

**The Society of
Medicine and Law in Israel**

Journal of Medicine and Law

Volume No. 39 - December 2008

www.med-law.co.il

The National Health Insurance Law – Procedures Enhancing Patient's Rights**Yitzhak Berlovitz¹, Oded Gorni² and Dorit Kedem³**

The National Health Insurance Law (hereinafter "The Law") confers the right upon every insured citizen to address the labor court regarding the implementation of the law. The law also suggests alternative ways for the resolution of disputes between the insured and the "sick funds" – the health maintenance organization ("HMO's").

A public ombudsman was appointed to cope with the complaints between the insured and the sick fund, and other service providers. The law was amended recently in an attempt to help enforce the ombudsman's decisions, in cases the sick funds do not comply with the ombudsman's decision.

The law also constructed an appellate committee for insured whose requests for the provision of health services in foreign countries had been denied.

The aim of the present study is to examine the weight of the ombudsman's and appellate committee's opinion on the labor court's decisions – the rate at which the those decisions were adopted or rejected by the court. The study also examined the trends in the court's verdicts during the 10 years of the law's implementation.

It has been shown, contrary to past fears, that the courts were not flooded by "health claims" since the law was implemented. 75% of the claims were rejected, with no award or other form of aid to the claimant.

The courts adopted the professional-medical stance the ombudsman in the majority of cases. In the cases the ombudsman's opinion was rejected, the court's decision was made on legal grounds, which did not undermine the ombudsman's superior professional authority.

In the cases in which the ombudsman's opinion was not adopted, the court favored the insured's interests as against those of the sick fund. Only rarely did the courts adopt the sick fund's positions, when contrary to the ombudsman's decision.

Only 25% of the cases dealt with in courts, were preceded by the insured's appeal to the ombudsman, despite the fact that a claim to the ombudsman is, in most cases, the fastest and effective way for the solution.

¹ Yitzhak Berlovitz, M.D. M.H.A., Director of E.Wolfson Medical Center, Holon

² Oded Gorni LL.M. Adv., Legal Counsel, CH. Sheba Medical Center, Ramat Gan

³ Dorit Kedem, LL.M. Adv.

Key words: National Health Insurance, "basket of services", ombudsman, labor court, appellate committee for overseas medical services, inequality, exception committee, provisional remedy

The Patient's Rights Law as Viewed by the Supreme Court – A Twelve Years' Retrospective

Moshe Seidenbaum¹

Patients' rights had been recognized in Israeli case law long before the Patient's Rights Law (henceforth – The Law) was enacted in 1996. The Law was instrumental in formalizing most aspects of the relationship between the medical personnel and the patient. This article reviews the Superior Court's interpretation of several of The Law's provisions, after The Law had been enacted.

Sixty rulings were issued by the Supreme Court, both in its capacity of Supreme Court of Appeal and as the Supreme Court of Justice (of a total of 332 adjudications in all instances). Most cases concerned the relationships between the medical personnel and the patients. However The Law was mentioned also in cases which involved other subjects.

The subjects most frequently dealt with by the Supreme Court were informed consent and medical records, followed by the issue of examination committees, one of the innovations in The Law. There were but few disputes concerning subjects such as the right to receive medical treatment, patient's discrimination, the right to a second opinion, the preservation of the patient's dignity and privacy, treatment in emergency situations, the performance of the Ethics Committee etc. Several subjects dealt with in The Law, have not been (yet?) addressed by the Supreme Court.

Israeli society could have dealt with medical-personnel-patient's relations without The Law. Disputes arising from such relationships could have been solved efficiently relying on other, more general legislation, principles of Medical Ethics and pre-existing case law. However, in view of the importance of human rights in general and patients' rights in particular, the enactment of a specific law had been deemed appropriate. The Law helps the patient with grievance against "the system" to exercise her/his right as laid down in The Law. This indeed was the main intention for this legislation as stated in the Explanatory Notes to the Bill of Patient's Rights.

¹ Dr. Moshe Zeidenbaum, LLB, MPH, MD, Dermatologist; Former Medical Director, Meuhedet Sick Fund, Jerusalem District. Graduate of the Ramat Gan College of Law

Complementary and Alternative Medicine - Legal Aspects

Tsafrir Bar Ilan¹

Complementary/ alternative medicine (CAM) is a conglomerate of treatment modalities, which undergoes fast growth in present times. The expansion of CAM is accompanied by a tendency to discredit its importance and healing potential, and derogate its theoretical basis. The legal aspects of the practice of CAM remain disregarded.

