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Received: 14 February, 2018

Accepted: 31 March, 2018

Published: 02 April, 2018

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<https://www.peertechz.com>

Review Article

Deep Brain Stimulation (DBS) and Spinal Cord Stimulation (SCS) – Ethical considerations in the use of Implants and Bio-Medical responsibility at manufacture

Introduction

Here in this brief we take a quick look into the use of certain biomedical devices and their benefits. At the same time, it is suggested that there are questionable practices by manufacturers, which raise concerns about corporate mores in general and around Ethics. As a Society, especially in these modern days, we need to be more aware of all that is going on and ensure accountability. Should not the primary objective be about saving lives and improving the quality of life, rather than putting the profit margin first. In this article we consider field of neuromodulation which is one of the fastest growing and the implantable devices such as pacemakers and IPGs. Let's start off with a bit of background.

Markedly there is nowadays more and more incidence of Parkinson's disease and other neurological disorders such as Dementia, besides the much considered Epilepsy [1, 2]. [Given the 'notoriety' and prevalence of epileptic condition, astute planning in diverse engineering fields takes into account potentially adverse outcomes due to the spontaneity of epileptic seizures and attacks, with due attentiveness by professional engineers.] Being aware that the incidence of Alzheimer's and other neurophysiological degenerative conditions are on the increase with globally ageing population; the over-Sixties age group is the fastest growing at the moment with currently over 700 million people around the world aged over sixty years of age. That's almost one billion and the New York-based U.N. Department of Economic and Social Affairs Population Division, 2007 [3,4], forecast that the figure will increase to over two billion by the year 2050. Accordingly by the year 2050, the number of adults over sixty suffering from Alzheimer's will increase by one hundred million (Ferric et al, Global prevalence of Dementia) [5], that figure being five percent of the population that are aged sixty and the over-sixties [6]. This is therefore globally a significant proportion

of the world population engaging valuable professional consideration especially for providing treatments whether through augmented neurosurgical, or even neuropsychological approaches; albeit not discounting neuro-pharmacological options are there, such alternatives will not be considered within this brief. As such, pioneering avenues and opportunities for biomedical applications can be explored. This is a step-forward in relieving or perhaps even removing entirely, a major stressor on society as a whole, because it will be apparent that the degenerative neurophysiological and neuropathological conditions [7], affect not only individuals but also their families and loved ones. It is definitely appreciable that caring for older individuals is a major public health concern, and a huge responsibility on society.

Characteristics of Alzheimer's are: a progressive pathophysiological changes ranging from cognitively unimpaired (preclinical); and mild cognitive impairment, all the way through to total Dementia. And it is believed that the neurophysiological-neuropathological process originates several years prior to its diagnosis [8], Currently work is underway to determine clinical bench-tests which would review biomarkers, epidemiological, and neuropsychological evidences which could ultimately define characteristics and factors to best predict detrimental progression risk.

In terms of addressing the condition and relieving the patient suffering/adverse experience, theories and practices are continually being developed and tested to help reduce the severity of Parkinson's, Alzheimer's and other neurological conditions [9]. These include and can be as diverse as Physiotherapeutic Specializations [10], and cognitive retraining of the neural pathways. Other simple disorders include chronic migraine syndrome and the comprehension of its pathophysiology is increasing rapidly resulting in a view of migraines rather than as simple vascular manifestation, more

