Medical Whistleblower Advocacy Network

Medical Disability, The Common Rule, and the ICCPR

Submission to the United Nations Universal Periodic Review of
United States of America
Third Cycle
Thirty Sixth Session of the UPR
Human Rights Council
May 2020

Submitted by:
Medical Whistleblower Advocacy Network
P.O. Box 4270
Washington, DC 20015
Contact Name: Dr. Janet Parker DVM
Email: MedicalWhistleblower@gmail.com

Medical Whistleblower Advocacy Network (MWAN) acts as a grassroots advocate for human rights for disabled persons and other individuals. MWAN provides information, referrals, and also direct human rights defender advocacy services. MWAN has allowed victims of human rights violations to directly tell their own stories, assisting them when necessary with their time lines, helping them access documents, and doing research and analysis of their situations. MWAN also works with other NGO organizations to advocate for the rights of the disabled and promote the protection of human rights.

I. Introduction : Threatened Deportation of Persons with Medical Deferred-action Cases

1. The Trump Administration suddenly decided on August 7, 2019 to revoke or modify procedures that have allowed certain immigrants to remain in the United States on humanitarian grounds including ethical considerations related to The Common Rule and the ICCPR. U.S. Citizenship and Immigration Service (USCIS) mailed notices saying the agency will no longer consider most deferrals of deportation for people with serious medical conditions. There was no public announcement of this policy change and thus no chance for public comment. The U.S. Congress was also not informed prior to the policy change.

2. The United States Citizenship and Immigration Services has now altered the medical "deferred action" policy which permitted immigrants with medical needs to avoid deportation while they or their relatives were undergoing lifesaving medical treatment. USCIS receives

about 1,000 deferred-action applications related to medical issues each year. Some of the cases were immigrants who were participants as human subjects in important medical research and thus subject to human rights protections under The Common Rule. One immigrant was a human subject in research on a very rare genetic disease called Maroteaux-Lamy Syndrome, also known as Mucopolysaccharidosis Type 6 (MPS-VI). This USCIS policy change affects the most vulnerable immigrants, patients who would die without their life-saving treatment, children being treated for cystic fibrosis, sickle-cell anemia, heart defects, spina bifida, neuromuscular disease, respiratory distress syndrome, cancer and other medical conditions. The deferred action policy also was applied to crime victims who have helped law enforcement, [i] [ii] and caretakers or relatives of sick children to remain in the U.S.A. Women can also apply for deferred-action based on the Violence Against Women Act. [iii] DACA or Deferred Action for Childhood Arrivals which was announced by President Barack Obama in 2012, is another form of deferred action. [iv]

3. According to the U.S. Citizenship & Immigration Services (USCIS), "deferred action" is a discretionary decision to temporarily postpone the removal from the United States of a person who is illegally present. [v] [vi] [vii] In the deferred action cases determinations are made by the Department of Homeland Security on a case-by-case basis. Medical Deferred-action cases are granted on a case-by-case humanitarian grounds. [viii] Discretionary decisions are to be based on the totality of the evidence and circumstances. [ix] Such cases had been decided based on the discretion of career USCIS employees, including, but not limited to considerations similar to the Department of State's consideration of B-2 visas, when such visas are requested for medical purposes. [x] Deferred action does not grant an alien lawful immigration status, nor does it excuse any past or future periods of unlawful presence.

4. On August 7, 2019 the U.S. Citizenship and Immigration Services (USCIS) began notifying individuals that they no longer were considered a deferred action case and they needed to leave the U.S.A. within 33 days. For many of these immigrants, deportation would be life endangering, as the medical treatment they need is not available in their home country. According to the recent USCIS notice, deferred action requests would now be processed by U.S. Immigration and Customs Enforcement (ICE) in the future. This change in the procedure would mean that an individual seeking deferred action would have to go through full removal proceedings and receive an order of removal, before being considered for deferred action.

