Chapter 5 Regulation of Medical Profession and Medical Research

The Medical Oaths and Codes

Medicine as a Profession

Professional virtues and codes of conduct were historically associated with the philosophy and ethos of each community. The medical profession, in particular, was esteemed by all nations and cultures. Imam Shafi [1] (767–820 CE) said: "There are two kinds of persons who are indispensable for people. The scholars (of religion and law = ulema) for dealing with their matters of religion, and physicians for dealing with their bodies. Abubaker AlRhazi [2] (864–925 CE) said: "The physicians possess traits that are not found in others, among such is the unanimous view of the followers of religion and authority, of the preference of their occupation, and the acknowledgement of both kings and laymen for the exigent need for their services; for their everlasting strive to discover the unknown in the field of knowledge, of their pursuance to improve their profession, and of their persistent concern of introducing happiness and comfort to others."

The medical profession should be practiced with efficiency and honesty. Prophet Muhammad (PBUH) said: "Allah likes when any one does a work, to do it with perfection" [3]. The physician should observe good conduct and fine character in both his acts and behavior. The manual guide for medical practitioners in Saudi Arabia [4] claims that: "The ethics of morals of profession mainly stem from the teachings of Islam which call for nobility of character, perfection of performance and fear of God in every act. The Prophet Muhammad said: "I have been sent to call for and complement high moral standards" [5].

Every nation and culture has its morals, mode of conduct, and ethics. The old Egyptians, Chinese, Indians, Persians, Babylonians, etc., had a mode of conduct for the medical profession, requirement for the priest physicians, and laws regulating the profession.

The Greeks were probably the most elaborate since the time of Hippocrates. The oath they promulgated and proclaimed became the cornerstone of medical ethics,

which should be taken by anyone who contemplates to be involved in this noble profession.

The Hippocratic Oath: is part of a collection of writings known as the Hippocratic Corpus. The oath is generally believed to have been written a hundred years after the time of Hippocrates who lived in the Island of Cos in ancient Greek, in the fifth century B.C. (460–350) [6]. Ludwig Eldestein (1967) thinks that the Hippocratic tradition arose from the Pythagorean Cult, which was interested in Science, Philosophy, Medicine, and Religion [7].

The oath starts with a pledge to Greek gods and goddesses Apollo, Asclepius (a deified physician) the god of Medicine, and his two daughters Hygeia (from which hygiene is derived) and Panacea (the drug that cures all maladies). When the Muslim physicians adopted the Hippocrates Oath, they omitted these pledges and pledged to God [8]. Similarly, early Christians were at odds with these idol worshippers, and hence destroyed the Hippocrates temple in the Island of Cos [9].

The oath of Hippocrates then pledges loyalty to the teacher and his posterity, and to keep the profession of medicine secret except to those who deserve it by their character, or being the children of previous physicians.

The oath then applied dietetic measures for the benefit of the sick, in order to keep the patients from harm and injustice. "I will never give a deadly drug to anybody if asked for it, and will not give a woman an abortive drug. In purity and holiness I will guard my life and my art. I will not use the knife, not even on sufferers from stone (in the urinary bladder which was amenable to treatment), but withdraw in favor of such men as engaged in this work."

The cause of abhorring surgery is religious, as holiness and purity implies not being contaminated by blood and waste products, which are religiously defiling [10].

Keeping Virtuous: The oath pledges: "Whatever houses I may visit, will come for the benefit of the sick, remaining free of all intentional injustice, of all mischief and in particular of sexual relations with both female and male persons, be they free or slave."

Keeping Secrets: "What I may see or hear in the course of the treatment, or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself such things shameful to be spoken about."

The Hippocratic Oath extolled the following principles:

(1) **Beneficence** [11]: in English language connotes acts of mercy, kindness, and charity. It includes all forms of action intended to benefit other persons.

Benevolence refers to the character trait or virtue of being disposed to benefit others.

The Principle of Beneficence: refers to moral obligation to act for the benefit of others.

Nonmaleficence

"Above all do no harm" or Primum non nocere is entwined with beneficence; it says: "I will use treatment to help the sick according to my ability and judgment, but I will never use it to injure or wrong them".

It clearly guards life, "I will never give a deadly drug to anybody, and will not give a woman an abortive drug and even will not use the knife," as surgery was hazardous at his time, and also for purity and religious reason avoiding blood and defiling religiously. The Hippocratic Oath is pro-life and vehemently against abortion, suicide, and any type of killing including Euthanasia. Doing harm in whatever way is abhorred, and should be avoided, even unintentionally. The physician should be careful in prescribing drugs and should take a detailed history of drug allergies, lest one of his drugs cause harm to his patient. More care will be needed in cases of surgery.

