abuse have little or no experience with Istanbul Protocol. Forensic psychiatric evaluations are usually done with the intent of committing someone to an institution or forced outpatient commitment, not for the purpose of proving abuse. Organizations who claim to investigate complaints of mistreatment within psychiatric institutions, routinely work closely with those medical professionals who run those very same institutions and are biased toward forced psychiatry and thus work to protect the medical professionals from a malpractice lawsuit.

MWAN found that organizations would not take seriously the right to due process for mental patients or the right to informed consent. Obtaining medical documents to submit in evidence is difficult if not impossible for psychiatric patients. Psychiatric institutions routinely withhold medical documentation from patients and their families, making it difficult if not impossible to

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prove the abuse happened. Doctors and other medical staff are adept in writing medical records in such a manner as to pass blame onto the mental patient rather than themselves.

When corroboration of the victim's testimony is required, other mental patients do not make reliable or credible witnesses. Staff wish to protect their employment and thus side with medical providers.

## LACK OF HUMAN RIGHTS TRAINING OF INSTITUTION STAFF

The U.S.A. has provided education and training of all law enforcement or military personnel on how to identify signs of torture and cruel, inhuman or degrading treatment and instructed personnel on how to report such incidents. The US government also ensures specific training for all medical personnel dealing with military or prison detainees in the detection of signs of torture and ill-treatment and so that the Istanbul Protocol of 1999 becomes an integral part of the training provided to physicians and others involved in care.

In comparison, individual complaints alleging torture in psychiatric facilities are handled in house (usually the ombudsman within the psychiatric institution). Istanbul Protocol training is not currently done for physicians, staff and personnel involved in psychiatric institutions, mental health facilities and other places of psychiatric detention.

The persons responsible for determining whether torture has occurred are the "qualified health care providers" and staff of the institution. These are the same professionals involved in forcing compliance of patients with forced drugging and electroshock therapy. It is within the secret confines of such lock-up facilities that torture, cruel and degrading treatment occurs to those deemed to have psychiatric disabilities.

## VICTIM COMPLIANCE WITH ABUSERS (HEALTH CARE PROVIDERS)

The process of pursuing a complaint against psychiatric abusers is at best an extremely complex, expensive, and emotionally grueling legal process. Perpetrators of human rights violations deliberately choose victims that are compliant. This compliancy is further reinforced by a dependence on care givers and the relatively powerless relationship which exists between individuals with disabilities and their service providers. It is estimated that risk of abuse increases by 78% due to the vulnerability of people with developmental disabilities and their need for personal assistance services. In a survey of individuals with disabilities who had been abused, 96% of the cases involved perpetrators who were known to their victim. The largest group of offenders (44%) were individuals who had a relationship with the victim specifically because of their disability (27.7% disability service providers, 5.4% specialized transportation, 4.3% specialized foster parents and 6.5% other disabled individuals).<sup>42</sup> (Sobsey and Doe, 1991).

## CRIPA - LENGTHY INVESTIGATIONS

DOJ's work has been slow—even in cases involving egregious conditions such as imminent threats to life. It is not unusual for investigations to take many months to complete, and lawsuits

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often are not initiated for many more months thereafter. DOJ has sometimes found that it was denied access into institutions, and then must put additional pressure to gain access – this delays investigation, meanwhile the vulnerable psychiatric patient is threatened into silence, documentary evidence disappears, and additional documentation created by staff to prevent prosecution. DOJ has chosen not to enforce CRIPA in a strategic way to address inappropriate incarceration of individuals due to behavior that is manifested due to their disability.

## CRIPA CONCILIATION RATHER THAN LITIGATION

DOJ has a policy of avoiding litigation and focuses on conciliation as a means of achieving compliance. The DOJ must wait 49 days after issuing a findings letter before they can file a suit against an institution. Prior to filing suit, the DOJ must negotiate with institutions and so investigations and negotiations can last for years. CRIPA allows only for equitable relief as a remedy to any violations – such as getting an injunction to stop certain practices, being ordered to upgrade facilities or increasing the size of the staff. DOJ relies on general rather than specific remedies, and has increasingly accepted private, unenforceable agreements to resolve cases.

DOJ staff should file complaints promptly and use temporary restraining orders, preliminary injunctions, and other enforcement tools available while litigation is pending in order to protect vulnerable populations and correct dangerous conditions as quickly as possible. DOJ staff should insist on specific outcomes rather than more general policies and procedures to remedy violations and to guard against regression when monitoring ends.