5The Trump administrations Executive Orders and DHS fact sheets have expanded enforcement priorities. The new orders have not delineated humanitarian factors to be considered for deferred-action cases.[xi] [xii] Thus, immigrants who received deportation notices had little faith that ICE would process their applications with the same compassion or proper humanitarian consideration as USCIS. Unfortunately, there is no appeals process for a decision to deny or terminate deferred action. On September 19, 2019, because of pressure by U.S. Congress members,[xiii] and the public, the Trump administration announced that it would reinstate the policy of granting temporary reprieve from deportation for immigrants facing life-threatening medical conditions and other humanitarian circumstances. USCIS confirmed that it would "revert" to the adjudication guidelines that had been in place on August 6, 2019. A USCIS official also said the agency had already reopened about 400 petitions it had denied this summer. But immigrants and their families still wait anxiously for further notice of whether their loved one will be deported.

II. Legal Basis

6. 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 International Covenant on Civil and Political Rights covenant was adopted in1966 and put in force in 1976, and is monitored by the United Nations Human Rights Committee. The ICCPR is part of the International Bill of Rights. Article 7 of the International Covenant on Civil and Political Rights, [xiv] states **"**no one shall be subjected without his free consent to medical or scientific experimentation."

7. The International Ethical Guidelines for Biomedical Research Involving Human Subjects, promulgated by the Council for International Organizations of Medical Sciences, define how the principles of the Declaration of Helsinki can be applied to human subjects of medical research.

8. Human subject research includes experiments and observational studies in basic biology, clinical medicine, nursing, psychology, and all other social sciences. The Congress of the United States of America ratified the ICCPR including Article 7. The United States Congress has also implemented Article 7 of the ICCPR in domestic legislation to protect human subjects from non-consensual experimentation – The Common Rule (45 CFR Part 46). The United States Congress clearly intended to protect human subjects by the following actions 1) Ratifying the ICCPR (including Article 7), 2) Holding extensive discussions regarding the ethical need for human subjects protections, 3) Publishing The Belmont Report and 4) Legislating The Common Rule.

9. The Convention on the Rights of Persons with Disabilities (CRPD) was signed by the President of the United States, Barack Obama.[xv] The UN Convention on the Rights of Persons with Disabilities was adopted to promote, protect, and ensure the full and enjoyment of human rights and fundamental freedoms by all persons with disabilities and to promote respect for their inherent dignity. Article 12 of the CRPD affirms the equal recognition before the law and legal capacity of the persons with disabilities. Article 13 of the CRPD affirms the effective access to justice for persons with disabilities. Article 25 specifies that "persons with disabilities have the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability." The Convention on the Rights of Persons with Disabilities (CRPD) also protects the integrity of the person. Article 17 of the CRPD states that every person with disabilities has a right to respect for his or her physical and mental integrity on an equal basis with others.

III. Background/ U.S. Compliance

10.On July 12, 1974, the United States National Research Act (Pub. L. 93-348) was signed into law, there-by creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider: 1) the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, 2) the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human

subjects, 3) appropriate guidelines for the selection of human subjects for participation in such research and 4) the nature and definition of informed consent in various research settings.
11.
11. The Belmont Report (1976) [xvi] is a formal statement by the United States government regarding the ethical standards and accepted legal norms regarding the use of human subjects in medical, behavioral or scientific experimentation. The Belmont Report, which took nearly 4 years of deliberations, summarizes the basic ethical principles for research with human subjects. It is a statement of basic ethical principles and guidelines to consider in the use of human subjects in research. It was published in the U.S. Federal Register so it could become ethical guidance for U.S. researchers, scientists, governmental employees and Institutional Review Boards (IRB).

