I met Sas Strauss for the first time in 1967 when as a final year LLB student at the University of Pretoria I was appointed an assistant in the Faculty of Law of the University of South Africa. Unfortunately I did not have much personal contact with Sas then, as I was only a young assistant in another department (Commercial Law) and he was already a senior and highly respected professor of criminal law.

In 1968 I joined the Department of Justice as, firstly, a public prosecutor in the magistrates' court and thereafter as state advocate on the staff of the Attorney-General of the Transvaal. In that capacity I met Sas for the second time: he acted as an assessor in the (in)famous (for those days) murder trial of the State versus Sonjia Swanepoel and Frans Vontsteen, who were indicted with murdering Sonjia's husband, former Springbok athlete, François Swanepoel. The presiding judge was Mr Justice VG Hiemstra, who later became Chief Justice of the Bophuthatswana Supreme Court. (He was also for a period of ten years Chancellor of the University of South Africa.) The other assessor was Dr Mosey Bliss QC, who acted as a judge on several occasions, who had been my advocate lecturer in civil procedure at the University of Pretoria in 1967 and who graduated with an LLD from the Rijks University at Leiden in 1933 with a doctoral dissertation entitled 'Belediging in die Suid-Afrikaanse Reg'. I was the junior state advocate with my senior André Erasmus, presently a judge of the Eastern Cape Division of the Supreme Court of South Africa. In one of the books that appeared after the trial the author described Sas as 'a brilliant young man with a grave politeness about him'. Brilliance and politeness, however, are only two of the many qualities that this perpetual 'young man'

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1Peter du Preez The Vontsteen Case 48 (Howard Timmins Cape Town 1972). In the same book (p 14) Erasmus' J handling of the state case was prophetically described as 'masterfully, with the veteran's coolness and sureness of touch'. The case was reported: see S v Vontsteen 1972 4 SA 1 (T) and S v Vontsteen 1972 4 SA 551 (A).
In April 1977 I joined the Department of Criminal and Procedural Law at Unisa as an associate professor with Sas as its Head. He promised that when I completed my doctoral thesis he would do all in his power to have me promoted to a chair. He kept his promise (as he always does): on 1 October 1977 I was promoted to my present position after completion of my thesis, with Sas as one of the examiners.

After nearly two decades as head of the Department, Sas stepped down. Many years later I succeeded his successor, prof AJ Middleton, in that position. In these reversed roles Sas was as polite a colleague as ever and it has been an exceptional honour and pleasure to have been a colleague and friend of this extraordinarily talented man (or rather 'person' in the present common parlance).

When I had to decide on the topic of this article I kept in mind our common love of, inter alia, American scenery and interest in the history of the American Indians (Native Americans). This article, therefore, had to be about something American. Thinking of Sas' involvement in the practice of law (and my own, while we both have been employed full-time as law professors) I thought of the empowerment of those not actively involved in the practice of law: lay persons, for instance.

The first possibility in this regard that one has to consider is the possible re-introduction of the jury into the South African legal system. I shall deal briefly with that option below. There is, however, another institution in the judicial empowerment of lay people that may be considered. The topic that I selected: the American grand jury.

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2 The belief is widely held that if he wanted those positions Sas could have been a Minister of State, ambassador, principal of a University and a judge of the Supreme Court, had he selected a career at the bar.
3 Die aksie weens seduksie (The action for seduction) with Sas's own former promoter, prof WA Joubert, as my promoter.
4 In 1993 I had the pleasure of visiting one of the most beautiful (to Sas and to me) places in the world: the unsurpassable monoliths of Monument Valley in the Navajo Tribal Park on the borders of Arizona and Utah.
5 See eg my article 'The undefended accused/defendant: a brief overview of the development of the American, American Indian and South African positions' 1991 CILSA 151.
6 It was not for nothing that at some stage of his career he was referred to as the 'pinball king'!
BRIEF REMARKS ON THE REINTRODUCTION OF THE JURY SYSTEM IN SOUTH AFRICA

The jury system in South Africa in civil trials was abolished in the Cape and Natal (the only provinces where there were such institutions) by s 3 of Act 11 of 1927 and in criminal matters by the Abolition of Juries Act 34 of 1969. Although these systems 'passed unwept, unhonoured and unsung', the reintroduction of a jury system in civil matters has been proposed. The main argument in favour of the jury is that it ensures the participation of citizens in the administration of justice. In criminal trials in the lower courts (magistrates'/district and regional courts) the magistrate may summon to his assistance one or two persons (also lay persons) who in his opinion may be of assistance either at the trial of the case, or in the determination of a proper sentence, i.e. a community-based punishment. This led to the suggestion that the above provision for lay assessors may be used in an adapted or modified jury system.