## VI. BARRIERS TO ACCOUNTABILITY AND REDRESS

The reality of available legal redress and reparations is quite different than the stated US governmental policy. MWAN has spoken to numerous individuals who were mistreated in psychiatric care and who have never received an impartial review of the conditions of their detention, nor any apology or redress for torture, inhumane treatment or abuse. Neither has appropriate rehabilitation been provided to victims of psychiatric abuse, instead perpetrators are protected by quasi-governmental immunity for their actions which protects them from criminal investigation as well as civil liability.

## LACK OF JUDICIAL REVIEW OF GUARDIANSHIP CASES

There is no federal oversight of the state probate court system which does administration of guardianship cases. More and more foster children, disabled persons, and the elderly are being committed to a system of care which has little transparency or oversight. The exact number of persons who are wards of the court is unknown. Most courts cannot track even major case events such as a change in guardian status. There is no transparency for oversight of complaints regarding psychiatric torture, abuse, mistreatment and neglect. There is no centralized system to monitor a persons' care and well-being while in psychiatric detention or outpatient treatment. Judges of the court do not receive regular reports regarding the wards situation. Judges

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automatically assume that substituted decision makers and “qualified health care providers” are doing what is in the best interest of the ward. Victims are held in locked institutions under the control of their abusers.

There remains little accurate information of who is in guardianship and the quality and nature of their medical care. There are approximately 1.5 million active pending adult guardianship cases in the United States, according to the 2011 National Center for State Courts report *Adult Guardianships: A "Best Guess" National Estimate and the Momentum for Reform*. However numerous reports have shown that many state court administrative offices did not receive complete information on guardianship from trial courts. It is often impossible to determine whether the case is an adult guardianship or a conservatorship. There is a lack of statewide case management systems that can even identify key case events. Some states cannot distinguish between guardianships granted to children, incapacitated young adults, and elders. There were major difficulties tracking caseloads, as these cases can remain open for years and sometimes decades.<sup>43 44 45 46 47 48</sup>

## LACK OF COMMUNICATION BETWEEN FDA AND JUDGES

There is no direct communication between the Food and Drug Administration and the Judges that are court ordering the forced treatment of patients. Judges are not trained in understanding the serious and life threatening adverse events that can happen with these mind altering medications. Judges do not consult the physician instruction insert and carefully consider the implications for personal and public safety when there is a serious FDA black box warning on a pharmaceutical product. Judges are not educated on how these medications work in the brain, or what their therapeutic effects really are, and how they can be used, but also abused by care providers. Yet Judges routinely make legal decisions forcing these drugs on wards of the court. Judges do not directly receive notices of FDA safety alert warnings, nor are they notified when the FDA is considering pulling a medication off the market due to safety concerns and adverse events.

Therefore, when a psychiatric drug or other treatment is facing sanctions by the FDA, the pharmaceutical marketing representatives increase pressure and incentives for those “qualified health care providers” to expand the use of the medication on wards of the court. This maximizes profits to the pharmaceutical company, who often will lose customers in the general public because of the FDA warning announcements. Wards of the court cannot sue for malpractice and can be forcibly made to take medication in spite of their concerns and over the strident objections of their families. In addition, Medicaid and Medicare will continue, in spite of the FDA warning, to pay for uninterrupted drug treatment for wards of the court.

Judges make these forced drugging decisions in absence of the FDA regulatory agency’s advice and without consulting the FDA database regarding adverse events caused by the pharmaceutical product. Most Judges do not really know what “off-label” use really entails. Wards of the court are also court ordered into other kinds of treatment, such as electroshock therapy, with little



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proof of safety or efficacy, and with little regard for the human rights implications of such treatments.

Judges are also not informed directly about findings of the Office of Inspector General's Health and Human Services research findings that relate to force-drugging of the elderly and other vulnerable populations under guardianship.<sup>49</sup>

## LACK OF COMMAND RESPONSIBILITY

With force-drugging of wards of the court, Judges are ultimately in the position of command responsibility. Command responsibility may also rest with the supervisors of medical care and the medical treatment team. There is a lack of command responsibility. Judges often do not personally see the ward for hearings but instead meet with the guardian who presents the written finding of the health care providers and hospital psychiatrist. The prohibition against torture relates not only to public officials, such as law enforcement agents in the strictest sense, but may apply to doctors, health professionals and social workers, including those working in private hospitals, other institutions and detention centers. Judges do not adequately track the medical care given to the wards under their jurisdiction and often do not prevent or punish those who abuse the ward for financial gain.

Wards of the court can be neglected or even abused by the very persons empowered by the court to protect them – their own guardians and care givers. The judges of the court may fail to question the actions of the qualified health care providers or the guardian. Most persons in positions of responsibility within the medical establishment are protected by quasi-governmental immunity as well as medical malpractice insurance. Wards of the court have usually been stripped of their own legal right to appear in court – legal death.