likely as a complex variable CNS disorder. With latest research leading to insights into genetic causes, besides anatomical and physiological features, without forgetting pharmacological mechanisms [11]. Despite the postulations of migraine-related genes and the function of cervical nerves in migraines and the development of other forms of migraine therapy, there is also another potential novel way of coping with Migraines in a similar fashion to previously mentioned pathophysiological conditions. It has been reported that utilisation of a biomedical device could help chronic migraine sufferers with a simple procedure involving insertion of electrodes under the skin on the scalp and this does not necessitate Deep Skull Surgery, and has been demonstrated to be one hundred percent effective in eighty-five percent of patients that have undertaken such treatment [12]. This is not to say that there is some ineffectiveness of this pain management system, it is more than likely that with those patients in whom the treatment is ineffective, there are other pathologies at play. If patients were to be screened and excluded, then a one hundred percent success rate could be claimed [13]. It is also conceivable that other neurophysiological conditions such as Meige Syndrome [14], and Multiple Sclerosis tremor could be controlled if not totally eradicated [15]. It has been proposed that synaptic transmission is done with the aid of neurotransmitters such as peptides and amino acids and pragmatic research by Philip E Lloyd [of the Department of Pharmacological and Physiological Sciences and Committee on Neurobiology, The University of Chicago and Chicago, Illinois 60637] has supported the postulation [16]. Communication within the Nervous System is effected through junctions between neurons called synapses using neuronal signaling molecules. Neuropeptides are small molecules similar in nature to proteins and influence brain activity, and the body, in a certain way. The synapses are not connected but separated by a forty nanometer wide 'Synaptic Cleft' (infinitesimally minute when compared to the width of a human hair which is around seventy-five thousand nanometers wide.) the signal-transmitting neuron is referred to as the pre-synaptic neuron (axon terminal) and the signal-receiving neuron is called the post-synaptic neuron. Towards the Synaptic end of neurons/axons there are hundreds if not thousands of small vesicles (sacs) consisting of thousands of chemical neurotransmitter molecules. The axon (pre-synaptic neuron) is excited by a brief potential difference of approximately one millisecond subsequently causing the vesicles to travel towards the end of the axon and release their neurotransmitter molecules into the synaptic cleft aided by neurotransmitter transporters which are voltage-gated channels sensitive to minute positive charge of Ca²⁺ calcium ions [17,18]. On the other side of the void, submicroscopic protrusions or spines on the dendrite surface of the post-synaptic axon receive the chemical transmission and this is modulated into an electrical charge to continue the communication as a potential difference to the next synaptic cleft until the destination, which in this case would be appropriate 'nociceptors' which tell the body that something is wrong or feels bad [19-22]. Once the 'Action' has been executed in the post-synaptic neuron, there may be redundant neurotransmitter material present in the synaptic cleft and this may just dissipate out of the gap through diffusion, or be

reabsorbed into the axon through a process called 'REUPTAKE' which results in the recycling of the neurotransmitters. In other cases, enzymes will break down the neurotransmitter and subsequently the catalyzed by-products are recovered into the pre-synaptic nerve cell to be synthesized into fresh neurotransmitter.

With this insight, scientists are able to research alternative methods of addressing the pain management of migraine and do so without the use of dependence-inducing opioids. In recent years there have been several studies on Neurophysiological processes in terms of Chemical and Electronic aspects. On the one hand, pharmacological solutions entail the development of some neuropeptide which could be ingested (?), or direct injection into the brain of an enzyme for simple pain-management of severe and chronic migraines [23, 24]. The enzyme would interfere with the operational function of the neurotransmitter by morphologically blocking their attachment to the receptor spines on the dendrite of the post-synaptic nerve cell. Thus alternatives are preferable, as recommended by the Headache Center of the Cleveland Clinic, Ohio, the use of Opioids in Migraine Treatment is not desirable with rapid physiologic consequences [25]. This is reference to oral medication that interacts with various vaso-active neurotransmitters - so basically a pharmacotherapeutic remedy which will interfere or disrupt the release of neurotransmitters which are produced with short bio-synthetic process utilizing plentiful and simple precursors including amino acids, peptides and monoamines (normally being nutritionally) readily available through normal human diet. Taking an oral supplement that would be digested and quickly absorbed into the bloodstream and affect the chemistry of the neurotransmitters that are packaged into synaptic vesicles clustered beneath the membrane in the axon terminal, on the presynaptic side of a synapse; whose release into and diffusion across the synaptic cleft may be arrested, thereby hindering their bind to specific receptors in the membrane on the postsynaptic side of the synapse [26-28]. There are available in the marketplace various analgesics, and other pain-relief medication such as 'triptans,' [29], and narcotic use is a first-line treatment at Emergency Departments for acute migraine presentations at various hospitals in Canada has been demonstrated as potentially ineffective resulting in consequential substance abuse [30]. Other scholarly reviews confirm that in the treating acute migraines, administration of certain drugs is ineffective, and certainly alternative approaches would be welcomed by patients and the general population [31].