12. The Belmont Report identifies three basic ethical principles that are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence and justice 1) The **Principle of Respect** for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy. 2) The **Principle of Beneficence** means that persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. 3) The **Principle of Justice** demands that the advantages of the medical research not only be available to those who can afford them, but that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent benefits of the research. Unfortunately, the burdens of serving as research subjects has historically fallen largely upon poor, socially disadvantaged groups like prisoners, welfare patients, institutionalized patients, and racial and ethnic minorities. This may be because of their easy availability, their compromised position, or their ability to be manipulated. The benefits of the research and improved medical care flowed to the higher economic status patients. Those who participate in the medical research and bear the burden of potential harm have the right to benefit from the new medical treatments and improved medical care made possible by their volunteering. An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly.

13. The United States has accepted ethical standards related to scientific or medical experimentation on human subjects and our moral obligations to human subjects by promulgating federal laws – The Common Rule – "The Federal Policy for the Protection of Human Subjects." The Common Rule (45 CFR Part 46) was adopted in 1991. 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.

14. Medical practice is meant to enhance the well-being of an individual patient or client and is expected to have a reasonable expectation of success. The first rule of medicine is Do No Harm. Within clinical medical practice, physicians are ethically required to obtain free prior informed consent for any treatment. Free prior informed consent for treatment is especially important when a clinician departs in any significant way from standard or accepted practice,

or utilizes a medication that the FDA has not approved for that use. Failure to obtain proper and legal free, prior and informed consent is considered medical malpractice. The process of obtaining consent must involve three elements: information, comprehension and voluntariness. Consent obtained by deceit, misinformation, or coercion is not legally valid. Information supplied in English to a patient whose only language is Spanish does not comply with the comprehension aspect of informed consent. Providing information only in very detailed scientific terminology that is not understood by lay person, is also not complying with the comprehension aspect of informed consent. Without free prior informed consent, experimental treatment on human subjects is prohibited by U.S. law. Thus, it is the responsibility of medical practice committees to demand that the ethical principles of the Belmont Report are applied and human rights of patients are protected.

15. Unfortunately there has been a pattern of discrimination towards vulnerable populations worldwide being utilized for medical experimentation by U.S. researchers. Beginning in 1946, the United States government conducted medical research on more than 5000 uninformed and unconsenting Guatemalan people who were intentionally infected with bacteria that cause sexually transmitted diseases. [xvii] [xviii] [xix] [xx] Many have been left untreated to the present day. [xxi] [xxii] The researchers knew of the harms that they caused. Although the US Presidential Commission for the Study of Bioethical Issues found the Guatemalan experiments morally wrong, little if anything has been done to compensate the victims and their families. [xxiii] [xxiv] U.S. President Barack Obama apologized in 2010. [xxv] The Guatemalan government issued a separate report, *Consentir el Daño: Experimentos Médicos de Estados Unidos en Guatemala* (To Agree to the Harm: Medical Experiments by the United States in Guatemala), which went beyond the US reports to state that the experiments were "a crime against humanity" and that racism and discrimination were present throughout the experiments in an explicit and conscious way. [xxvi]

16. It is a violation of the principle of U.S. Justice to discriminate against persons based on their race, color, national origin, or socioeconomic position. [xxvii] [xxviii] This is especially important when research deals with minority and medically vulnerable populations, such as are necessary for medical research into rare diseases. [xxix] These medically needy individuals are clearly unique, thus the possible harm of the medical experimentation weighs more heavily on them than on persons in the general population. Individuals who volunteer with informed consent to participate in medical research should be afforded care after the experiment is over, otherwise the use of them as human subjects is just exploitative, and certainly is a violation of both U.S. law and international human rights standards. [xxx] [xxxi]

17. The Trump administrations goal of deporting persons who had previously been granted medically deferred-action status prevents those vulnerable patients the right to the continuation of their experimental medical treatment. It constitutes the use of a particular group of medically vulnerable persons as human subjects, without consideration of their welfare, and thus violates substantive human rights and procedural norms.