## CRIPA -LACK OF COMMUNICATION TO THE US CONGRESS

The DOJ should improve its CRIPA enforcement reports to Congress by including the full range of data required under the statute. Currently annual reports do not always provide all the information the statute requires. For example: DOJ's annual reports do not quantify or qualify the conditions under which wards of the court are kept. DOJ's annual reports mention investigations launched with no tracking to indicate outcomes. A strong annual report would help leverage voluntary compliance and encourage people to report illegal conditions in institutions. A more strategic enforcement to proactively protect the rights of institutional residents would further the goals of Congress. Congress should also increase its oversight of DOJ's enforcement of CRIPA and ensure that DOJ has sufficient funding and other support to do its work.

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## LACK OF COORDINATION BETWEEN FEDERAL AGENCIES

There is a lack of coordination among federal agencies in regards to federal enforcement of disability rights. The Department of Justice may find serious violations but Health and Human Services (HHS) may still continue to fully fund the facility.

## CRIPA -LACK OF PUBLIC PUBLICATION OF DOJ FINDINGS

Institutions are resistant to change, they are entrenched organizations and it takes more than litigation to make them change policies and practices. Sunshine helps dispel darkness and when media exposes egregious violations, then institutions are more likely to reform. DOJ limits its effectiveness by using a narrow, traditional approach to law enforcement. Because the DOJ doesn't advertise investigations, it weakens its ability to gather information from people with relevant evidence. Remaining silent about its victories, the DOJ fails to maximize the deterrent effect of its work.

## VII. VULNERABLE POPULATIONS

### WARDS OF THE COURT

When the government steps in to make decisions for someone, it is called *Parens Patriae*, (parent of the nation.) In order for the government to be able to assert this right, it has to prove the person is incompetent to decide for him or herself. In addition, in order to be constitutional the court ordered drugging must be in the person's medical interest. Thus it may be questioned whether it is in the wards medical interest to be force-drugged with off-label drugs that have not been proven to be safe or effective.

In 1979, the United States Court of Appeals for the First Circuit established in *Rogers v. Okin* that a competent patient committed to a psychiatric hospital has the right to refuse treatment in non-emergency situations. The case of *Rennie v. Klein* established that an involuntarily committed individual has a constitutional right to refuse psychotropic medication without a court order. *Rogers v. Okin* established the patient's right to make treatment decisions. Additional U.S. Supreme Court decisions have added more restraints to involuntary commitment and treatment.  
50 51

Psychiatrists' predictions regarding "dangerousness" and the possibility of future violence are totally unreliable. Attorney James B. Gottstein JD estimated that no more 10% of involuntary commitments actually meet the legal standard for commitment.<sup>52</sup> The non-prisoner patient has more legal right to refuse force-drugging with off-label medications. In the *Faith Myers v Alaska Psychiatric Institute*<sup>53</sup> case ruling means doctors cannot force patients to take psychotropic, or mind-altering, drugs against their will unless a court "expressly finds by clear and convincing evidence that the proposed treatment is in the patient's best interests and no less

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intrusive alternative is available.” The Soteria study done by Dr. Loren Mosher, found that establishing a trusting relationship between the patient and the doctor meant that he never had to resort to involuntary commission of anyone. People diagnosed with serious mental illness are not any more dangerous than the general public. In reality, coercion (force) is very counterproductive and quite understandably increases, rather than decreases violence.

Wards of the court have assigned surrogate decision makers for both legal and medical decisions,<sup>54 55 56</sup> thus wards are prevented even from effective appeal to the Judge or even to their US Congressmen/Congresswomen.<sup>57</sup> 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—foster children, the disabled and elderly.<sup>58 59 60 61 62 63</sup>

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.<sup>64 65</sup> 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.<sup>66 67</sup> 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.<sup>68</sup> 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 apprised of the court proceedings until after emergency guardianship has been already established – thus depowering them to act as advocates for their family member.

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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.<sup>69</sup>

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. But Judges routinely 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.<sup>70</sup>

### PRISONERS AND DETAINEES

According to the 2004 federal Bureau of Justice Statistics (BJS) report, Mental Health Problems of Prison and Jail Inmates more than half of all prison and state inmates reported mental health problems. In 2011, there were 1,382,418 inmates in state prisons with approximately 15% of them (207,000) seriously mentally ill.<sup>71</sup> The numbers of mentally ill in the state prison population is five times greater (56%) than in the general adult population (11%). The number of individuals with serious mental illness in prisons and jails is now estimated to exceed the number in state psychiatric hospitals tenfold. The increase in the use of antipsychotics and antidepressants increased dramatically over the last 5 years with the largest cost going for off-label patented medications. Prisons distribute psychotropic medications to their inmates at an estimated cost to taxpayers of about \$9 billion annually.<sup>72</sup>