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Keeping the secrets of the patient, his family and even his servants and slaves, whom the physician comes across while visiting the patient at his home, should be kept secret "I will keep to myself such things shameful to be spoken about." This attitude is also part and parcel of benefiting the patient "Beneficence" and not doing any harm to him "Non Maleficence." However, if divulging the secret may be of benefit to the patient, as considered by his physician, then it should be exposed, as far as it is beneficial to him or warding off harm thwarted against him.

Paternalistic Attitude

The physician in the Hippocratic Oath is obviously paternalistic who is looking after his patient, as if he is his son or daughter, trying his best to benefit him, and prevent any harm that would befall him/her, and keeping all the secrets he comes across during his treatment of the patient, unless exposure is going to benefit the patient or ward off harm befalling him.

The Hippocratic Code endorsed the virtues of modesty, sobriety, patience, promptness, and piety. The physician must be upright and pure in character, diligent, and conscientious in caring for the sick.

The paternalistic attitude should be praiseworthy. But as changes occurred in the West, the enlightenment era approached and the liberal attitudes appeared, this attitude was disregarded and considered obsolete.

In the late eighteenth century an epidemic of typhus and typhoid fevers broke out in Manchester, England, and the Manchester infirmary staff were overworked. The medical practitioners were divided into dieticians, apothecaries (working with drugs), and surgeons and were blaming each other of negligence, as nobody exactly knew his duty in this epidemic. Percival, a well-educated retired physician wrote for them a medical code of conduct in 1803. It was in the Hippocratic tradition, which stressed the duty of the physician to benefit the patient, and placed no emphasis on the rights of patients in matters such as informed consent or open disclosure.

This duty to benefit the patient with absence of any recognition of the rights of patients is the hallmark of the Hippocratic tradition. It is one of the major differences between medical ethics that is Hippocratic and many of the other religious and secular ethics [10].

The American Medical Association (AMA) of 1847 turned to Percival's Code, taking whole sections of it and incorporating in the 1847 Code of Ethics. Both Britain and USA have Codes of Ethics that are essentially Hippocratic. However, both mention the duties of physicians to benefit the society, which was never mentioned in Hippocratic Code of Ethics.

The American Medical Association (AMA) Code (1957–1980) endorsed the virtues that Hippocrates commended: modesty, sobriety, patience, promptness, and piety. However, in contrast to the first code in 1847, the AMA over the years has deemphasized virtues in its codes. In 1980, it eliminated all traces of virtues except in the admonition to expose those physicians deficient in character or competence [12].

The paternalistic virtues of benevolence, nonmaleficence, and compassion were extolled, while in recent attitudes of autonomy, these virtues are not called for; instead the virtue of respectfulness is more prominent and important. The contractual natures of medicine and health profession as a whole, became a business, ruled by contracts, mistrust, and litigations, which needed changes in medical codes, its by-laws and ethics.

However, the Hippocratic Oath remained with minor alteration in the World Medical Association Declaration of Geneva 1948 and 1956 [10].

Post-Soviet Russia constructed an oath for the Russian physician in 1993, which replaced the previous Marxist oath, and adopted the World Medical Association of 1956, which is Hippocratic [10].

But gradually the Hippocratic attitudes were replaced by autonomy and respect for the individual and his wishes. From 1970, the Hippocratic tradition started to collapse. The rights of the patient became more important, and the ethics of respect for persons (duty-based principles) were dominant. These included fidelity, autonomy, and veracity.

Not all the old codes of ethics were paternalistic like the Hippocratic Oath. Hinduism, Buddhism, various Chinese traditions, and Islamic teachings all differ from the paternalistic approach of the Hippocratic Oath.

Islam is considered as the religion of all the Prophets and Messengers of God. Islam means submission to God. Since monotheism is the true religion of Allah (God) from primordial times, as Adam, Noah, Abraham, Moses, Jesus, and all the Messengers of Allah were all of them monotheists, then Islam should be defended, expounded, and proclaimed. However, there is no compulsion in religion. "There shall be no compulsion in (the acceptance of) religion. The right course has become clear from the wrong" (Surah AlBaqarah 2/256).

And say: The truth is from your Lord, so whoever wills let him believe; and whoever wills let him disbelieve (Sura AlKahf 18/29).