A further reason advanced for the reintroduction of the jury system is to render our legal system more acceptable and relevant to the majority of the population. The involvement of untrained members of the public in the legal domain should help adjust the public's negative views of all sectors of the legal profession as they become involved in the issues of the day, forced to weigh and address them during the course of the trial. The idea is that such a system would enable magistrates to invite people of colour, in addition to whites, to sit with them on the bench.

The above idea, however, seems to have little prospect of viability, mainly for two reasons. First because, as far as decision making in terms of our legal system is concerned, it is not practicable for a professional functionary to function on exactly the same footing as complete laymen; and secondly because the utilisation of lay assessors would cause criminal trials to take at least twice as long to dispose of.

A further possibility is then raised: a system similar to that of British lay magistrates. These magistrates are selected with the utmost care and they undergo basic training. They function on a part-time basis and follow a variety of callings or are retired. More than one — normally three — magistrates sit together. It is said that a better illustration of 'trial by peers' can hardly be

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7Hahlo and Kahn South Africa — the development of its laws and constitution (1960) 257.
81988 DR 490.
10Section 93ter of the Magistrates' Court Act 32 of 1944. See also an interview with the Minister of Justice, Dullah Omar 1994 DR 489 492.
111992 DR 296.
121991 DR 6.
13Ibid 7.
14April 1991 Consultus 3.
visualised.\textsuperscript{15}

The present-day apologists for the jury system, in pleading for its reintroduction, argue that this will result in a democratisation of the judicial process. That will lead to the legitimisation of the judicial system in the eyes of the community and enable it to achieve a respected position as a dispenser of justice.\textsuperscript{16}

It has been contended, however, that the real argument of the reintroductionists is not a legal or a moral or even a practical argument, but a political one and it depends largely on what one sees the role of the jury to be: is it a trier of fact, a buffer against unpopular laws or simply a means whereby society can be made to feel satisfied that it has a recognised interest, and a role to play, in the administration of justice?\textsuperscript{17}

However, the majority of South African writers on the subject of the jury system, have serious reservations about its reintroduction, if not straightforward opposition thereto.

Hiemstra is critical of the rule which expects untrained people to make complicated decisions of fact.\textsuperscript{18} It is also ironic that the champions of the jury wish to reintroduce it for the same reason that its opponents originally abolished it — because it alienated the man in the street from the judicial system as a result of acquittals and convictions contrary to the evidence and contrary to justice.\textsuperscript{19}

For Mullineux the most serious argument against the jury system is the absence of a requirement that the jurors should give reasons for their findings.\textsuperscript{20} Most, if not all, of the ills attributed to the jury system could be avoided if juries were required to give reasons for their findings, and if an appropriate right of appeal were granted to both sides in the case where the reasons are invalid or insufficient.\textsuperscript{21}

Mullineux doubts whether this will be an entirely satisfactory solution of the problem. If the fears of experienced persons and those who have studied the

\textsuperscript{15}Ibid 5. See also 1993 DR 721.
\textsuperscript{16}1993 DR 721. See also 1990 DR 507.
\textsuperscript{17}John Baldwin and Michael McConville \textit{Jury trials} (Clarendon Press 1979) 19, quoted ibid.
\textsuperscript{18}Suid-Afrikaanse Strafproses 1 ed (1967) 128.
\textsuperscript{19}See the article in 1916 SAIJ 177.
\textsuperscript{20}1993 DR 727.
\textsuperscript{21}Ibid. I agree with Mullineux who has always found it incomprehensible that a patently correct verdict could be overturned on appeal because the judge, in summing up, failed to direct the jury in sufficiently clear terms as to the quantum of proof required. On the contrary a doubtful verdict preceded by a correct direction as to the quantum need not necessarily suffer the same fate. The obvious solution — according to Mullineux — to require from the jury reasons for judgment which would make the correctness of the verdict a matter for rational discussion instead of speculation — has for inexplicable reasons never been adopted — \textit{ibid} 728 note 4.
deliberations of juries are anything to go by, the courts can expect a surfeit of appeals from improperly substantiated factual findings by juries.\textsuperscript{22}