In the U.S.A. it is the belief of courts and correctional facilities that locking people up and drugging them against their will decrease the violent tendencies of the prisoner. However, since the advent of the massive use off-label use of neuroleptic medications on increasing numbers of

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mentally ill in prisons and jails, we have seen the severity of inmates' illnesses increase. It is well-established by scientific evidence that psychiatric drugs increase, rather than decrease violence.<sup>73</sup> These psychiatric drugs have a FDA black box warning labels that indicate that these drugs increase violent thoughts and suicidal ideation. In addition, medications forced on prisoners have long term effects on the brain and can cause chronic mental health problems, thus leading to a revolving door of release, re-offending and re-incarceration. When released, prisoners may suddenly go off their medications and this sudden withdrawal from psychiatric medications may also cause them to be violent or suicidal. There are numerous court cases which address prisoner rights and forcible medication.<sup>74 75</sup>

Once a person has been convicted of a crime and committed to a prison situation they have the least legal protection against forced drugging. Prisoners have a liberty interest, protected by the Fourteenth Amendment, in not being treated against their will. The extent of this liberty interest was defined in *Washington v. Harper*.<sup>76</sup> The court has routinely granted decision making power to the prison psychiatrist, who was to ensure that the prisoner was mentally ill and dangerous and the use of medication was appropriate. The court assumes that the prison psychiatrist has integrity as a medical professional and is serving the best interests of the prisoner and the needs of prison safety and security. Prisoners may not refuse testing or treatment for a condition that would threaten the health and safety of the prison community, including communicable diseases and treatable psychiatric conditions. Prisoners may also be forced to accept treatment that is necessary to protect their health from permanent injury. Prisoners with religious objections to medical treatment may be treated against these objections if the treatment is necessary to preserve prison discipline.

In addition, the reasoning that finds someone incompetent to decline medication or electroshock is often flawed – if the person agrees to take medication he/she is deemed competent but if alternatively he/she declines medication the person is incompetent. Force drugging on prisoners is also used to restore a prisoner to competency so that he can be competent to stand trial. This is because a defendant must be able to understand the nature of the charges and be able to assist his or her lawyer. So the argument to be able to put someone on trial for murder is considered to be an important enough governmental interest.<sup>77</sup>

Some prisoners do decide voluntarily to take off-label psychiatric medications, even knowing their lack of effectiveness and potential for harm. However, it is questionable whether a court can legitimately find by clear and convincing evidence that forcing someone to take off-label psychiatric medications labeled with the FDA black box warning, is actually in the patients best interest, especially under the preponderance of evidence standard. Yet in spite of that legal reasoning, prisoners are routinely forced to take off-label psychiatric drugs without their informed consent.

Immigration and Customs Enforcement (ICE) officials claim that Department of Homeland Security law enforcement personnel may not and do not prescribe or administer medication to detainees. ICE states that "Only trained and qualified medical professionals, including officers of the U.S. Public Health Service, may prescribe or administer medication." Officials say doctors say they are required to see patients in person before such drugs are administered.

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But there is a pattern of the use of powerful mind altering drugs on persons in immigration detention. There are no records maintained by ICE relating to whether the psychiatric drugs used are FDA approved for that use. Many of the newer patented injectable drugs are used off-label without FDA approval in the U.S.A. Federal officials have seldom acknowledged publicly that they sedate people for deportation. Official statements indicate that such drugging is rare and an act of last resort and used for sedation only if the person has a mental illness requiring the drugs, or if he/she is so aggressive that they imperil themselves or people around them. But first person reports and other documents show that the U.S. government during deportation has injected hundreds of foreigners with dangerous psychotropic drugs against their will. Sometimes this force drugging with a "pre-flight cocktail" was to keep them sedated during the trip back to their home country. The use of forced antipsychotic drugs has been documented on people who have no history of mental illness.<sup>78</sup> Involuntary chemical restraint of detainees is only supposed to be used if there is a medical justification. However, multiple cases have shown that this practice is continuing and is not rare. In 2007 Sen. Joe Lieberman, from Connecticut brought up the concern of psychiatric drugs used on deportees in violation of Immigration and Customs Enforcement's own rules.<sup>79</sup> He voiced his concerns during the re-nomination hearing of Immigration and Customs Enforcement (ICE) chief Julie Myers. Myers admitted to the US Congress that 56 immigration detainees received psychotropic medications during the removal process. One of the drugs in question was the potent anti-psychotic drug Haldol, which is often used to treat schizophrenia or other mental illnesses. It is an extremely potent and powerful chemical restraint agent capable of totally incapacitating an adult person.