Are you going (O Mohammed) to compel the people to believe (Sura Yunus 10/99).

You are not in control of them (Sura AlGhashiya 88/22).

The Qur'an is replete with such verses, which orders freedom of faith and human personal responsibility.

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Verily God does not change men's condition unless they change their inner selves (Sura Ar-Rad/The Thunder 13/11).

Every soul will be held responsible for what it had done (Sura AlMuda'ththir/The Cloaked One 74/38).

If there is no compulsion in accepting religion (which is the most important thing for humans), then there is no compulsion in accepting medicine by drugs or surgery.

The consent of the person to be treated should be obtained if he/she is adult and competent. If he is a minor (a child) or mentally incapacitated then the consent of the guardian should be obtained. Only in life saving situations that consent may be ignored. Otherwise, it is imperative to obtain the consent prior to any medical or surgical intervention. If the guardian refuses to give consent for the child or incompetent person under his guardianship, and the physicians think it is very important to operate or give kidney dialysis or whatever medical intervention, then the magistrate can appoint another guardian who will give consent. There are many ways in implementing this treatment immediately, and in cases of emergency and life saving situations there will be no need for the consent.

The Islamic jurisprudence considers seeking remedy depends on the situation. Seeking remedy in Islamic jurisprudence may be obligatory (mandatory) in certain life saving situations or may be preferred or encouraged (Mandoob) in other situations. It may be facultative or optional and may be Makrooh, i.e., not preferred and in some situations and with certain type of treatment may be Haram, i.e., not allowed.

Ibn Taimyiah said: "seeking remedy may be Haram (not allowed) or Makrooh (not preferred), may be facultative i.e. optional (Mubaah), it may be preferred (Mandoob) or may be obligatory when it is life saving" [13]. He also said: "seeking remedy is not obligatory in the opinion of majority of Ulema (religious law experts), they however differed which is better: to seek remedy or not, for those stoics who can forebear" [14]. During that time, almost all modes of therapy were of doubtful results and many involved certain dangers, especially when surgery was contemplated.

Seeking Remedy: Obligatory (Mandatory)

It is incumbent that everyone should seek remedy in life saving situations. In such cases, if the person is unconscious or he is a minor, there is no need to wait for obtaining consent from proxy or guardian. The physician (or nurse) should do his/her best to save the life, organ, or limb without waiting for due consent. He/she would be liable otherwise. In case of infectious diseases that will endanger the health of the community, the government has the power to enforce treatment on a patient, irrespective of his will [15]. However, in cases like appendicitis, the doctor cannot enforce treatment if the patient refuses, except in case of a minor; then the court will appoint another guardian to give consent for treatment [16].

If the patient requires a caesarian section, the consent of the lady is sufficient and there is no need for consent of her husband, a practice common in many Arab countries where the consent of the husband is thought imperative [17].

In case where the life of the fetus is endangered, e.g., prolapsed cord, many jurists would advise caesarian section even without the consent of both parents [18].

The governments impose mandatory immunization schemes for children and in case of epidemics such as meningitis; vaccination is required for many Hajj seasons. Such actions have been supported and encouraged by many Fatwas (decision 67/5/7 of Islamic (jurisprudence 7th meeting) [15].

Seeking Remedy: Encouraged and Preferred

- a. In all cases where therapy is likely successful and harm from that mode of therapy is most unlikely.
- b. In all cases where the ailment is going to hinder the activities and duties of a Muslim to himself, his family, and his community.
- c. The mode of therapy is "Halal." In case of "Haram" medication, it will be allowed if there is no alternative, if it is deemed necessary to cure the ailment and/or it is prescribed by Muslim physician [19].

Prophet Muhammad (PBUH) said: "O servants of Allah seek remedy, for Allah has not put an ailment except that he puts its remedy except one ailment. They asked: what ailment? He said: old age". And in another Hadith he said: death.

Seeking Remedy: Facultative (optional)

- a. Where benefit is not proved or even doubtful.
- b. Where ill effects of that mode of therapy are uncertain.
- c. The person should have autonomy and decide for himself, whether to accept or refuse that modality of treatment.
- d. Informed consent is mandatory except in emergency situations.

Abstaining from Remedy Is the Better Option

Seeking remedy may be **Makrooh** (not preferred) in the following conditions:

- a. When therapy is unlikely to bring benefit.
- b. Where harm or even inconvenience from therapy may exceed its benefit.