In 1992 the General Council of the Bar (the official mouthpiece of all practising advocates organised in bars) resolved that the reintroduction of a jury system in South Africa was neither feasible nor desirable.\textsuperscript{23}

Experience in other countries, like the United States of America, has shown that it is fatal to pretend that racial or ethnical differences do not play a role in the courts.\textsuperscript{24} It is quite conceivable and even distinctly probable that the jury system requires for its ideal working a basic homogeneity in the population.\textsuperscript{25} It is difficult, therefore, for the jury system to operate satisfactorily in a multi-racial and heterogeneous community.\textsuperscript{26}

It is doubtful, therefore, whether the jury system can be introduced again in South Africa with any measure of success, or whether it will achieve any of the aims that a restructured legal system seeks.\textsuperscript{27} Mr Justice Tebbutt of the Provincial Division Cape of Good Hope, who presided over the last jury trial conducted in the Cape, is strongly against the re-introduction of the jury system, which he considers a retrogressive step.\textsuperscript{28}

\section*{THE AMERICAN GRAND JURY}

\subsection*{History of the grand jury\textsuperscript{29}}

The formal separation of the grand jury from the trial jury occurred in 1350 when the English Parliament passed a statute forbidding grand jurors from sitting on the trial juries of defendants they had indicted.\textsuperscript{30} Thereafter, when one of the king’s many travelling justices arrived to hear the disputes of a community, the sheriff would pick twelve men from the immediate surrounding community to serve as local jurors; he would then select an additional group of twenty-four men, usually knights, from a larger area to serve as an accusing body for the entire county. These twenty-four men, after eliminating one member to preclude the possibility of a deadlock, began investigating incidents throughout the county under the title of ‘le graunde inquest’, and

\begin{footnotes}
\item[22]1993 \textit{DR} 727, and see prof E Kahn ‘Restore the jury? or ‘reform?’ reform? Aren’t things bad enough already?’ 1992 \textit{SAIJ} 87, especially from 105, and in note 161 on 109. See also MJD Wallis SC ‘Some thoughts on juries’ 1991 \textit{Consultus} 112.
\item[23]See April 1992 \textit{Consultus} 12.
\item[26]J Ashton Chubb 1956 \textit{SAIJ} 199. See also an interview with the Minister of Justice, Dullah Omar, 1994 \textit{DR} 489 492.
\item[27]L Rood ‘A return to the jury system?’ 1990 \textit{DR} 749 750.
\item[28]1993 \textit{DR} 555.
\item[30]25 Edw 3 c 3 (1350).
\end{footnotes}
quickly took over the entire burden of filing indictments.31

The form of the grand jury was thus established at an early date, but over 300 years passed before the independence of the grand jury was finally recognised. In 1681, eleven years after the trial jury’s independence had been established in Bushell’s Case,32 the grand jury of London refused to return an indictment against Stephen Colledge, who was accused of treason. After hearing the prosecutions’ witnesses and questioning them in private, the grand jurors returned the bill presented by the prosecutor with the word ‘ignoramus’33 written on its back. The royal authorities then presented the same evidence before the Oxford grand jury which returned the indictment, apparently not sharing the politics of its counterpart in London.34 The principle that a grand jury could stand between the king and the accused was nonetheless established and spread quickly throughout England as well as to the American Colonies.

Independent grand juries played an important role in the years before the American Revolution.35 During the early debates in the Massachusetts Legislature over the ratification of the Constitution, before the Bill of Rights had been written and presented to the states, Abraham Holmes complained:

(T)here is no provision made in the Constitution to prevent the attorney-general from filing information against any person, whether he is indicted by the grand jury or not; in consequence of which the most innocent person in the commonwealth may be taken by virtue of a warrant issued in consequence of such information ...

Because of this fear, when the Bill of Rights was prepared, the protection of the grand jury was provided for in the proposed fifth amendment as a bulwark against governmental oppression, and was accepted as part of the Bill of Rights without debate.37

The fifth amendment to the US Constitution
The framers of the United States Constitution made the grand jury a part of the fifth amendment which provides, inter alia, as follows:

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury ...