It is the aim of this article to review the legal subjects relevant to CAM, with regard to necessary amendments in the existing laws, as suggested in several court rulings and other legal authorities. The suggested changes may help form a more suitable medical climate, with better quality standard of health care for society.

The article presents a concise general background of CAM, followed by a discussion of the various legal aspects of the practice of CAM in Israel, the use of Cam-medicines, professional insurance of practitioners etc. The stance of Jewish Law towards CAM is presented, as well as a short review of comparative law.

¹ LLB – Academic College of Law, Kiryat Ono

The Neuropsychological Opinion: An Essential Document in Legal Procedures Concerning Brain Damaged Patients

Chanan David¹

The present discussion - in both its conceptual and clinical-'practical' aspects is best viewed in the light of the psycho-physical problem - that is the unsolved issue concerning the relationship between brain and mind.

The practical aspect of this philosophical problem becomes crucial in cases of brain injury, and the role of neuropsychological assessment in these cases is most important, mainly in those which are dealt with in court. The cognitive and affective-behavioral problems that might be diagnosed, especially in cases in which there are no significant neuropathological findings, are crucial for the determination of the functional disability that sustained by the patient.

Three main features characterize the neuropsychological assessment: **1.** It is based on the qualitative analysis of the findings in the tests used, and on the interpretation of the findings of the test; **2.** It strives towards differential diagnosis concerning the cause the damage found in

the patient's performance; **3.** It should be based on adequate tests, but their use must be flexible so it could be applied to the immense variability of brain damaged patients.

¹ Chanan David (Ph.d) Clinical Neuropsychologist; Lowenstein Hospital Rehabilitation Center, Raanana.

Market Exclusivity by Law for New Drugs in Israel

Zohar Yahalom¹ and Segev Shani²

In April 2005 the Pharmacists Ordinance was amended (the 11th amendment) to include Article 47D titled "Protection of confidential information submitted as part of an application for the authorization of marketing of a drug". Article 47D is unique in Israeli legislation – it restricts the ability of regulatory authorities to approve the marketing of new drugs, regardless of regulatory considerations and intellectual property rights.

The pharmaceutical industry is a knowledge based industry whose sales are generated from original products protected by patents which can be sold without competition. The legislation in the USA and the European Community provides protection for the information submitted by a pharmaceutical company to the relevant regulatory authority, as part of the application for the authorization for marketing the product. This legislation acknowledges the need to protect such information, which provides additional protection to the originator/ inventor in addition to the intellectual property protection, known as data exclusivity.

The Israeli government, after years of being lobbied by local affiliates of multinational originator pharmaceutical companies, the US government and the EU, agreed to consider amending the Pharmacists Ordinance in a unique way which would accept the pharmaceutical industry requirements without acknowledging the concern over the confidentiality of the data.

It seems that the rationale of this legislation is maintaining foreign relations of Israel by balancing between needs of the local generic industry and the requirements of multinational pharmaceutical companies, backed by their governments. The solution given in the 11th amendment of the Pharmacists Ordinance is differs from that of the US and the EU, and provides only partial protection against approval of a new drug based on data submitted to the regulatory authority for a defined period of time, known as market exclusivity. This new legislation carries a considerable impact on the Israeli pharmaceutical market and the Israeli legislation as a whole.

¹ Zohar Yahalom, Yahalom Law Offices.

² Dr. Segev Shani, Department of Healthcare Administration, Faculty of Health Sciences, Ben-Gurion University.

Key Words: Market exclusivity, Data exclusivity, Intellectual property

Surrogacy with Ovum Donations: Legal and Halakhic Aspects ***Rachel Chishlevitz¹**

On March 7, 1996, the Surrogacy Law was enacted by the Knesset, thus regulating the process of surrogacy in the State of Israel. The law expresses great sensitivity towards Halakhic subjects relating to laws of pedigree and status, and can be explained in accordance to the spirit of Jewish Law. The law prohibits partial surrogacy, permitting full surrogacy only. Consequently, the prospective mother may be assisted with an ovum donation, as long as it is not obtained from the surrogate mother.