Consideration can also be given at this point to the non-degenerative Tourette's syndrome; a neurological disorder characterized by involuntary motor movements or vocalizations (tics) or both. Another novel idea is to introduce a specialized device which would deliver electronic pulses directly into the affecting nerves inside the brain. Such therapy would require implementation of pre-determined algorithms encoded into a pacemaker-like device. Now, given that the implant would not be housed inside the skull but rather in a cavernous or more accommodating part of the body, it becomes necessary that the

corrective impulse current is physically delivered by current conducting wires. Once again, another consideration would be an addressing treatment of the (hypothetical?) ADD/ADHD phenomenon which seemingly afflicts the Youth of Today's (overly-) liberal society.

Very briefly then, the implementation of the Pulse Stimulator device necessitates a neurosurgical procedure with the objective of implanting a medical neurostimulator device which sends impulses through electrodes implanted beneath the skull to target specific area in the brain nuclei.

To commence the solution - Deep Brain Stimulation entails complex surgery using advanced techniques with the aid of CT/MRI Scans and careful mapping of the brain. Separate surgical procedures wherein wires are inserted into the brain will open up the right and left sides of the skull. Electrodes are then inserted as required and the neurosurgical procedures have been improved and refined over the course of the past three decades. Once the electrodes are secured, the surgical team must house the neurostimulator, usually in the chest and connect back to the electrodes. As stated above, DBS is a complex surgical procedure and quite understandably not without complications, and in a few cases there have been hemorrhaging issues and whilst the incidence in the study had been substantially small in the scheme of things, it is not negligible or easily dismissed, or even to be ignored [32]. Surely, there are a few factors in play when any surgical procedure is being executed and we are concerned with the sanctity of human life every precaution must be taken and is definitely considered by the excellent practitioners.

An unfortunate event led to the development of implantable devices and mention of reference is made as an aside and by way of historical interlude; however, besides being an interesting episode, there are factors which may rely upon this particular relation further in the discussion. Over half a century ago, in 1966, the heart of Dr Harry Heller stopped beating, and had he been in the hospital, then he would probably have been saved by use of an external defibrillator. Sadly being far removed from a hospital, Dr Heller died. This sad episode left Dr Heller's friend and colleague distraught and almost immediately the grief-stricken Dr Mioczyslaw (Michel) Mirowski determined to invent a portable and implantable cardioverter defibrillator. A few years later, Mirowski teamed up with Dr Morton Mower, William Staewen, and Dr. Bernard Tabatznik and Albert Mendeloff and developed the Standby Automatic Defibrillator [33]. This they did in the face of skeptical resistant by experts in sudden death and cardiac arrhythmias, all of whom commented that it could not be done. Although Mirowski's pioneering team decade-long quest result was too late to save DR Mirowski's best friend - Dr Heller, it is without doubt that "in the decades since ICDs have been on the market, they have saved tens of thousands of lives. See, e.g., Kastor, JA, "Michel Mirowski and the Automatic Implantable Defibrillator," *Am. J. Cardiology* 1989; 63:977-82, 1121-26[34]." This paragraph will play an important part in the determination of and comment on Ethical Conduct and Corporate Responsibility only thus then becoming apparent.

Surgical options for operations treating PD have expanded rapidly with varying degrees of success in terms of end-result on the actual condition being treated. These include profound ablative procedures, deep brain stimulation, and cell transplantation; with target nuclei for both ablative surgery and deep brain stimulation being the motor thalamus, the globus pallidus, and the sub thalamic nucleus [35]. Due to several factors there has recently been a resurgent interest in treating Parkinson's disease surgically. These factors being: 1) recognition that long-term (drug-based) medical therapy for PD effectively is unsatisfactory, and patients suffering side effects eventuating the side effects experienced from drug-induced dyskinesia (total body even), motor fluctuations, and variable responses to medication, mostly attributed to long-term use, or higher dosage administration of levodopa [36], a much improved comprehension of the pathophysiology of PD, resulting in a better scientific rationale for improving on historical procedures and suggesting new targets; and 3) technological improvements, including computed tomography- and magnetic resonance imaging-guided stereotaxy [37-40], precise and accurate surgical intervention in the basal ganglia using single-unit microelectrode recording. A similar pulse generating neurostimulator device (IPG) is utilized for treating chronic pain the Spinal Cord Stimulator [41], and this requires spinal surgery. Surgeon will make incision at T10 (mid-back) and the right flank. Following laminectomy, the lead is inserted at T10 vertebra and advanced up to T8 vertebra and is placed next to the spinal cord. In many cases, it is also possible to complete by using an epidural. By using a sub-dermal tunneling technique the stimulator lead-line is connected back to the stimulator device which is embedded in the right flank. This type of surgical procedure has also been in use for the past four decades and is quite experientially well-defined.