The purpose of this constitutional provision was to protect the citizens

31 F Pollack and F Maitland History of English law (2ed 1898, reissued 1968) 646–70; 3 Reeves History of the English law (3 ed 1814) 133.
32 124 Eng Rep 1006 (CP 1670).
33 'We are ignorant' or 'we ignore it'.
34 The trial of Stephen Colledge, at Oxford, for high treason, (1681) 8 How St Tr 550.
35 For a discussion of the development of the grand jury in the American Colonies during the seventeenth and early eighteenth centuries, see Van Dyke and Wolinsky, Quadra v Superior Court of San Francisco: a challenge to the composition of the San Francisco grand jury, 1976 The Hastings LJ 565, 592–93.
36 2 Elliot’s Debates 110 (2 ed 1881).
'against unfounded accusation, whether it comes from (the) government, or (is) prompted by partisan passion or private enmity'.

In a presentment the grand jury initiates an investigation based on its own knowledge or on submitted evidence. An indictment differs from a presentment in that the government presents a written accusation to the grand jury.

A person should, therefore, not be placed in jeopardy of a felony prosecution unless a body of citizens finds it probable that he committed the offence charged.

However, the Supreme Court has held that the federal right to a grand jury indictment does not apply to the states. In *Hurtado v California* the Court stated that an indictment by a grand jury was not necessary to due process of law under the Fourteenth Amendment. Today, the Fifth Amendment right to a grand jury remains among the few Bill of Rights' guarantees not applicable to the states. Nevertheless, several state constitutions provide that with certain limited exceptions, felonies shall be prosecuted solely on grand jury indictments. Some states permit prosecution of felonies to be initiated by the filing of an information or indictment at the option of the prosecutor. Several states allow the use of the judicial inquest or 'one-man grand jury'.

Where prosecution of felonies may be initiated by information, several states require that some form of preliminary examination be employed to determine probable cause for prosecution thereby achieving much the same check on unfounded charges as is implicit in the requirement of a grand jury indictment.

A California survey revealed that prosecutors found the grand jury procedure advantageous in the following instances:

1. when the accused has evaded apprehension and the statute of limitations will soon bar an information requiring the presence of the accused;
2. when the district attorney desires to avoid premature cross-examination of emotional or reluctant witnesses;
3. where there is a great public interest in the case and the district attorney, for political reasons, desires to share responsibility for prosecution with the grand jury;

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38 *Ex Parte Bain*, 121 US 1, 11 (1887).
41110 US 516, 4 S Ct 111 (1884).
42Whitebread *Criminal Procedure* 375.
43Ibid 376.
(4) when the investigative powers of the grand jury are useful, as in complex fraud cases or those involving corruption in public office; and

(5) when the district attorney believes that employing the grand jury would be speedier than using preliminary examination procedures, as in cases involving multiple defendants or offences.44

GRAND JURY PROCEDURE
Historically, a prosecutor will initiate a grand jury investigation when he has evidence of wrongdoing, no matter how slight.45 The grand jury subsequently must assess whether probable cause exists to believe that a crime has been committed.46 The prosecutor directs the grand jury investigation, determining which witnesses the grand jury will subpoena, selecting the documents or evidence presented and criminal charges pursued, explaining the law and instructing the grand jury on the burden of proof.47 If probable cause is found, a grand jury may return an indictment but is not constitutionally required to do so. As was stated by Judge Wisdom:

By refusing to indict, the grand jury has the unchallenged power to defend the innocent from government oppression by unjust prosecution. And it has the equally unchallengeable power to shield the guilty, should the whims of the jurors or their conscious or subconscious response to community pressures induce twelve or more jurors to give sanctuary to the guilty.48

If no indictment is returned, constituting a ‘no bill’, the prosecutor may, upon approval by an assistant attorney-general, resubmit the case to another grand jury.49 Double jeopardy or collateral estoppel defenses do not apply to multiple grand jury proceedings.50 Grand jury proceedings are conducted in secret, with only the jurors, prosecutor, witnesses, stenographer, recording device operator or interpreter present.51