Some jurists from the Hanbali School thought that abstaining from remedy is the better option in the following conditions:

- a. Non-life threatening conditions.
- b. No danger to the health of the individual.
- c. Not encroaching on other's health.
- d. In terminal cases.

There are two hadiths of Prophet Muhammad (PBUH), which encourage abstaining from remedy. They are:

a. "There are 70,000 of my people will enter paradise without being questioned; they are the ones who do not seek remedy by ruqia, the ones who don't consult talismans, the ones who don't allow themselves to be cauterized; and they leave the matters in the hands of their Lord and completely depend on His grace" [20].

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b. A black lady complained to the Prophet (PBUH) that she got convulsions and got naked during these attacks and asked him to pray for her to get cured. He said: "If you persevere and be patient you will enter paradise". She said: "I will be patient but I don't want to get exposed (i.e. naked); he said: "I will pray for you that you might not get exposed."

She had attacks but never got exposed after that incident. (Narrated by AlBukhari) [21].

Many companions refused therapy in their last illness, as they felt it would be futile e.g. Abubaker Assidiq-The First Caliph, Muath ibn Jabal and Abu Darda'a.

Seeking Remedy is Prohibited

- a. If it involves amulets, (other than Qur'an), sorcery, divination, or talisman. It encroaches on creed [22, 23].
- b. Any medication made of liquor or any intoxicating drink [23, 24].
- c. Use of pork or porcine material [25].
- d. Killing animals, e.g., frogs, etc., and using them as medicine [26].
- e. Using blood [27].

Only in conditions or situations, when it becomes life saving that these substances will be allowed. It will also be allowed to use these substances if there is no alternative medication. A competent Muslim physician should prescribe it [19].

The Oath of a Muslim Physician

Many oaths were presented in the First International Conference on Islamic Medicine in Kuwait, January 1981, which were similar, and Hippocratic with minor differences. The one adopted was that presented by Dr. Hassan Hatout. Many Schools of Medicine adopted it in a shorter version.

The Oath of a Muslim Physician

In the name of Allah, Most Gracious, Most Merciful.

Praise to Allah, the Sustainer of His Creation, the All-Knowing.

Glory to be Him, the Eternal, the All-Pervading.

O Allah, Thou art the only Healer, I serve none but Thee, and, as the instrument of Thy Will, I commit myself to Thee.

I render this Oath in Thy Holy Name and I Undertake:

To be the instrument of Thy Will and Mercy, and, in all humbleness, to exercise justice, love and compassion for all Thy Creation; To extend my hand of service to one and all, to the rich and to the poor, to friend and foe alike, regardless of race, religion or color; To hold human life as precious and sacred, and to protect and honor it at all times and under all circumstances in accordance with Thy Law; To do my utmost to alleviate pain and misery and to comfort and counsel human beings in sickness and in anxiety; To respect the confidence and guard the secrets of all my

patients; To maintain the dignity of healthcare, and to honor the teachers, students, and members of my profession; To strive in the pursuit of knowledge in Thy name for the benefit of mankind and to uphold human honor and dignity; To acquire the courage to admit my mistakes, mend my ways and to forgive the wrongs of others; To be ever-conscious of my duty to Allah and His Messenger (PBUH), and to follow the precepts of Islam in private and in public. "O Allah grant me the strength, patience and dedication to adhere to this Oath at all times".

New Codes and Oaths Breaking with Hippocratic Tradition

The Nuremberg Code 1946 appeared after Nuremberg Trials of the Nazi Physicians (World War II) who experimented with prisoners of war, gave them lethal drugs, caused pain and suffering to all of them and ended in death of many. All the experiments were not serving any benefit to those researched and of course, were done without any consent. The physicians claimed that these experiments were advancing knowledge and science, while in fact they did very little in this aspect. They were sadistic brutal experiments.

The Nazi physicians had abandoned the traditional ethical commitment of the physician to the individual patient welfare. They were committed and found guilty.

The appearance of Nuremberg Code is considered a landmark in the history of medical ethics research, which emphasized the importance of consent of those to be researched with their own free will.

The Nuremberg Code is a public document of International law, not one written by the medical profession. The Nuremberg Code is grounded in liberal political philosophy and henceforth changed gradually the medical ethics codes and philosophy, which refused the paternalistic attitudes and gave all its attention to the respect of human being, which became dominant. These included autonomy, fidelity, veracity and care for the rights of patients.