The procedure required for ovum donations is currently not established in primary legislation. It is regulated by Public Health Regulations (In Vitro Fertilization) of 1987. The amendment (2A) added to the regulations in 2001, allowed the obtainment of ovum donations from non-Jewish women from out of Israel.

The paper presents an argument that such use of ovum donations creates a Halakhic controversy, concerning the legal identity of the mother, which has not been resolved decisively. The use of ovum donated by a non-Jewish woman, may carry grave implications as to the religious affiliation of the newborn.

It is further argued that many of the Rabbinical authorities hold, that as a rule, the religious status of the child is determined by the religion of the genetic mother. Furthermore, this view is accepted by the Halakhic authorities who maintain that natural pedigree is determined, without exception, by the mother who gives birth to the baby.

The article draws the attention to the existing relationship between the primary legislation with the existing secondary regulations, the latter detrimental the objectives of Paragraph 2(5) of the Law, allowing the birth of children whose religious status may be subject to controversy among Rabbinical Halakhic authorities.

Several possible solutions are suggested for the amendment of Israeli legislation, in line with the prevalent Halakhic issues and their solutions.

¹ This article is based in part upon my M.A thesis presented to the Bar-Ilan University, under the supervision of Dr. Yechiel Bar-Ilan: *Surrogacy – The Status of the parties in the light of Jewish religious and the Israeli Law*

I wish to express my gratitude to Dr. Yechiel Bar-Ilan for his most useful comments.

On the Uniqueness of the DNA Profile – Theory and Results from Computerized Simulations of DNA Profiles in Large Population

Mordechai Halpert¹

This article illustrates, using theoretical calculations and computerized numeric simulations, the meaning of random match probability of DNA evidence and the mathematical conditions to determine its uniqueness.

The research answers two questions: A. How many pairs, triplets and so on of people exist in a population the size of the population of the state of Israel, have an identical genetic profile? B. Is there a possibility for a person whose genetic profile is included in a large database held by the authorities, to be incriminated as a result of a crime committed by a person whose genetic profile is not in that database? The research assumption is that the origin of genetic profiles is from a homogenous Jewish population. The research does not take into account the existence of sub-populations, family association and laboratory errors, thus making the results only a low boundary of the answers for the research questions. In order to answer the first question, the research uses theoretical results and a computerized simulation of 7 million genetic profiles which were constructed by a computer program in accordance with the prevalence of alleles in the Jewish population in Israel. The research finds that in genetic profiles composed of nine loci, there are about 14865 pairs of identical profiles. Among them, there are hundreds triplets and several quadruplets of identical profiles. In a genetic profile composed of only six loci there are numerous duplications, and in particular, there is one genetic profile owned by 250 individuals. In order to solve the second question, the research uses theoretical tools and a computerized simulation for investigations of many crimes with the assistance of a database consisted of one million genetic profiles. The answer to the second question is that there is a possibility for incriminating a person whose genetic profile is in a large database, as a result of a crime committed by a person whose genetic profile is not in the database, even when the random match probability is one in many billions and when the genetic profiles are composed of nine loci. Other results are: A. For genetic profiles composed of six loci it is expected that on average, a matching pair will be found within 1140 profiles. For genetic profiles composed of nine loci it is expected that on average, a matching pair will be found within 57413 profiles. B. In order to determine the uniqueness of a genetic profile in a way that on average there will be only 0.01 pairs of identical profiles all over the globe, holding about 7 billion people, a random match probability of 4.08×10^{-22} is required. C. In order to determine the uniqueness of a genetic profile in a way that on average there will be only 0.01 pairs of identical profiles in Israel alone, populated by about 7 million people, a random match probability of 4.08×10^{-16} is required. The research conclusions are that genetic profiles composed of nine loci are not satisfactory for

determining the uniqueness of the genetic profile, making it necessary to increase the number of loci on which the test is performed. The authorities must find a way that on the one hand, will protect the privacy of the people whose genetic profiles are in the database, and on the other hand, will enable an investigation of the database and examination of the forensic theory using the data in the database.