45See Blair v United States, 250 US 273, 282 (1919) (prosecutor may initiate grand jury investigation on mere rumours and tips).
46See United States v Calandra, 414 US 338, 343 (1974) (grand jury proceeding is nonadversarial and does not serve to adjudicate guilt or innocence).
47See, eg, Campbell ‘Eliminate the grand jury’ 1973 J Crim L and Criminology 174, 177 (explaining prosecutor’s role in conducting grand jury investigation). Moreover, the prosecutor, as the representative of the government, will instruct the jury as to the level of proof necessary to sustain an indictment.
48United States v Cox 342 US 167, 189-90 (5th Cir).
49United States Attorney’s Manual § 11.220 (1988). The manual recommends that such approval be withheld in the absence of additional or newly discovered evidence or a clear circumstance of a miscarriage of justice.
50United States v Thompson 251 US 407, 412-13 (1920) (grand jury has power to indict upon charge previously ignored by another grand jury).
51Fed R Crim P 6(d) See in general, Ron S Chun ‘The right to grand jury indictment’ 1989 American Criminal Law Review 1457. The rule of secrecy needs to be re-examined: William B Lytton ‘Grand jury secrecy — time for a reevaluation’ 1984 The Journal of Criminal Law and Criminology 1100. See, also, note 93 infra. The secret proceedings of grand juries are largely unreviewable. See Thomas P Sullivan and Robert D Nachman ‘If it ain’t broke, don’t fix it: why the grand jury’s accusatory
The grand jury is credited by observers and participants in the American criminal justice system with being one of the most effective tools in a prosecutor’s arsenal.\textsuperscript{52} Ironically, the contemporary function of the grand jury distorts its historical roots; the grand jury functions less to protect individual rights against arbitrary prosecution and more as effective aid for zealous law enforcement.\textsuperscript{53} Despite the grand jury’s history of independence, there is a recognised need for the prosecutor to direct its proceedings.\textsuperscript{54}

In the recent past the grand jury has been criticized as no longer being an independent body, but simply a rubber stamp of the prosecutor.\textsuperscript{55} The Supreme Court also has expressed some doubt concerning the independence of the grand jury:

> The grand jury may not always serve its historic role as a protection bulwark standing between the ordinary citizen and an overzealous prosecutor ...\textsuperscript{56}

The grand jury remains one of the most effective methods in a criminal investigation for compelling the appearance of witnesses and the production of documents. An attorney is of the opinion that without the investigatory power of the grand jury, successful investigations of official corruption, large scale financial fraud, or organized crime would be dramatically reduced.\textsuperscript{57}

The importance of the investigative role of the grand jury, however, must not be permitted to overshadow its role as an independent accusatory body. A balance must be maintained between the two roles. The key to the balance lies with the integrity and the professionalism of the prosecutor.\textsuperscript{58}

The different functions of the grand jury may now be discussed.
Types of grand juries
Grand juries serve three functions: a charging function (generally found in states east of the Mississippi River); an investigatory function (found throughout the United States); and a supervisory function (also found nationwide).

The charging function of the grand jury
The role of the charging grand jury is to determine whether there is probable cause to proceed with the prosecution of a particular defendant. Since the prosecutor presents the evidence, the grand jury is sometimes merely a rubber stamp for the state. Unlike a trial, no one in a grand jury proceeding is obligated to produce evidence tending to undermine the prosecutor's case.

If the charging jury does hear evidence for the accused, however, it must base its decision on all the evidence taken.

In theory, one function of the grand jury is to act as a safeguard against unfounded charges. In this regard states apply two different standards for indictment: the probable cause standard and the prima facie case standard. Under the former the quantum of proof necessary for the return of an indictment is not as great as that necessary to convict. Under the latter standard, the government must establish each element of the crime with the quantum of proof sufficient to make out a prima facie case at trial.

The number of grand jurors whose concurrence is necessary to return an indictment, as well as the number of grand jurors on the panel, is set by statute, and varies greatly from jurisdiction to jurisdiction.

59 Whitebread Criminal Procedure 377. The following discussion about the functions, powers, rights and composition of the grand jury has been taken largely from Whitebread's work.