18. Under the Principle of Justice, if you bring immigrants to the United States so that they can become human subjects in a medical research program, those same immigrants should be afforded equal protection under U.S. law as human subjects. It is the ethical obligation of the

United States, as a nation state, to prevent the exploitation of human subjects for medical experimentation and to ensure that human rights values are maintained for those patients brave enough to participate in a medical research program. The Trump Administrations hasty decision to deport patients currently under treatment by medical research programs is a violation of The Common Rule. The threatened deportation order disregarded the ethical values contained in The Belmont Report.

IV. Recommendations:

19. The U.S. Citizenship and Immigration Services ("USCIS") should continue to process deferred action cases for these vulnerable persons.

20. The administration processes should be more transparent, so that vulnerable immigrants, patients and their advocates know how to advocate for their human rights.

21. The U.S.A. should honor the ethical, moral and human rights values stated in the ICCPR (Article 6 & 7), The Common Rule and the Belmont Report.

VI Conclusions:

22. In the U.S. Presidential Commission for the Study of Bioethical Issues its *Ethically Impossible* report [xxxii] addressing the Guatemalan experiments, the Commission expressed the need to be ever vigilant to ensure that such reprehensible exploitation of our fellow human beings is never repeated. As such, it is critical to adopt legal and ethical reforms to provide treatment and compensation for individuals involved in improperly conducted human experiments, waive sovereign immunity for federally funded human research in the United States and abroad, ensure that parallel protections apply to privately funded research, and respect autonomy and equality for all.

---

[i] U.S. Citizenship and Immigration Services, Victims of Criminal Activity: U Nonimmigrant Status (June 12, 2018), https://www.uscis.gov/humanitarian/victims-human-trafficking-other-crimes/victims-criminal-activity-u-nonimmigrant-status/victims-criminal-activity-u-nonimmigrant-status

[ii] U.S. Citizenship and Immigration Services, Victims of Human Trafficking: T Nonimmigrant status (May 10, 2018), https://www.uscis.gov/humanitarian/victims-human-trafficking-other-crimes/victims-human-trafficking-t-nonimmigrant-status.

[iii] William A Kanel, US Congressional Research Service, Immigration Provisions of the Violence Against Women Act (VAWA) 4 (May 15, 2012), https://fas.org/sgp/crs/misc/R42477.pdf

[iv] Memorandum from Janet Napolitano, Secretary of Homeland Security, to David V. Aguilar, Acting Commissioner, U.S. Customs and Border Protection, Alejandro Mayorkas, Director, U.S. Citizenship and Immigration Services, and John Morton, Director, U.S. Immigration and Customs Enforcement, on Exercising Prosecutorial Discretion with Respect to Individuals Who Came to the United States as

Children (June 15, 2012) (on file with the U.S. Department of Homeland Security), https://www.dhs.gov/xlibrary/assets/s1-exercising-prosecutorial-discretion-individuals-who-came-to-us-as-children.pdf.

[v] Memorandum from Sam Bernsen, General Counsel, Immigration and Naturalization Service, to Commissioner, Immigration and Naturalization Service, Legal Opinion Regarding Service Exercise of Prosecutorial Discretion (July 15, 1976) (on file with U.S. Immigration and Customs Enforcement), https://www.ice.gov/doclib/foia/prosecutorial-discretion/service-exercise-pd.pdf.

[vi] Memorandum from John Morton, Director, U.S. Immigration and Customs Enforcement, to All Field Office Directors, All Special Agents in Charge, All Chief Counsel, U.S. Immigration and Customs Enforcement, on Exercising Prosecutorial Discretion Consistent with the Civil Immigration Enforcement Priorities of the Agency for the Apprehension, Detention, and Removal of Aliens, (June 17, 2011) (on file with U.S. Immigration and Customs Enforcement), http://www.ice.gov/doclib/secure-communities/pdf/prosecutorial-discretion-memo.pdf.