¹Dr. Mordechai Halpert is a physicist involved in industrial research and development

**Identification of Skeletal Remains of MIA* Soldiers
from the War of Independence Using DNA Analysis
Ethical, Theological, Legal and Scientific Aspects**

Y. Epstein¹, PhD, N. Erely², MSc, M. Freund³, PhD and E. Pras⁴, MD

The importance of proper identification and burial of the dead is well established in the Jewish tradition. DNA is a very stable molecule, even under harsh environmental conditions, and its extraction from biological specimens is feasible even many years after death. Based on unique DNA polymorphisms, forensic molecular genetics is at present a powerful tool in the identification of missing persons, such as in Mass Casualty Events or in identifying Missing in Action (MIA) soldiers. This is demonstrated by the case of seven soldiers, MIA from the battle near the city of Holon (April 1948). Five of these soldiers were buried as 'anonymous'. Recently, the IDF MIA Division, by using forensic molecular genetics, was able to identify the remains of these five soldiers. The scientific milieu and the court accept the DNA analyses (typing and sequencing) as a well-established process and the data retrieved as reliable. However, the data is considered but as scientific circumstantial evidence, that is dependent on statistics. By describing the process of identification of these MIA soldiers, we review the scientific aspects of forensic molecular genetics, as well as the ethical, theological and legal issues involved with the implementation of this technique.

* MIA – Missing in Action

¹ Head, Environmental Physiology Division, Heller Institute of Medical Research, Sheba Medical Center, Tel Hashomer.

² IDF Manpower Directorate, MIA Division.

³ Head, Forensic biology Laboratory, The National Center of Forensic Medicine.

⁴ Director, The Gertner Institute of human Genetics, Sheba Medical Center, Tel Hashomer.

**The Portrait of a Doctor as an Expert Witness
Reflections on Documents and Verdict of SuprStJ 9198/02
The Israel Medical Association and Others vs
The Attorney General and Others**

Avraham Sahar¹

In a recent decision, the Supreme Court of Justice partly upheld a joint petition by the Israel Medical Association (IMA) and the Israel Bar Association (IBA) to annul the State Employees' Regulation which barred state-employed doctors from giving evidence in court against any government agency. The state was ordered to present a list of medical fields in which the forbiddance may endanger access to justice. The court limited the ban to evidence against the specific medical institution in which the doctor-expert-witness is employed.

The subject of the present paper is not the dispute as such, or its outcome, but the way the Physician-as-Expert is portrayed in the various documents involved.

The petition claimed that the ban infringes upon two basic principles (laws) – The Freedom of Occupation Choice (of the doctor – IMA) and Access to Justice (of persons unable to sue the government agency – IBA). The Expert Opinion is to be held as a professional, based in science and objective document. Scientific problems, very much like legal ones may have more than one solution, equally correct and fair.

The respondent – The State – emphasized its status as employer, the relevance of which was recognized by the court, as well as its role as a public authority. The state rejected the petitioners' claims, depicting the medical expert in rather non-complimentary way.

The senior state-employed doctor is portrayed as one whose professional status and clout is endowed upon his solely by the state's authority, disregarding the prerequisites to the eligibility for the post. Despite such statements there is a wide discrepancy between the trusting attitude towards the doctor as therapist, and the suspiciousness towards his performance as an expert in court. The distrust towards the Opinion is asymmetric – the expert is trustworthy when appointed by the court, or acting on behalf of a state agency (or rather – the lawyers for the insurer of the state-agency, which pays the expert's fees. However, when acting on the request of another party' and against a state agency, the expert's integrity is questioned. The expert's fee is considered as related to his position, and therefore its legality is questionable or unfit. The respondents also suggested that divided opinions, both presented by state-employed doctors, one for and the other against a state agency, may disrupt the work relation within the various state health institutions. However no restriction was ever claimed, when such opposing

opinions were presented in disputes to which the state was not a party.

Such presentation of the medical expert was opposed only by the Doctors' representatives. The Court kept its dissertation strictly to legal principles and arguments, and carefully abstained from touching upon values or ideological involvement.

To demonstrate a contradictive point of view, the stance of the English law was presented – the presumption of the expert's overriding duty to the court – the expert's role as an Officer of the Law.

The paper recommends careful preliminary, joint examination of the opinion by both doctor and lawyer involved, as part of the latter's duty as the one who submits the document unto the court.

The paper also suggested considering the possibility of sanctions to be taken against experts who breach the trust required of persons who are regarded as honorably representing the opinion of science.