## CHILDREN AND YOUTH

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.<sup>80</sup> 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. Over 510,000 American children are in foster care,<sup>81</sup> taken away when their families are in crisis and when families are unable to care for them. Coming from backgrounds of abuse and trauma, these emotionally vulnerable young people are exposed to physical, emotional, psychological and sexual abuse often occurs in youth psychiatric facilities. U.S. institutions are often overcrowded, poorly maintained. This is both unjust and discriminatory. Often these

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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.

Food and Drug Administration (FDA) “approved” means that the FDA has reviewed limited data on safety and efficacy for a drug for one indication, usually in one population. Most psychotropic medication classes lack scientific evidence of their efficacy or safety in children and youth.<sup>82 83 84 85 86</sup> Fewer than 10% of psychotropic drugs are FDA-approved for any psychiatric use in children.<sup>87</sup>

Almost all psychiatric drugs have been shown to cause brain damage in the form of abnormal cell growth, cell death and other detrimental effects, which is especially harmful for growing and developing children and youth.<sup>88</sup> Psychotropic drugs given to children and youth cause drug-induced adverse effects and behavioral changes, including apathy, agitation, aggression, mania, suicidal ideation and psychosis, known as "behavioral toxicity."<sup>89</sup> Psychotropic drugs given to children and youth suppress learning and cognition and produce cognitive neurotoxicity, interfering with the basic mental development of the child, which adverse effects often do not go away after the drugs are withdrawn.<sup>90 91</sup>

There is a disproportionate representation of African-American children placed in Child Protective Services foster care. It was found in one study that African-American children had 44% higher odds of foster care placement when compared with Caucasian children.<sup>92</sup> Thus African-American children in foster care are routinely force drugged, often with multiple medications and in a manner detrimental to their health.<sup>93 94</sup>

More than 10.5 million children in the United States will spend some time in foster care.<sup>95</sup> Every year, approximately 18,000 youth will emancipate or "age-out" of the foster care system when they reach age 18 or finish high school. 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. Unfortunately, while in foster care youth frequently do not receive adequate help for them to successfully complete high school, find employment, access health care, get continued educational opportunities, and obtain housing and transitional living arrangements. Studies of youth who have left foster care have shown they are more likely than those in the general population to not finish high school, be unemployed, and be dependent on public assistance. Many end up homeless. According to the US Department of Health and Human Services, 287,691 children exited foster care in 2006,<sup>96</sup> (16%) left to live with relatives (some through guardianships).

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.<sup>97 98</sup> It is estimated that over 8 million children are drugged in the U.S.A. with 1,300 deaths due to this practice.<sup>99</sup>

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## 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.

The prevalence of mental disorders is estimated to be higher among African Americans than among whites. However this difference does not appear to be due to intrinsic differences between the races; rather, it appears to be due to socioeconomic differences. It is the lower socioeconomic status of African Americans that places them at higher risk for mental disorders.<sup>100</sup>

African Americans are more likely than whites to use the emergency room for mental health problems. Their overreliance on emergency care for mental health problems is an extension of their overreliance on emergency care for other health problems.<sup>101</sup> The practice of using the emergency room for routine care is generally attributed to a lack of health care providers in the community willing to offer routine treatment to people without insurance. 20% of African Americans are uninsured. Thus African Americans are least likely to have a long-term continuous doctor-patient relationship with a medical doctor they trust. African Americans were less likely than others to have received treatment that conformed to recommended practices.

African Americans' poverty and deep-poverty rates are higher than those of Whites, and African Americans' poverty spells last longer. Furthermore, non-poor African Americans are especially likely to slip into poverty, and over the course of a lifetime, very many African Americans will experience poverty. Accordingly, African Americans are disproportionately likely to be assisted by safety net programs providing income support and health and social assistance.<sup>102</sup> Thus they are less likely to have free choice in their care and more likely to be coerced into programs that provide the greatest financial support to the health care providers. African Americans are also overrepresented among persons undergoing involuntary civil commitment.<sup>103 104</sup> African Americans are also overrepresented in the prison population.

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



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and Asians have slower metabolic rates compared with Caucasians. Many health care providers were not aware of this and thus commonly over dosed these populations. 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)<sup>105</sup> But an awareness of this problem is necessary and need to be vigilant to make sure there are proper reductions in the medications for these ethnic groups

Latinos make up about 15% of the U.S. population and are the fastest growing minority – expected to make up nearly one-fourth of the population by 2050. Nationally, 33% of Hispanics are uninsured, compared to 16% percent of all Americans and 11% White/Non-Hispanic are uninsured.(U.S. Census 2008) This is the main reason that this group is not using expensive off-label psychiatric drugs. The pharmaceutical industry is targeting this group as a new customer base for off-label psychiatric products. Estimates of the use of alternative and complementary therapies by Hispanic Americans have ranged from 7 to 44%.<sup>106</sup>

### 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."<sup>107 108 109</sup>

In the US, a veteran dies by suicide every 80 minutes, 18 a day, or 6,500 suicides a year.<sup>110</sup> Many of these veterans are taking off-label psychiatric drugs which carry a FDA black box warning that the drug increases the risk of suicide. Suicide occurs at alarmingly high levels among Native American veterans and post-traumatic stress disorder has been identified as especially prevalent in Native American veterans as compared to whites.