[vii] Memorandum from Janet Napolitano, Secretary of Homeland Security, to David V. Aguilar, Acting Commissioner, U.S. Customs and Border Protection, Alejandro Mayorkas, Director, U.S. Citizenship and Immigration Services, and John Morton, Director, U.S. Immigration and Customs Enforcement, on Exercising Prosecutorial Discretion with Respect to Individuals Who Came to the United States as Children (June 15, 2012) (on file with the U.S. Department of Homeland Security), https://www.dhs.gov/xlibrary/assets/s1-exercising-prosecutorial-discretion-individuals-who-came-to-us-as-children.pdf.

[viii] 8 U.S.C. § 1182(d)(5)(A) ("The Attorney General may…in his discretion parole into the United States temporarily under such conditions as he may prescribe only on a case-by-case basis for urgent humanitarian reasons or significant public benefit any alien applying for admission to the United States, but such parole of such alien shall not be regarded as an admission.…").

[ix] Memorandum from Jeh Charles Johnson, Secretary of U.S. Department of Homeland Security, to Thomas S. Winkowski, Acting Director, U.S. Immigration and Customs Enforcement, R. Gil Kerlikowske, Commissioner, U.S. Customs and Border Protection, Leon Rodriguez, Director, U.S. Citizenship and Immigration Services, and Alan D. Bersin, Acting Assistant Secretary for Policy, U.S. Department of Homeland Security, on Policies for the Apprehension, Detention and Removal of Undocumented Immigrants, (Nov. 20, 2014) (on file with the U.S. Department of Homeland Security), https://www.dhs.gov/sites/default/files/publications/14_1120_memo_prosecutorial_discretion.pdf.

[x] The Ombudsman Office of DHS also summarizes the deferred action process: "Normally, a deferred action request is reviewed at the local office. A summary sheet explaining the positive and negative equities associated with the deferred action request is completed. The district director reviews the summary and makes a recommendation. That recommendation is forwarded to the regional director. The regional director issues a decision on the recommendation and returns the final decision to the district director so that he/she may deliver it to the requestor. Deferred action requests are not filed on a standardized application form and no fee is collected to defray the costs associated with processing deferred action requests." January Contreras, U.S. Citizenship and Immigration Services Ombudsman, Deferred-action: Recommendations to improve transparency and consistency in the USCIS process (July 11, 2011), https://www.dhs.gov/xlibrary/assets/cisomb-combined-dar.pdf.

[xi] U.S. Immigration and Customs Enforcement, Fiscal Year 2017 ICE Enforcement and Removal Operations Report (Dec. 13, 2017), https://www.ice.gov/removal-statistics/2017

[xii] American Immigration Council, The end of the immigration priorities under the Trump Administration (Mar. 2018), https://www.americanimmigrationcouncil.org/sites/default/files/research/the_end_of_immigration_enforcement_pripriorit_under_the_trump_administration.pdf.

[xiii] U.S. Congress of the United States, House of Representatives, Committee on Oversight and Reform, Subcommittee on Civil Rights and Civil Liberties, Hearing on "The Administration's Apparent Revocation of Medical Deferred Action for Critically Ill Children", Wednesday, September 11, 2019, at 12:00 p.m., in room 2154 of the Rayburn House Office Building, Washington, DC. 20515 -6143

[xiv] Office of the United Nations High Commissioner for Human Rights. International Covenant on Civil and Political Rights. Available at: http://www.ohchr.org/EN/ProfessionalInterest/Pages/CCPR.aspx.