¹ Avraham Sahar, M.D., LL.B., Professor Emeritus of Neurosurgery, T.A. University, Attorney at Law

False Confessions Due to Mental Conditions: Theoretical Background and Practical Implications

Eliezer Witztum¹, Jacob Margolin² and Avraham Lavi³

Verdicts based on admission of guilt by the accused are frequent phenomena. In the past such an admission was considered as best evidence. According to Jewish Law a person cannot incriminate himself and the court may not produce a conviction based on a confession. The testimony of two honest persons is obligatory for conviction. The Israeli criminal law recognizes The right of a person not to incriminate himself, both during police interrogation and as a defendant at his own trial. However, once a defendant confessed, the confession may be used against him, irrespective of the person(s) present at the confession. However an out-of-courtroom admission of guilt requires of the prosecution proof of the defendant's good and free will. The confession is suppressed if pressure in any form had been exerted on the defendant by a person of authority (e.g. police investigator), and such pressure resulted in the admission. Mentally defective defendants, due to their vulnerability and sensitivity, are relatively easily impressed, and liable to surrender to pressure to confess despite their innocence.

The article reviews false confessions which resulted from mental conditions. The psychological background and the mental disorders of the subjects as related to false confessions is

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being discussed. The inherent hazards of confessions are illustrated by an exemplary case. Recommendations to minimize the possibilities of receiving false confessions of mentally disabled suspects or defendants are offered.

¹ Eliezer Witztum MD, Professor of Psychiatry, Faculty of Health Sciences, Ben-Gurion University of the Negev, Beer Sheva, and "Ezrath Nashim" Community Mental Health Center, Jerusalem, Israel

² Jacob Margolin MD, MPA, Secretary, Israel Society for Forensic Psychiatry, District Psychiatrist of Tel Aviv (RET.), Ministry of Health and Medical Director of "Eitanim- Kfar Shaul" Mental Health Center, Jerusalem, Israel

³ Avraham Lavi LLB, Attorney at Law.

Key words: false confession; false verdict; mentally ill defendant; psychology of false confessions.

Reduced Punishment for Murder in Israel

Guidelines of the Israel Psychiatric Association: Comments and Elucidations

**Yuval Melamed¹, Jacob Margolin², Shmuel Fennig³, Roberto Mester⁴,
Aubrey Zabow⁵ and Avi Bleich⁶**

Since the implementation in 1995 of Article 300A(A) of the Israeli Penal Law, which deals with the possibility of reduced punishment for murder, many verdicts were issued by the Israeli courts. In each verdict, the court discussed the mental health state of the convict as a base for a possible adjudication of reduced punishment. The court may decide on a lesser than the maximum obligatory life sentence for murder, when, among other circumstances, the court finds that the murder was committed while the convict was in a state of "severe mental disorder".

The Israel Psychiatric Association published a position paper of professional guidelines, for the use in expert psychiatric opinions which deal with the issue of reduced punishment for murder. It is the aim of the authors to draw the attention to this position paper and the guidelines, and invite further comments on this important subject, to further clarify its implications for forensic psychiatric practice in Israel.

¹ Yuval Melamed, MD, MPH, Senior Lecturer, Sackler Faculty of Medicine, Tel-Aviv University; Deputy Director, Lev-Hasharon Mental Health Center; Secretary, Israel Psychiatric Association, Israel

² Jacob Margolin, MD, MPA, Secretary, Israel Society for Forensic Psychiatry; Formerly the District Psychiatrist, Tel-Aviv Area, Israel

³ Shmuel Fennig, MD, Shalvata Mental Health Center; Associate Professor of Psychiatry, Sackler Faculty of Medicine, Tel-Aviv University, Israel

⁴ Roberto Mester, MD, Formerly Director of Ness-Ziona Mental Health Center and the District Psychiatrist, Central Area; Head, Department of Mental Health, Law and Ethics of the International Center for Health, Law and Ethics, Faculty of Law, Haifa University; Associate Professor of Psychiatry, Sackler Faculty of Medicine, Tel-Aviv University, Israel

⁵ Aubrey Zabow, MD, Formerly Director of Beer-Sheva Mental Health Center and the District Psychiatrist, Southern Area, Israel

⁶ Avi Bleich, MD, MPA, Professor of Psychiatry, Sackler Faculty of Medicine, Tel-Aviv University; Director, Lev-Hasharon Mental Health Center; Chairman, Israel Psychiatric Association, Israel

Key words: reduced punishment for murder, severe mental disorder, position paper, expert opinion.