Ethical Codes

Nuremberg Code 1947 and 1946

- "The voluntary consent of the human subject is absolutely essential."
- Research Subjects "should be so situated as to be able to exercise free power of choice."
- Research Subjects "should have sufficient knowledge and comprehension of the elements of the subject matter involved as to make an understanding and enlightened decision."

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Nuremberg Code 1947

10 Rules for "Permissible Medical Experiments"

- (1) Voluntary consent without coercion.
- (2) Results must benefit society and must only use human subjects when there is no alternative.
- (3) Should be based upon non-human studies with justifiable expected results.
- (4) Avoidance of all unnecessary physical and mental suffering.
- (5) No experimentation where death or serious disability is foreseen unless performed on the medical provider as a subject.
- (6) Degree of risk less than potential benefit.
- (7) Proper preparations must be made to minimize injury.
- (8) Experiment should be conducted by only scientifically qualified person.
- (9) Subjects can cease their participation at any time.
- (10) Experimentor must stop if it is believed it will result in death or serious disability.

This was followed by many codes, which regulated Bioethical Research. These codes stressed not only consent but informed consent and made many requirements for accepting or allowing biomedical research e.g. the research should be approved by Institution Review Board (IRB). The National Commission for the protection of Human Subjects of Biomedical and Behavioral Research instituted the National Research Act in 1974 in USA. It required the formation of institution Review Boards (IRB) in order to evaluate any research proposal.

This was followed by Belmont Report 1978 and World Medical Association: Declaration of Helsinki, which was amended several times since it was declared in 1964.

The prominent features of these two codes are given here.

The main issues in Medical Research are as follows:

The Belmont Report—Department of Health, Education and Welfare, April 18, 1978

The Belmont Report summarizes ethical principles and guidelines for research involving human subjects. Three core principles are identified: respect for persons, beneficence, and justice. Three primary areas of application are also stated. They are informed consent, assessment of risks and benefits, and selection of subjects.

World Medical Association—Declaration of Helsinki 1964–Present

- (1) Physician's responsibility to protect the life, health, privacy and dignity of the human subject.
- (2) Research must follow accepted scientific guidelines.
- (3) The welfare of the environment and animals must be respected.
- (4) A protocol must be submitted to an ethical review committee
 - Ethical considerations must be explained
 - Prediction of risks, burdens and benefits should be enunciated

- (5) Conducted only by scientifically qualified persons
- (6) Each potential subject must be informed, understand and consent after being told of all the material facts
- (7) Consent must be given without coercion
 - Legal guardians must provide consent for those that cannot give consent
 - Minors must assent to the research
- (8) Researchers must utilize scientific integrity in reporting.

Consent

Consent should be informed. The research should be fully explained to the participants in simple language, which he could fully comprehend. Any questions should be answered. A written document in simple language should be given to the participant. He should be given enough time to review it, ask questions and have free choice to accept or refuse participation; alternatives (in case of refusal) should be explained.

Refusal of Participation

Refusal of participation will not in anyway affect his/her right to full treatment and management.

Participant Withdrawal

The participant can withdraw at any time frame. The researched person even then, will not affect his right to full treatment and management.

Risks to Participants

- 1. The foreseeable risks, discomforts, and hazards should be explained, indicating the probability, magnitude, and duration.
- 2. The risks should include the physical, psychological, social, legal, and economic risks
- If any hazard occurs during research, the research should be stopped immediately and the participants should be informed, treated of any injury, and compensated duly.
- 4. All the consent documents in Saudi Arabia declare that no compensation will be paid in case of injury or even death. (This should be changed, and some IRB's do not accept the research until the sponsors agree to treatment and compensation).

Consent of Minors

Children should not be exposed to nontherapeutic clinical research. The consent of the minor is invalid and hence it is obligatory to obtain the consent of the guardian. Children under seven cannot comprehend the intricacies of medical research. However, children who can comprehend and understand should be informed in

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simple language and their consent obtained. If they refuse, no research should be done on them, despite the consent of the guardian.

Consent of Incompetent Adults

Incompetent adults should not be exposed to any nontherapeutic research. The consent of the guardian is imperative. The research should be useful to the person (patient) or his group. There should be no other alternative to obtain that information.

Consent of Prisoners

Prisoners and incarcerated persons should not be exposed to research unless it is going to help the person or group. The consent of the prisoner is legally invalid, however it should be obtained without duress.