Dr. Peter Breggin MD warns that the newer antidepressants frequently cause suicide, violence, and manic-like symptoms of activation or overstimulation, presenting serious hazards to active-duty soldiers who carry weapons under stressful conditions. Dr. Breggin recommends that antidepressants should not be prescribed to soldiers during or after deployment. The symptoms induced by antidepressants can mimic posttraumatic stress disorder and are likely to worsen this common disorder in soldiers, increasing the hazard when they are prescribed to military personnel.<sup>111</sup>

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## VIII. REVIEW OF PSYCHIATRIC DRUGGING

### EFFECTS OF PSYCHIATRIC MEDICATIONS

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.

However 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.<sup>112</sup> 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.

### ADVERSE EFFECTS OF NEUROLEPTIC/ANTI-PSYCHOTIC 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, neuroleptic 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.

These drugs, over time, produce these results:

- They increase the likelihood that a person will become chronically ill.
- They cause a host of debilitating side effects and dramatically decrease recovery.

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- They lead to early death.
- They increase rather than decrease violence

Some of the serious, debilitating and sometimes fatal side effects of psychiatric medications include:

- Parkinson's disease
- Serotonin Syndrome
- Neuroleptic Malignant Syndrome
- Neuroleptic Induced Deficit Syndrome:
- Tardive Dyskinesia
- SSRI Discontinuation Syndrome
- Serotonin Syndrome
- Tardive Dysmetria and Tardive Psychosis
- Neuroleptic Induced Deficit Syndrome
- White blood cell abnormalities
- Acute Closed Angle Glaucoma
- Hyperglycemia and Diabetes Mellitus
- Seizures
- Cognitive Dysfunction

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.<sup>113 114 115 116 117</sup> 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.<sup>118</sup> 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.

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In the late 1970's, akathisia was formally recognized and known to be a predisposing factor to violence. (Keckich 1978) 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. 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. This is why these medications carry a Food and Drug Administration black box warning label stating that they can cause violent thoughts, actions and

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.

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.

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.<sup>119 120</sup>

There is a lot of research that indicates that there is decreased life expectancy for persons taking neuroleptic medication.<sup>121</sup> 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).<sup>122</sup> 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.<sup>123</sup> 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.<sup>124</sup> "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

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welfare system.<sup>125</sup> 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.<sup>126 127 128</sup> 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.<sup>129</sup> "Off-label" use of anti-psychotic medications is common, particularly among the elderly and children/adolescents.<sup>130</sup> Because funding for FDA regulatory operations is tied to user fees paid by the pharmaceutical industry, profits in that industry are directly related to the FDA budget.

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.<sup>131</sup>

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)<sup>132</sup>

The Food and Drug Administration (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.<sup>133</sup>

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## OFF-LABEL PROMOTION/DECEPTIVE MARKETING OF PSYCHIATRIC DRUGS

The practice of marketing drugs for purposes not backed by science is called “off-label promotion.”<sup>134 135 136 137 138</sup> 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 for which it is prescribed. 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)<sup>139 140 141</sup>

This antipsychotic drug, Risperdal costs 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).<sup>142 143 144</sup> 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.<sup>145 146 147</sup> Research studies delineating concerns for the newer drugs’ safety and efficacy were suppressed.<sup>148</sup> 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. So 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. Janssen promoted its long-acting version of Risperdal–Consta injectable to be recommended in the Texas Medical Algorithm Project (TMAP). (Rosenheck et al 2011)<sup>149</sup> 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.<sup>150 151 152</sup> Among the many marketing strategies used by the pharmaceutical industry are: 1) One-to-one detail marketing to doctors and

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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.<sup>153 154 155</sup>

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.

In addition, pharmaceutical companies are now offering free or low cost advanced digital record computer software to prospective researchers and clinicians who agree to share with them personal confidential medical information of patients. When the patient enters the medical office they are given a survey on a computer input device. These computer surveys are designed to make the patient provide the doctor the legal right to share their digital medical information with corporate partners. By not allowing patients to write their own statement on the form, opt out of questions, or refuse to answer inappropriate questioning – the computer input device gets around HIPPA protections and helps force patient compliance with pharmaceutical marketing objectives and providing data desired. The pharmaceutical industry maintains a large database of private confidential patient medical information gathered from its corporate partners - cooperating researchers, doctors, nurses, and pharmacists. Social workers are also financially rewarded for providing confidential information about their clients to pharmaceutical industry representatives.