60 See United States v Dardi 330 F 2d 316, 336 (2d Cir 1964) cert denied 379 US 845, 85 S Ct 50.
they will not dismiss the indictment unless the defendant can show prejudice.65 One state, Missouri, does prohibit grand jury subpoena of a person after the return of an indictment, when that person is likely to be called as a defence witness.66

The investigatory function of the grand jury

Unlike the charging grand jury, the investigatory grand jury is not confined to acting upon a specific charge against a particular defendant. Rather, the determination of the identity of the accused and of probable cause to charge him is made at the culmination of the investigation. Thus, there is no formal charge submitted to the grand jury, and a prosecutor generally has no say as to the limits of the grand jury’s investigation. Since it is assumed that grand jurors know of the commission of offenses before they begin hearing evidence, it has been held that prejudicial preindictment publicity is not grounds for quashing a subsequent indictment.67

The scope of the grand jury’s investigation extends to all criminal offenses committed within the jurisdiction of the court which called it. Because of the extremely broad standards of relevancy applicable to such investigations, grand juries frequently pursue matters having only a peripheral relation to criminal offenses.68 In addition, the grand jury inquiry is not circumscribed by the rules of evidence. Thus, the grand jury can engage in a ‘fishing expedition’ when exercising its investigatory power.69

The supervising function of the grand jury

Virtually every state vests in the grand jury a supervisory function, ranging from investigating conditions in county jails,70 to perusing public records and recommending on matters of policy,71 to investigating wilful and corrupt misconduct in public offices.72 A major issue pertaining to this supervisory role involves the extent to which a grand jury may report on government operations — perhaps thereby reflecting discredit on public officers — without rendering any criminal charges. Most states require statutory authority for the issuance of such reports. They have set limits on the reporting power of grand juries by either (1) prohibiting such reports altogether;73 (2) limiting reports

65See United States v Star 470 F 2d 1214, 1217 (9th Cir 1972).
67Silvertbome v United States 400 F 2d 627 (9lh Cir 1968).
to proposals or recommendations for future action;\(^{74}\) (3) limiting reference to public officials to cases where the official's conduct was intimately connected with the general condition investigated;\(^{75}\) or (4) permitting only such reports as emanate from legitimate inquiry into criminal conduct or corrupt activity.\(^{76}\)

Such limits are warranted, since the public will view reports as authoritative even though the censured official — not having been indicted — will not have had an opportunity to vindicate himself. Had an indictment been returned, the official would have been accorded a trial and a forum in which to clear his name. It is important to note in this regard that a grand jury which exceeds its statutory authority may not be privileged in a subsequent libel action.\(^{77}\)

As a rule, a grand jury may not use a report as an alternative to an indictment, and any actual charges of criminal activity will be expunged from the report.\(^{78}\) Although reports may be issued in conjunction with the return of indictments, they will often be expunged if a court feels the report will prove prejudicial to the trial. For example, the Ohio grand jury that investigated the events on the Kent State University campus in May 1970 indicted twenty-five persons for forty-three offenses. The grand jury also returned a report in which it recounted its interpretation of what occurred and made the finding that 'beyond doubt' the charged offenses had been committed. The federal district court, in *Hammond v Brown*,\(^{79}\) ordered the report expunged on the grounds that the grand jury had exceeded its authority and that the report's continued existence in the court files would impair the defendant's right to fair trials.

It seems, therefore, that grand juries possess wide powers which would in South Africa be performed by the attorney-general, his staff and public prosecutors, the police and various other official bodies. It is my submission that despite all other considerations pro or contra the grand jury, this constitution's success in South Africa will depend mainly and perhaps exclusively on its composition in the light of the multi-cultural face of South Africa.

### The powers of grand juries

The grand jury possesses several means of investigating crime, a fact which gives it a unique position in the criminal justice system and are of great help.

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\(^{75}\) *NJ Ct R 3–9*.
\(^{77}\) *Bennett v Stockwell* 197 Mich 50, 163 NW 482 (1917). See also *Ryon v Shaw* 77 So 2d 455 (Fla 1955).
\(^{78}\) *In re Messano* 16 NJ 142, 106 A 2d 537 (1954); *State v Bramlett* 166 SC 323, 164 SE 873 (1932); *Ex parte Faulkner* 221 Ark 37, 251 SW 2d 822 (1952).
\(^{79}\) 323 F Supp 326 (ND Ohio) aff'd 450 F 2d 480 (6th Cir 1971).
Compelling witness attendance

In most federal and state jurisdictions, the prosecutor cannot compel the attendance of witnesses during the course of his own independent investigation. Once a grand jury has been convened, however, he acquires this power in order to make his presentation to the grand jury. In addition, under the supervision of the court, the grand jury itself may summon or direct the prosecution to summon witnesses. No showing of probable cause is required to subpoena a witness before the grand jury.

A witness may be held in criminal or civil contempt for failing to obey a grand jury subpoena or for being unresponsive to questions asked him before the grand jury.