Our discussion here is not to question the established operational methodologies of DBS and SCS surgeries. Nor is it to take-up some opposing stance against the electronic solution. Rather we must give careful consideration to the manufacturing and production of any devices (and prosthetics) utilized within the human body. After all substandard manufacturing procedures and use of low quality materials could be injurious in a biological system.

Technical standards

As with most things, various stands have been developed and there is ISO Standard 14708 extant and this covers Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer. Specifies particular requirements for those equipment. This standard specifies exact requirements for active implantable medical devices for electrical stimulation of either central or peripheral nervous system, particularly to provide basic assurance of safety for both patients and users.

"ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees.

Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization [42].”

The majority of manufacturers (biomedical devices) must basically comply with IEC 60601-1-2 Medical EMC, which requires implantable devices to comply with ISO 14708-3 standard and, specifically Section 27 of said standard [43].

Neuromodulation or neurostimulator devices produce controlled electrical pulses that are delivered through electrodes which are in contact with a specific target area. More often than not some form of extension is required as a conveyance of stimulation pulses to the electrodes from the generator.

Not included in the scope of ISO 14708 are non-implantable medical devices, such as external neurostimulators and RF-coupled neurostimulators, even though such devices might have implantable parts, because they are covered under the IEC 60601-1 series of standards.

ISO 14708 testing provides an assessment of a devices’ ability to protect a patient from the following hazards:

External neurostimulators including RF-coupled devices are not regulated within the scope of ISO 14708, despite their having implantable parts, however they are included in IEC 60601-1 series of standards.

Devices’ ability, under ISO 14708 testing, is to provide assessment of each device to protect a patient from the following:

- Unintentional biological effects being caused by the active implantable medical device.
- Harm to the patient or user caused by external physical features of the active implantable medical device.
- Harm to the patient caused by electricity.
- Harm to the patient caused by heat.
- Ionizing radiation released or emitted from the active implantable medical device.
- Unintended effects caused by the active implantable medical device.

In addition to protecting the patient, the ISO 14708-3 test also aims to protect the active implantable device from the following hazards:

- Damage caused by external defibrillators.
- Changes caused by electrical Fields applied directly to the patient.
- Changes caused by miscellaneous medical treatments.

- Mechanical forces.
- Damage caused by electrostatic discharge.
- Damage caused by atmospheric pressure changes.
- Damage caused by temperature changes.
- Electromagnetic non-ionizing radiation.

Shortcomings...

It can happen that when you buy something that is not “as reliable as a Volkswagen” you could end up with a lemon, especially if VAG fudged the Emissions test reports. What happens when you get an IPG or ICD that has been passed off as fit for purpose through some legal loophole? There is a provision by USFDA which allows manufacturers to take advantage of a contracted submission of one hundred calendar days if they can adequately prove that there is extant a similar product already in the marketplace. What happens then if substandard components are utilized, or poor quality raw materials are used in the making of the device? And as an uninformed and more importantly unaware Jo Public, most of us would continue in blissful ignorance of USFDA 510k Submission process in which manufacturers can follow any of three options and choose a “method for obtaining 510(k) marketing clearance under certain instances: Special 510(k) and Abbreviated 510(k) [44].”

It is essential that all precautions and endeavours are taken, with rigorous multiple trials over extended periods are conducted by disparate investigation teams prior to even approaching an Authority for submission. This must be the de facto case in all matters concerning an augmentation or treatment for the quality of an individual’s health and life. However, in researching for this and other articles, concerns surfaced and are here now referenced.