### 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.

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## 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.<sup>156</sup> 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.<sup>157</sup> 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.



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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 health care providers. 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) <sup>158 159</sup> 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

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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.<sup>160</sup>

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 J 2011)

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.<sup>161</sup> 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 2011)<sup>162 163 164</sup>

## 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 (me too drugs).

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"

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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. <sup>165 166 167 168</sup>

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* <sup>169</sup> 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.

## IX. LACK OF APPROPRIATE REHABILITATION PROGRAMS FOR VICTIMS OF TORTURE AND ILL-TREATMENT

The CAT Committee in 2012 stated that “*The USA should ensure that appropriate rehabilitation programmes are provided to all victims of torture and ill-treatment, including medical and psychological assistance.*”<sup>170</sup> Medical Whistleblower Advocacy Network recently attended the National Consortium of Torture Treatment Programs (NCTTP) in Washington DC March 4, 2015. The NCTTP estimates that there are between 600,000 to 1,200,000 torture survivors who were tortured by foreign governments and who now live in the U.S.A. The NCTTP has currently established 24 torture rehabilitation programs in 17 states that serve persons tortured by foreign governments – these programs serve refugees, asylum seekers and those who were granted asylum in the U.S.A.

Current torture survivor programs run primarily with pro-bono legal and medical services and do not provide services to U.S. citizens. There are no established rehabilitation programs for victims of torture and ill-treatment that are U.S. citizens and who were abused on U.S. soil. U.S. victims of psychiatric torture and abuse still need safe havens in which to obtain needed medical and psychological assistance.

Most established U.S. mental health programs emphasize forced drugging with psychiatric drugs as mental health treatment, and in some states even support the use of electroshock and even

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psychosurgery. Survivors of psychiatric torture therefore avoid the U.S. mental health system and have established a network of those willing to provide help and assistance to those traumatized by forced drugging and electroshock therapy. These services are sparse and inadequate for the needs of these much traumatized individuals and sympathetic MD doctors are critically needed by psychiatric abuse survivors.

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<sup>1</sup> 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].

<sup>2</sup> 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.

<sup>3</sup> Leonnig, Carol D., Lena H. Sun and Sarah Cohen. (2003) "Misplaced Trust: Special Report." The Washington Post (June 15-16, 2003).

<sup>4</sup> Fields, Robin; Larrubia, Evelyn and Leonard, Jack. (2005) "Guardians for Profit." Los Angeles Times (November 13-16, 2005).

<sup>5</sup> 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.

<sup>6</sup> Wood, Erica F. (2006) "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.

<sup>7</sup> Yeoman, Barry. (2004) "Stolen Lives." AARP: The Magazine (January-February 2004).

<sup>8</sup> Jones, Allen. (2004) "TMAP Critique," January 20, 2004, PschRights.org, (see: <http://psychrights.org/Drugs/AllenJonesTMAPJanuary20.pdf>).

<sup>9</sup> 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.

<sup>10</sup> Jones, Allen, (2004) "Introduction to the documents on Big Pharma Corruption in Research & Clinical Trials," Revised January 20, 2004, The Law Project for Psychiatric Rights, (see <http://psychrights.org/>)

<sup>11</sup> Jackson, Grace E., MD, (2004) "What Doctors May Not Tell You About Psychiatric Drugs" Public Lecture, UCE Birmingham June 2004.

<sup>12</sup> 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.

<sup>13</sup> Jackson, Grace E. (2005) "Rethinking Psychiatric Drugs: A Guide for Informed Consent." Bloomington, IN: Author House. ISBN-13: 978-1420867428, ISBN-10: 1420867423.

<sup>14</sup> World Medical Association Declaration Of Helsinki.

<sup>15</sup> The Belmont Report Ethical Principles and Guidelines for the Protection of Human Subjects of Research.

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<sup>16</sup> Human Subjects Guidance by Health and Human Services, (see:<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>).

<sup>17</sup> In re *Cincinnati Radiation Litigation*, 874 F. Supp. 796 (S.D. Ohio, 1995), at 810-811, stating “[t]he right to be free of state-sponsored invasion of a person's bodily integrity is protected by the [constitutional] guarantee of due process.”

<sup>18</sup> See 21 U.S.C. 355 (i.) (4) and 360j (g) (3) (D).

<sup>19</sup> Nuremberg Code Directives for Human Experimentation.

<sup>20</sup> World Medical Association Declaration Of Helsinki.