Research on Pregnant and Lactating Ladies

- Ladies should be scrutinized for pregnancy prior to any research. If there is any harm expected to the mother or fetus no research should be carried on. The lady should avoid pregnancy, if the research period is prolonged and contraception should be used.
- 2. The informed consent of the lady should be obtained. The consent of the husband or any other member of the family is not enough.
- 3. The consent of the husband may be essential in research involving reproduction.

Benefit of Research

- 1. The research should benefit the pregnant lady, her fetus, or the group.
- 2. The clinical research should in no way expose the pregnant lady, nursing mother, her fetus, or baby to any harm.

Monitoring Research

- 1. Provision to monitor data for the safety of the participants should be available.
- 2. Potential benefits to the participants, his group or community should be explained to the participant.
- Protection of privacy and confidentiality of the participant /patient should be assured.
- 4. Medical care and compensation for injury. If the research involves more than minimal risk of the participant (discomfort during medical exam) provisions for medical care and compensation should be explained to the participant prior to carrying the research. Pharma companies in developing countries declare that they will not compensate for any harm caused by the experiment.

Holding No Responsibility

1. The researcher should not obtain from the researched subject, any agreement that makes him irresponsible for any injury that can accrue from the research. Even if he gets a written consent, it is considered invalid legally. The subject has the right for proper compensation for any injury.

2. Costs and payments to the researched subjects should be explained prior to starting the research. The amount should be appropriate to compensate the subjects for their lost time.

Research on Embryos and Fetuses

- 1. Research on embryos and fetuses is not allowed unless the research is going to benefit the embryos or fetus.
- 2. Left over pre-embryos (fertilized ova) in IVF projects could be used in stem cell research after obtaining the consent of the parents.

The Fatwa of the Islamic Jurisprudence Council of the Islamic World in Makkah Al-Mukarama in its 17th session (19-23-10-1424H 13-17 December 2003G)

Stem Cell Therapy

Decision

<u>First:</u> It is permissible to obtain stem cells to be grown and used for therapy, or for permissible scientific research, if its source is legitimate, as for example:

- 1. Adults if they give permission, without inflicting harm on them.
- 2. Children provided that their guardians allow it, for a legal benefit and without inflicting harm on the children.
- 3. The placenta or the umbilical cord, with the parent's permission.
- 4. A fetus if spontaneously aborted, or when aborted for a therapeutic reason permitted by Sharia'a, with the parent's permission (be reminded of decision 7 of the council in its 12th session about abortion).
- 5. Leftover Zygotes remaining from in vitro fertilization, if donated by the parents, when it is ascertained that they will not be used in an illegal pregnancy.

Second: It is forbidden to use stem cell, if their source is illegal as for example:

- 1. Intentionally aborted fetuses (that is, abortion without a legal medical reason).
- 2. Intentional fertilization between a donated ovum and sperm.
- 3. Therapeutic human cloning.

Bioethics Research Without Control Despite Ethical Codes

Despite the fact of many local and international ethical codes, there were many irregularities, deceits, and unethical practices which were exposed by Western physicians, moralists, and media. The occurrence of blatant unethical procedures is disappearing in the West. The drug companies pushed their experiments and unethical procedures in third-world countries. But even there, the international codes are exposing them.

Despite all these codes and regulations medical research is replete with horrendous stories of cheating, maiming and even killing many innocent persons, both Stem Cell Therapy 97

prior to Nuremberg Code and after. The Nuremberg trials of the Nazi Physicians opened the eyes for what was happening both in the democratic countries of the West and the heinous experiments of the Nazi Germany.

Here are some examples of what happened in the USA and International drug companies up to 2012.

1915

The U.S. Public Health produced Pellagra in 12 Mississippi inmates to find a cure for the disease. In 1935, after millions died from the disease, the director of the U.S. Public Health Office said that they had known Niacin as a cure for this disease for some time, but withheld it as it affected NEGROES, as he called them.

1941

- Dr. William Black infected a 12-month-old baby with herpes as part of a medical experiment.
- Doctors infected children to produce Vincent's angina.
- Doctors gave 800 poor pregnant women radioactive Iron, to study requirements in pregnancy.

1945

- Col. Safford Warren, of the University of Rochester, injected plutonium into patients of the University Hospital without their knowledge.
- 3 patients at the University of Chicago's Billings hospital were similarly injected with plutonium.

1950 Experiments

- Dr. Josef Strokes of Pennsylvania infected 200 female prisoners with viral hepatitis.
- Doctors in Cleveland Hospital studied cerebral blood flow by spinal anesthesia, inserting needles in jugular veins and brachial arteries, causing blood loss and paralysis.