The Nursing Profession in Israel: Its Legal Status – Present, Proposed and Amended

Shani Hasson¹

In the present era of economic paradigms, rhetoric regards Health as a basic human right, but in reality it is one of several resources, available but limited by budgets. Nursing as part of the larger field of Healthcare, has no independent legal existence in Israel. It is dealt with within an updated British Mandate Government Ordinance.

This paper proposes to regard Nursing, on the basis of its history, as an integral and indispensable component of the healthcare system. There is a marked and painful gap between the complicated skills required in everyday tasks, diversity of duties – clinical, technological, administrative, and those in research – and the way nursing is viewed by both the public, and employers.

Historically, nursing evolved into a profession. This development involved both by the creation of a teaching and training system as well as by the evolution of professional organizations. The latter established their internal organs, their principles and standards, their ethical code foremost among other ones. The legal recognition of Nursing, the rules of accreditation, conduct etc., within the wider framework of the Healthcare system followed suit – in most developed countries.

The present unsatisfactory legal framework is being discussed and ways for improvement are recommended. All these in compliance with the country's labor laws. The new Bill of Nursing which is presently processed by the Knesset is being discussed, and certain amendments were suggested.

The article favors the strengthening of the nursing profession, and advocates the empowerment of the Nurses' Association in a way similar to that of the Bar Association. A more independent

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nurses' body will be able to promote nurses' education, social recognition and economical status. It will also be able to further develop and enforce its ethical (=legal) code.

¹ BA in Nursing, Haifa University; RN; LLB Haifa University School of Law.

The author wishes to acknowledge the contribution of Mrs. Sarah Shahaf, R.N. whose advice and assistance contributed greatly to this paper.

Factors Influencing the Quality of Decision-Making of Nurses in Clinical Setting

Alla Nubik-Tulchinsky¹ and Nili Tabak²

Decision making in which concerns subjects related to patient care is an everyday and inseparable part of nurses' duties.

This paper is a report of an attempt to investigate the process by which nurses make clinical decisions, and the factors which influence it. The theoretical framework of this research was based on two models: Klein's model of decision-making, and the model of "conflict theory in decision-making" of Mann and Ganis.

Nine questionnaires were used as tools in this investigation. The questionnaires were presented to eighty nurses who serve in six departments of medicine of a major medical center.

A significant correlation was found between the quality of decision making and the quality of interpersonal relationships within nursing staff members, management support, and the complexity of the situation under consideration.

¹ RN - This paper is a part of a thesis, as part of requirements towards a Master's Degree in Nursing, presented to the School of Nursing, , Tel Aviv University

² RN, LLB, PhD – Head of Graduate Program, School of Nursing, Tel Aviv University

**The Abortion Procedure as Set in Criminal Law:
Is it Consistent with the Public Interest?**

Dr. Yossi Green¹

Generally, five interested parties are involved in the decision on abortion: the pregnant mother, the father of the fetus, and a doctor – all of whom have legal standing with regard to the abortion, the fetus, who bears the consequences however is devoid of legal standing to determine 'its' fate, and the State, as represented by an abortion committee, and in many cases by the court. In cases in which medical opinion recommends abortion, at any stage of fetal development, it may be assumed that there is unanimity of interests of all parties involved, even of the fetus who would prefer not to exist with severe disability. This is not the case, however, where the reasons for the abortion are other than medical.

The article outlines the interests of each of the parties involved in the procedure, in the context of the present legal situation in Israel. Three arguments are made:

- A. Despite the legal autonomy of the bearer of the fetus and of her right to plan her family, she may not have the right to decide to terminate the pregnancy. This may be determined only by the Government-appointed Committee on Abortions.
- B. Even though the father of the fetus was involved in its creation, he too has the right to plan his family/ It seems wrong to deny him the right to present his case before the Committee on Abortions. The present situation must be righted.
- C. The existence of two committees concerned with abortion, the first with the early stages of pregnancy, and the second, which supervises cases in later stages of pregnancy, is not congruous with the terms of existing law.