<sup>21</sup> Health and Human Services – Human Subjects Guidance, (see: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html> ).

<sup>22</sup> The Belmont Report Ethical Principles and Guidelines for the Protection of Human Subjects of Research.

<sup>23</sup> Guidelines for Conduct of Research Involving Human Subjects at NIH.

<sup>24</sup> The Tuskegee Syphilis Experiment and the unethical use of human subjects was the reason for the National Research Act (1974).

<sup>25</sup> *Mills v. Rogers*, 457 U.S. 291, 299 (1982).

<sup>26</sup> *Rennie v. Klein*, 476 F. Supp. 1294, 1313 (D.N.J. 1979).

<sup>27</sup> *Brandt v. Monte*, 626 F. Supp.2d 469, 486 (D.N.J. 2009) (citing *Rochin v. California*, 342 U.S. 165, 172-74 (1952)).

<sup>28</sup> *Mills*, 457 U.S. at 293 n.1, and “alter the chemical balance in a patient’s brain, leading to changes in his or her cognitive processes.” *Harper*, 494 U.S. at 229.

<sup>29</sup> *Scott v. Plante*, 532 F.2d 939, 946 (3d Cir. 1976).

<sup>30</sup> *Addington v. Texas*, 441 U.S. 418 (1979) (civil commitment).

<sup>31</sup> *U.S. v. Sell*, *Riggins v. Nevada*, 504 U.S. 97 (1992).

<sup>32</sup> See U.N. Doc. A/63/175 (2008), particularly paragraphs 40, 44, 47, 49, 50, 61-65, 73-74.

<sup>33</sup> *Meador v. Stahler and Gheridian* (Middlesex Superior Court C.A. No. 88-6450, Mass. 1993).

<sup>34</sup> Jackson, G.R., (2005). *Rethinking psychiatric drugs: A guide to informed consent*. Bloomington, IN: Author House.

<sup>35</sup> The Human Rights and Special Prosecution Section of the U.S. Department of Justice Criminal Division, Kathleen O’Connor, Keeney Building, Suite 200, 950 Pennsylvania Ave. NW, Washington, D.C. 20530-0001, 1-800-813-5863.

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<sup>36</sup> CRIPA cases in 2014 in Alabama, Delaware, District of Columbia, Georgia, New Jersey, New Hampshire, Oregon, Pennsylvania and Virginia. *Alabama Disabilities Advocacy Program v. SafetyNet Youth, Inc. et al.*, Delaware Mental Health System, District of Columbia - *Evans & United States v. Williams*, Georgia State Hospitals and Georgia Mental Health and Developmental Disabilities Systems, New Hampshire Mental Health System, New Jersey - *Sciarrillo v. Christie*, Oregon State Hospital and Mental Health System, Virginia System for Serving People with Developmental Disabilities, and *Smith v. Department of Public Welfare of the Commonwealth of Pennsylvania*.

<sup>37</sup> Testimony of Leslie G. Aronovitz before the Senate Special Committee on Aging, March 4, 2002. Aronovitz is the director of Health Care—Program Administration and Integrity Issues, Government Accounting Office.

<sup>38</sup> California Protection and Advocacy, Inc., State Council on Developmental Disabilities, USC University Affiliated Program, The Tarjan Center for Developmental Disabilities, UCLA, “Abuse and Neglect of Adults with Developmental Disabilities: A Public Health Priority for the State of California,” August 2003. The report is available at [www.pai-ca.org/pubs/701901.pdf](http://www.pai-ca.org/pubs/701901.pdf).

<sup>39</sup> Petersilia, J., Foote, J., & Crowell, N.A. (Eds.) (2001). *Crime Victims with Developmental Disabilities: Report of a Workshop*. Washington D.C. National Academy Press.

<sup>40</sup> Physicians for Human Rights (PHR) 2011, 256 W 38th Street, 9th Floor, New York, NY 10018 // Tel 646.564.3720 // Fax 646.564.3750, 185 Devonshire Street, Suite M102, Boston, MA 02110 // Tel 617.301.4200 // Fax 617.301.4250, 1110 Vermont Avenue, NW, 5th Floor, Washington DC 20005 // Tel 202.728.5335 // Fax 202.728.3053 – (See more at: <http://physiciansforhumanrights.org/issues/torture/us-torture/background.html>).

<sup>41</sup> Physicians for Human Rights, (2005) “Break Them Down, Systematic Use of Psychological Torture by US Forces” by Gretchen Borchelt, JD May 2005. Psychologically abusive methods of interrogation were at the core of US intelligence gathering. (See more at: <http://physiciansforhumanrights.org/library/reports/us-torture-break-them-down-2005.html> ).

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