One such concern is in contravention of afore-mentioned ISO standard wherein the device must “protect a patient from...Harm...caused by electricity.” and in subsection of same standard, “the ISO 14708-3 test also aims to protect the active implantable device from...Damage caused by electrostatic discharge.” Over in Europe, German company that marketed pacemakers informed physicians in 2005 that a hermetic sealing component might experience gradual degradation, leading to premature battery depletion [45]. Question arises whether adequate testing and sufficient pre-release trials were conducted.

Another concern is that of frangibility or fragility of componentry parts. If say for example, microscopic part of a sheath dislodged into the body caused by deterioration due to poor quality raw materials used at time of manufacture, can we consider the detrimental consequences caused thereby? Perhaps such has been the case with quality of electrodes used in some products, (please see Endnote 29 for referenced article,) and this again raises another question.

When the driver for the manufacturer is purely profit and not really the benefit of their products to members of Society,

one must question the integrity and mores of not only the individuals representing and steering the manufacturer at leadership and executive level, but also that of the organization and the company ethos. For really whilst strategically operating and managing the business of a corporate entity there must be an application of a moral code of conduct. Now and then though it becomes evident that manufacturers will where possible extract over and above what would be deemed as fair and just cost for a product or service [46].

Post-operative complications

Whilst the concept of electronic remediation for both pain management and degenerative Neuro-pathological conditions is a viable alternative and one that can be effective in treating patients there are considerable shortcomings in surgery or actual device implementation. Although no major study on adverse events about operational or device issues was available at time of writing, there seems to be much anecdotal reports and some official complaints to the USFDA over issues with the devices or peripheral equipment. Such complaint was recorded as 'Injury' and was result in patient undergoing pocket revision of Spectra® IPG due to it becoming hot when recharging. Apparently, post-operative condition was acceptable to patient [47].

Now there are also occasions when the device or its periphery could either malfunction or break. And despite assurances during the research of this article that there have is no such possibility, there was product recall in 2015 of USFDA approved Chariot Guiding Sheath / Guidewire after bits of it broke off and lodged within the patient's body[48]. Another unfortunate incident was recall of a blood clot removing catheter involving the same corporation [49]. Although these two items are not IPG/ICD type devices, here is demonstrated that there seems to be lack of corporate responsibility to the patient in antithesis to basic provisions where the aim is to safeguard the patient from harm. In the case of the IPG devices and their peripheral accessories, it is quite possible the electrodes or leads may break due to sudden impact or degradation. In the referenced article there is also mention of lawsuits regarding Trans Vaginal Mesh implants – mention is made for the sake of insight, although this is actually explored in a similarly authored separate article.

Ethical considerations

At the turn of the century, C Christopher Hook discusses Cybernetics and how scientists at Germany's Max Planck Institute for Biological Cybernetics are researching the fusion of silicon chips with neurons and describes control of a cockroach's movements whose motor-neurons are integrally connected with a microprocessor amongst other recently developments. Yet he also discusses whether the rewiring of brains, or prosthetic limbs for improvement as opposed to remedial enhancement are justifiable? Whilst he does acknowledge the augmentation avenues available to counter disabilities and conditions are a remarkable and wonderful aid to those with disabilities, he makes alludes to Cybernetics and by definition a Cyborg would be a marriage between man and machine. So does having an ICD or Pulse Generator controlling

say cerebral palsy make one bionic? Certainly the cost for procedures and biomedical devices has come down however there could still be a few Six Million Dollar men out there.

Besides looking into the Do's and Don't's of Deep Brain Surgery or Spinal Surgery, and the quality and experience of the practitioners, for this context our focus should be centered around not only the implantable devices and related peripheral hardware, but also the behavior and conduct of the manufacturer.

Previously it was mentioned that the Commission Electrotechnique Internationale (IEC) and the International Standards Organisation (ISO) have determined basic standards for amongst other things such implantable devices as with which we are concerned. To refresh, the basic standard is ISO 14708 and IEC 60601-1-2 Medical EMC (which ensures adherence with ISO 14708). Therefore it's an established fact that there are at least technical / engineering standards that should be complied to.

Corporate community responsibility, Ethical behaviour and duty of care.