[xv]

Article 12 of the Convention affirms the equal recognition before the law and legal capacity of the persons with disabilities. States Parties should: 1) Reaffirm that persons with disabilities have the right to recognition everywhere as a person before the law. 2) Recognize that persons with disabilities enjoy legal capacity on an equal basis with others in all aspects of life. 3) Take appropriate measures to provide access by persons with disabilities to the support they may require in exercising their legal capacity. 4) Ensure that all measures that relate to the exercise of legal capacity provide for appropriate and effective safeguards to prevent abuse in accordance with international human rights law. Such safeguards shall ensure that measures relating to the exercise of legal capacity respect the rights, will and preferences of the person, are free of conflict of interest and undue influence, are proportional and tailored to the person's circumstance, apply for the shortest time possible and are subject to regular review by a competent, independent and impartial authority or judicial body. The safeguards shall be proportional to the degree to which such measures affect the person's rights and interests.

[xvi]

The Belmont Report was published in the Federal Register, and reprints are provided upon request to scientists, members of Institutional Review Boards, and Federal employees. The two-volume Appendix, containing the lengthy reports of experts and specialists who assisted the Commission in fulfilling this part of its charge, is available as DHEW Publication No. (OS) 78-0013 and No. (OS) 78-0014, for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

[xvii] Reverby SM. "Normal exposure" and inoculation syphilis: A PHS "Tuskegee" doctor in Guatemala, 1946–1948. J Policy History. 2011;23(1):6–28.

[xviii] Human Rights Office of the Archdiocese of Guatemala. Guatemala: Never Again! The Human Rights Report. Maryknoll, NY: Orbis Books; 1998.

[xix] Centers for Disease Control and Prevention. US Public Health Service syphilis study at Tuskegee: frequently asked questions. Available at: http://www.cdc.gov/tuskegee/faq.htm.

[xx] Gray FD. The Tuskegee Syphilis Study: The Real Story and Beyond. Montgomery, AL: New South Books; 1998. [Google Scholar]

[xxi] *Gudiel Garcia v. Sebelius*, 867 F. Supp. 2d 125 (D.D.C. 2012), appeal dismissed, 2013 U.S. App. LEXIS 13873.

[xxii] Cohen IG, Adashi EY. In the wake of Guatemala: the case for voluntary compensation and remediation. Am J Public Health. 2012;102(2):e4–e6. [PMC free article] [PubMed] [Google Scholar]

[xxiii] Galarneau C. "Ever vigilant" in "ethically impossible": structural injustice and responsibility in PHS research in Guatemala. Available at: http://onlinelibrary.wiley.com/doi/10.1002/hast.161/pdf. Accessed July 19, 2013. [PubMed] [Google Scholar]

[xxiv] Childress JF. Compensating injured research subjects. Hastings Center Rep. 1976;6(6):21–27. [PubMed] [Google Scholar]

[xxv] United Nations Historical Clarification Commission. Guatemala: memory of silence. Available at: http://www.documentcloud.org/documents/357870-guatemala-memory-of-silence-the-commission-for.html.

[xxvi] Guatemalan Presidential Commission. Consentir el daño: experimentos medicos de Estados Unidos

en Guatemala. Available at: . http://www.cityprojectca.org/blog/archives/14922

[xxvii] *Village of Arlington Heights v Metropolitan Housing Dev. Corp.*, 429 US 252, 265 (1977)

[xxviii] *Guardians Ass'n v Civil Serv. Comm'n*, 463 US 582 (1983)

[xxix] Peel M. Human rights and medical ethics. J R Soc Med. 2005;98(4):171–173. [PMC free article] [PubMed] [Google Scholar]

[xxx] US Department of Health and Human Services. HHS commits nearly $1.8 million to health initiatives in Guatemala and to improving global human research protections. Available at: http://www.hhs.gov/news/press/2012pres/01/20120110a.html.

[xxxi] Gillon R. Medical ethics: four principles plus attention to scope. BMJ. 1994;309(6948):184–188. [PMC free article] [PubMed] [Google Scholar]

[xxxii] Presidential Commission for the Study of Bioethical Issues. "Ethically impossible" STD research in Guatemala from 1946–1948. Available at: http://bioethics.gov/sites/default/files/Ethically%20Impossible%20%28with%20linked%20historical%20documents%29%202.7.13.pdf