CIA Trials 1947-1953

CIA and U.S. Navy trials on LSD, Scopolamine and Mescaline involved military and civilians who were given these hallucinating drugs without their knowledge.

1950–1953 U.S. Army released chemical clouds on 6 American and Canadian cities that resulted in increase of respiratory illness.

1950 U.S. Navy Trials

U.S. Navy sprayed a cloud of Bacillus globigii over San Francisco shoreline.
 Many residents developed pneumonia like illness.

1953

 U.S. Atomic Energy Commission gave 200 pregnant women high doses of I-131 and then aborted them at different stages to learn at what stages the serious effect occurs.

1952–1953 Experiment

• Ohio State Prison inmates were injected with live cancer cells to study the progress of the disease by Dr. Chester Southam, of Sloan-Kettering Institute.

Post-Awareness Research

Cincinnati Radiation Experiment

1960-1972

- Mostly African American cancer patients with lower than average intelligence were exposed to large doses of whole body radiation.
- None of the patients consented to the experiment or had any idea of the potential side effects.
- This experiment was sponsored by the United States Military. Subjects experienced severe burns and some died prematurely as a direct result of the experiment.

Post-Awareness Research

Jewish Chronic Disease Hospital, 1963

- 22 chronically ill and debilitated noncancer patients were injected with live human cancer cells.
- Patients were not told of the cancer injection. Hospital covered up the lack of consent and tried to fraudulently obtain consent.
- 2 years after the investigation, the American Cancer Society appointed the principle investigator as a Vice President.

Experimentation

Tuskegee Syphilis Experiment

1932-1972

- Targeted 600 poor and illiterate African American males (399 with syphilis and 201 without).
- Told they were being treated for "bad blood."
- Followed their progress without providing penicillin, which was a known antidote as of 1943.
- Conducted painful lumbar punctures under the fraudulent precept of "free treatment" to test the progression without providing any benefit to the researchees.
- Provided no beneficial treatment and admittedly shortened the lives of the researchees.

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 29 men died directly from syphilis and 100 others died of illnesses related to syphilis.

Pfizer Company Deceived Nigerians 1996

- Pfizer agreed to pay 75 million dollars as compensation for the death of 11 Nigerian children, used as guinea pigs in nonconsensual unlicensed trial in 1996.
- The company deceived them and distributed a new drug "Trovan" as a proven useful drug for meningitis.

USA Today September 2, 2009 Published the Following

Pfizer to Pay \$2.3 Billion Fine

Pfizer was ordered to pay \$2.3 billion to resolve criminal and civil allegations that the company illegally promoted 4 drugs: Pain Killer Bextra, antipsychotic Geodon, antibiotic Zyvox and antiepileptic Lyrica, which were promoted in off label uses.

Porcine H1N1 Influenza Vaccine 2010 Hoax

- Alarmed people all over the world.
- WHO experts received money from big Pharmaceutical companies.
- Drug companies gained billions.
- Governments and nations lost billions.

2012: GlaxoSmithKline to pay \$3B in Largest Healthcare Fraud Settlement in US History (Published in the Media and Internet):

- British drugmaker GlaxoSmith Kline will pay \$3 billion in fines—the largest healthcare fraud settlement in U.S. history—for criminal and civil violations involving 10 drugs that are taken by millions of people.
- The Justice Department said that GlaxoSmithKline PLC pleaded guilty to promoting popular antidepressants Paxil and Wellbutrin for unapproved uses. The company also pleaded guilty to failing to report to the Government for seven years some safety problems with diabetes drug Avandia, which was restricted in the U.S. and banned in Europe after it was found in 2007 to sharply increase the risks of heart attacks and congestive heart failure.
- In addition to the fine, Glaxo agreed to resolve civil liability for promoting Paxil, Wellbutrin, asthma drug Advair and two lesser-known drugs for unapproved uses. The company also resolved accusations that it overcharged the government funded Medicaid program for some drugs, and that it paid kickbacks to doctors to prescribe several drugs including asthma drug Flovent and herpes medicine Valtrex.
- Thorpe (who works with Glaxo) said in a statement that he was penalized after
 he reported kickbacks being paid to doctors and sales reps encouraging doctors
 to promote drugs for unapproved uses, including using Paxil and Wellbutrin in
 children.