The author, who favors the formation and involvement of the Appeals/Supervising Committee, suggests that appropriate amendments to the law be made

¹ Dr. Yosi Green is a Senior Lecturer at The Faculty of Law, The Academic College of Netanya.

The Director General's Guidelines as a Tool to Counter Liability

Jonathan Davies¹

Clinical guidelines are normative standards regarded as indicative of the standard of care. They may be used as a tool for the assessment of questionable conduct.

Termination of pregnancy is illegal under the penal law. However, the law provides broad defenses (or rather exemptions) which permit a Committee of 3 doctors and a social worker to recommend the termination of pregnancy, on evidence for expected of considerable damage, either to the fetus or to the mother if the pregnancy is allowed to continue.

Israeli Case law has developed cause of action, to the handicapped child for Wrongful Life and to the Parents for Wrongful Birth, for failing to provide full information to the mother. The mother may claim damages for the costs of raising a handicapped child, since she would have elected abortion, had she been fully and accurately informed of the facts.

The assumption is that the doctor was in possession of the information regarding the outcome, and that it was communicated to the expectant mother in a timely fashion. Wrongful Birth is also applicable in cases where an abnormality is missed on ultrasound scanning. The potential for structural abnormalities to be overlooked during a routine scan is high. The major structural defects are likely diagnosed, but minor abnormalities, which may indicative of a later but more complicated problem, may frequently constitute a source of controversy.

Israeli law does not put an age limit on the termination of pregnancy. Theoretically the abortion could be performed even immediately prior to birth. Jewish Law is not applicable in State courts. The decision for the termination of pregnancy is solely that of the parents, who are autonomous in their right to decide. It is the duty of the doctors is to provide the mother with the full necessary information to enable her to make an informed decision based on the information received.

The Ministry of Health in Israel has Developed Guidelines for the Assessment of Functional Disability of the Fetus at the viable period, i.e. - 24 weeks and later, as criteria for recommendations for termination of pregnancy. It is our opinion that these criteria are not applicable since it is impossible, for any medical expert, to foresee future incapacity of 30% prior to birth.

The Guidelines further recommend that the doctors, who serve as members of the medical committees for termination of pregnancy, be exempt of personal responsibility of their actions. This recommendation is legally wrong and contradicts the law.

Clinical guidelines are not considered as the legal standards of clinical care, but they do provide the courts with a benchmark, helping the judge in considering clinical conduct. It is therefore

that Clinical Guidelines should not be used as a tool to influence and counter legal liability. The Ministry of Health misused its authority and power to enact clinical guidelines, in order to influence the court and promote special interest groups rather than the interest of the general public.

¹ Jonathan Davis LLB, www.med-law.co.il

The Appointment of an Expert Witness by the Court
Comments on the Report of the
Committee on Court-Appointed, Remunerated Functionaries

Avraham Sahar¹

The Committee consisted of a retired Supreme Court Justice, the President of the National Labor Court and the President of a District Court. The Report deals with a variety of problems pertaining to the wide range of experts who assist the Court's endeavors. This paper is concerned solely with the Court-appointed Medical Expert. The subjects reviewed by the committee were: the paramount importance of transparency of the appointment; ways to ensure maximum suitability of the expert to the issue to be discussed, both as to the professional aspects as well as to the expert's personal integrity; the application of "the reasonable doubt" principle in the examination of a possible conflict of interests of the expert. Strict equality in appointments was seen as imperative.

The primary operational recommendations of the committee were to establish a Unit within the Office of the Director of Courts which to be entrusted with the preparation of a list of all qualified experts, classified by their respective exact specializations. Such a list would help choose the correct expert, and at the same time it will help the proper distribution of the burden among the experts in any given medical field. Conflict of interest will be prevented by full disclosure of past contacts and/or other possible dealings with any of the parties concerned. The committee recommended the principles for the remuneration of experts, but avoided details.

The paper brings up several of the problems which may arise by attempts to implement the above recommendations, and suggested ways to avoid and solve them. The paper suggests that the sitting judge be the appropriate authority to appoint the expert; most suitable to examine the suitability of the expert, as for the subject to be examined, and the expert's personal integrity and/or her/his conflict of interests. A novel idea was submitted – the formation of a list of Independent Trusted Experts who will confine their court-related activity to serving the court alone.

¹ Professor Emeritus of Neurosurgery, Attorney at Law, author of **Expert Witness Law** (2003).