Given the fact that corporations exist and that their activities are executed by directors who should according to Law ensure that the organization adheres to and complies with all relevant and applicable Federal and State Laws, and has a moral obligation to act in good faith and although the director or directress must act in the best interest for the company and with proper purpose, they should also exercise independent judgment amidst pertinent and relevant facts, materials and other views whilst assessing what the best interests of the company are. And a breach of that involves fraud, dishonesty and even recklessness which could attract Criminal penalties. However, there is not much mention of the duties and obligations that corporate entities or their agents have to the public at large and society as a whole. Reference to the development of the implantable cardiac generator was made to address Ethical behavior with the outcome of the case in favour of the plaintiff (Mirowski Family LLC) whereby jury awarded a nine figure sum against the defendant, despite counterclaim to have original case dismissed [50,51]. This then throws more than a shadow of doubt on the ethos of corporate behavior and of the executive leadership.

According to Johnson and Scholes [52,53], in the world of Commerce and realm of Business there would be three levels of ethics and the pair has provided a clever way of classifying the diversity of comprised elements...

At the highest level, or Macro level, one must consider the role of the business within the national and international organization of Society, and the relative virtues of differing political and social systems. This platform would also take into consideration international relationships and the role of the business at the global level.

Corporate social responsibility would be taken into account, at the second or corporate level when formulating and

implementing strategies, along-with ethical issues facing the individual corporate entity whether it be in the public sector or a private company.

Last but not least, there is the behavioral conduct of individuals within the organization.

Earlier, it was demonstrated in Technical Standards section that the IPG device must not cause harm to the individual by way of heat or electrostatic discharge as well as several others. We have already seen that there was the case of Maude Adverse Event Report against a Manufacturer's neuro-modulating Spinal Cord Stimulator. [Please see, Endnote 20.]

All the above notwithstanding, we can see precedence and behavioral pattern demonstrating lackadaisical adherence to and much disregard to not only technical and legal obligations, also to moral and ethical considerations for fellow members of Society at large. What we need to question here then is not the surgical procedures, not the efficacy of neuromodulation, not the effectiveness of ICDs, none of these. What should be given utmost consideration is the value of Human Life over that of monetary profit and corporate greed. At this juncture, one could now recount the experiences of Dr Mieczyslaw Mirowski and the corrupt double and triple dealing that he challenged in Court, and as summarily detailed in the beginning of this section and also in an earlier paragraph within this article.

Now considering 'Ethics' in terms of good or bad moral behavior as a generalization, it can be seen that there is the theoretical meaning and determination of Truth Values if at all. More importantly with Biomedical Engineering and its proponents, extra consideration should be given to the mundane everyday pragmatism and that all activities are pursue moral guidelines. With equal import then, one needs to ensure that the application of Ethical behavior is in accordance with the obligations and permissibility of action in specific domain or particular circumstance. Given that there are various conceivable different interpretations or presentations of Ethics as moral actions, it would be prudent to delve a little further into professional ethics and with regard to Medicine as a profession, it is apparent that Ethics and the very best behavior go hand in hand with the practitioners, as a whole, being of unquestionable and outstanding moral calibre. However, the new functionality of doctors is that of 'Health Care Provider' and the patient becomes known as a 'client'[54]. To which end the medical relationship between patient and doctor is diluted and turns more into a transactional business-type deal, where the key is commercial outcome and regardless of the individual's optimal health, it is imperative that the client be kept alive inasmuch that more consultations can be charged, and more drugs can be administered or prescribed, thereby maximizing revenue streams for both the medical entity now governing the doctors role, and also ensuring profit upon profit for the pharmaceutical companies[55].

Professor Arthur J Dyck [56] succinctly writes in the opening paragraph of his scholarly journal article [57]. "The declarations of Nuremberg symbolize and express two significant characteristics of the contemporary situation of

medicine: a heightened responsiveness to the needs, wants and rights of patients; a heightened awareness of the increasing difficulty of knowing what is right, and hence of knowing how best to benefit the patient and prevent harm. These concerns have arisen within the medical profession itself, but they are shared by the public at large."