Merck Vaccine Fraud Exposed by Two Merck Virologists; Company Faked Mumps Vaccine Efficacy Results for Over a Decade, Says Lawsuit

According to Stephen Krahling and Joan Wlochowski, both former Merck virologists, the Merck Company engaged in all the following behavior:

- Merck knowingly falsified its mumps vaccine test results to fabricate a "95 % efficacy rate".
- In order to do this, Merck spiked the blood test with animal antibodies in order to artificially inflate the appearance of immune system antibodies. As reported in CourthouseNews.com: Merck also added animal antibodies to blood samples to achieve more favorable test results, though it knew that human immune system would never produce such antibodies, and that the antibodies created a laboratory testing scenario that "did not in any way correspond to, correlate with, or represent real life ... virus neutralization in vaccinated people", according to the complaint.
- Merck then used the falsified trial results to swindle the U.S. Government out of "hundreds of millions of dollars for a vaccine that does not provide adequate immunization".
- Merck vaccine fraud has actually contributed to the continuation of mumps across America, causing more children to become infected with mumps.
- Merck used its false claims of "95 % effectiveness" to monopolize the vaccine market and eliminate possible competitors.
- The Merck vaccine fraud has been going on since the late 1990's, says the Merck virologists.
- Testing of Merck's vaccine was never done against "real-world" mumps viruses in the wild. Instead, test results were simply falsified to achieve the desired outcome.
- This entire fraud took place "with the knowledge, authority and approval of Merck's senior management."
- Merck scientists "witnessed firsthand the improper testing and data falsification in which Merck engaged to artificially inflate the vaccine's efficacy findings," according to court documents.

The exposure of the big Pharma (drug companies) continues, and the media every now and then brings horrific stories. The above examples are sufficient to give an idea of how these companies are implicated in fraudulent activities. The latest one exposed by a BBC report on 2nd November 2012 where Western companies are carrying out trials on ignorant people, without taking consent and telling the patients that they are provided by charities of important expensive drugs. More than 500 persons were reported dead because of these new experimental drugs. The companies bear no responsibility at all.

The Royal College of Physicians Journal (Clinical Medicine) (2002, 2, (2): 116-18) published a charter of medical professionalism project announced by American and European Medical Associations.

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The fundamental principles were:

(1) <u>Principle of Primacy of Patient Welfare</u>: based on a dedication to serving the interest of the patient with altruism from the side of the treating physicians, when needs arise.

- (2) Principle of Patient Autonomy
- (3) Principle of Social Justice

A set of professional responsibilities involve the following:

- (1) <u>Commitment to Professional Competence</u> with life long learning and teamwork.
- (2) <u>Commitment to Honesty with Patients</u> including reporting to the patient of medical error that resulted in his injury. Reporting and analyzing medical errors provides the basis for appropriate prevention and improvement strategies.
- (3) <u>Commitment to Patients Confidentiality</u> especially that access to patients data, genetic makeup, and secrets are becoming easier with electronic information and computerization.
- (4) <u>Commitment to Maintaining Appropriate Relations with Patients</u>. Physicians should never exploit patients for any sexual advantage, personal financial gain, or other private purpose.
- (5) <u>Commitment to Improving Quality Care</u>: Increasing medical competence, reducing medical errors, increasing patient's safety, and optimizing the outcome of medical care.
- (6) Commitment to Improving Access to Care. (Equity) Physicians must individually and collectively strive to reduce barriers to equitable healthcare aiming to eliminate barriers based on education, laws, finances, ethnicity, and social discrimination. Commitment to equity entails the promotion of public health and preventative medicine.
- (7) Commitment to a Just Distribution of Limited Resources.
 - Guidelines for cost-effective care
 - Appropriate allocation of resources
 - Avoidance of superfluous tests and procedures

(8) Commitment to Scientific Knowledge

- Prompting research
- Creating new avenues of management of disease and their prevention
- Appropriate use of new knowledge

(9) Commitment to Maintain Trust

- Avoiding conflict of interest, private gain or personal advantage
- Management and supervision of medical and pharmaceutical industries whose aim is profit and profit alone. Exposure of any misconduct of these giant corporations involving the medical trials the effect of drugs or

procedures or equipment's, is a responsibility of the physicians along with appropriate bodies of licensing and censure.

(10) Commitment to Professional Responsibilities

- Collaborative work
- Self-regulation
- Discipline of members of the profession when required.
- Education and standard setting of current and future members of the medical profession.
- Accepting internal and external scrutiny of all aspects of professional performance.

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