The argument is that given the two examples above, if the self-respecting adherents of the dignified profession of Medicine take on ethical considerations at each juncture questioning what they are doing, then why cannot other professionals also aspire to such ideals and moral conviction? Engineers are in themselves bound by rules and codes to remain within conventional boundaries, although free to explore and investigate beneficial possibilities in advancing the contribution of Engineering to Society and for the betterment of Mankind.

Reflecting on the instances of devices afore-mentioned, although there are only a few examples of defective and injurious events with at least one fatality. It is evident that Corporations seek to stay above the Law despite their flagrant violations of Ethical and Moral Conduct and Integrity, they reserve a battalion of attorneys and lawyers and corporate counsels to cancel out any prosecutable misdemeanor, and to always be on the alert for any licit projectiles they can hurl at anyone that might challenge the Corporate Status Quo. All this despite flagrant violation, despite disdainful and condescending considerations for the community, despite the imperious attitude and overbearing pride.

The question arises...

What value on Human life?

Is there any amount of money that can replace the loss of a loved one? Even if it is not a loved one, can any amount of money bring someone back, or could Steve Jobs have stayed an extra five minutes on his deathbed in exchange for even all of his wealth? IT seems that even with all the technological advances in Biotechnology and other Medical fields such as Organ Transplants, and emerging medical technologies, there is an appointed term that a person will remain alive, regardless of multiple heart and kidney transplants.

Question therefore, whether corporate actions of greed to bolster the share price or increasing ROI the return on for shareholders with full knowledge of product shortcomings are more important than the life of a fellow human brother or sister?

To answer the question albeit briefly, even the corporate executives must hold human life to be of value as they are marketing products which are intended to prolong life of an individual. So now that is established, then should the manufacturer not exercise duty of care to ensure there is no detrimental effect of their products?

Unfortunately, in the examples and case studies mentioned previously, there seems to be a pattern with manufacturers avoiding their Societal and Civil and Moral and Ethical and

Technical and Legal responsibilities to ensure that their products are not going to cause harm at any stage whatsoever during the life of their product. It has been demonstrated that there is precedence of poor management and there seems to be repetitive corporate behavior to such extent that it could be perceived as habitual mismanagement and disregard to Duty of Care.

Could it be that in some instances, due to the desire to appease investors and reward shareholders alike, the Corporate Entity overlooks or technically dismisses its moral and ethical obligations and responsibilities on a macro level, and that at the Corporate and Individual levels, the promise of profit results in negligence of and the Duty of Care due to individual people. We can see that corporations are faced with the occasional lawsuit and prosecution case on a regular basis and then it becomes apparent why there is such a high number of in-house attorneys not only protecting patents, but also protecting the entity from disciplinary legal action. Such being the case, where corporations can get away in a Court of Law by using deceptive agents to protect questionable practices and nefarious motives, there seems to be little hope for the future of Society.

Question is... What can be done about it? As a collective and as individuals we need to be mindful of what is going on around us and refuse to accept everything that is thrown at us or proffered as a solution, lest we be herded and farmed like the inhabitants of the cities in Aldous Huxley's futuristic utopia authored in the Fifties and encroaching upon us increasingly with every sunset and sunrise ...

Should we not, as a Collective, stand-up and demand that there be increased testing and multiple trials prior to a product being reviewed and approved by whichever Authority is involved. Should we not take to task the violators and perpetrators of these criminal acts and demand that they be suspended from all commercial activities until such time that they make good. Should not the death of even one person be investigated and assessed on the same level as homicide, and should the entire executive and leadership team be held accountable, either by association or in complicity.

As a suggestion a stringent code of conduct should be mandatory for all corporations whether Biomedical or not. The author is spearheading and underway, together with colleagues in diverse professions overseas, to establish NGO-type lobby group advocating the implementation of minimum ethical standards across all manufacturing and service industries involved with providing medical and technological solutions and products primarily to other humans. The primary objectives will be to raise public awareness and highlight shortcomings with manufacturing, testing and approval processes at regulatory level; recommendations for more stringent standards, and introduction of randomised evaluation by independent body.

“The voluntary consent of the human subject is absolutely essential”.

This means that the person involved should have legal

capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity. “- The Nuremberg Code 1947 [58].

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