Subpoenas duces tecum

Grand juries also have the power to issue subpoenas duces tecum. These subpoenas may be modified or quashed if they are overly broad or unreasonable. In United States v Gurule the court identified three criteria for a valid grand jury subpoena duces tecum:

- The subpoena may command only the production of things relevant to the investigation;
- specification of things to be produced must be made with reasonable particularity; and
- production of records covering only a reasonable period of time may be required.

Immunity grants

Another major power of the grand jury is the ability to have the appropriate authority grant a witness immunity from any subsequent prosecution based on the witness's testimony before the grand jury. Immunity is granted by the prosecutor or the court, depending on the jurisdiction. In the federal system, the immunity order is issued by the district court at the request of the prosecution. Since in theory immunised testimony cannot be used against him, the witness may no longer invoke his Fifth Amendment privilege against self-

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81 Ibid.
82 Fraser v United States 452 F 2d 616, 620–21 (7th Cir 1971).
84 437 F 2d 239 (10th Cir 1970), cert denied 403 US 904, 91 S Ct 2202 (1971).
85 437 F 2d 239, 241. Reform proponents of the grand jury note that subpoenas are, in effect, issued by the prosecutor in the name of the grand jury without the knowledge or consent of the grand jurors. See ME Hixson 'Bringing down the curtain on the absurd drama of entrances and exits-witness representation in the grand jury room' 1978 The American Criminal Law Review 307 308.
86 18 USCA §§ 6000–6005.
incrimination in response to questions within the scope of the immunity.\textsuperscript{87} Immunity is of two types. ‘Transactional’ immunity absolutely bars the witness’s future prosecution as to any transaction to which he has testified. ‘Use and derivative use’ immunity merely bars the use or derivative use of his own testimony in a prosecution against him.\textsuperscript{88} If independent evidence of his crime is found, he may still be prosecuted. The Supreme Court upheld the constitutionality of use immunity in \textit{Kastigar v United States}.\textsuperscript{89}

\textbf{The role of the court}

The principal function of the court \textit{vis-à-vis} the grand jury is to enforce the grand jury’s subpoena, immunity, and contempt powers. The judge who calls the grand jury will usually charge its members on the nature and tradition of grand jury investigation, and may instruct them on points of law; however, he is not present during their sessions.\textsuperscript{90}

Courts do not take an active role regarding the charging function of the grand jury. Generally, evidence will not be reviewed, and when it is, courts will allow an indictment to stand on the slightest \textit{quantum} of legal evidence.\textsuperscript{91} Courts will, however, take a more active role as to reports rendered by investigatory and special grand juries, expunging those portions of the report which exceed the grand jury’s authority.

\textbf{Secrecy of grand jury proceedings}\textsuperscript{92}

One of the major distinguishing features of the grand jury is that its sessions are conducted in secret. Grand jury secrecy appears to have arisen from the need to protect grand jurors from government intimidation and reprisal.\textsuperscript{93} The modern justifications were articulated by the Supreme Court in \textit{Pittsburg Plate Glass Co v United States}.\textsuperscript{94}

- To prevent the accused from escaping before he is indicted and arrested or from tampering with the witnesses against him.
- To prevent disclosure of derogatory information presented to the grand jury against an accused who has not been indicted.
- To encourage the grand jurors to engage in uninhibited investigation and deliberation by barring disclosure of their votes and comments during the proceedings.\textsuperscript{95}

In current practice, grand jury secrecy works to the advantage of the prosecutor. While the grand jury proceeding can serve as a thorough

\textsuperscript{87}Whitebread \textit{Criminal Procedure} 382.

\textsuperscript{88}See \textit{In re Kilgo} 484 F 2d 1215, 1220 (4th Cir 1973).

\textsuperscript{89}406 US 441, 92 S Ct 1653 (1972).

\textsuperscript{90}Fed R Crim P 6(d); Cal Penal Code § 934 (West 1970); Va Code Ann § 19.2-199 (1975).

\textsuperscript{91}See \textit{State v Goldberg} 261 NC 181, 134 SE 2d 334 (1964) cert denied.

\textsuperscript{92}See also, note 52 \textit{supra} and Whitebread \textit{Criminal Procedure} 383–4.


\textsuperscript{94}350 US 395, 79 S Ct 1237 (1959).

\textsuperscript{95}360 US 395, 405, 79 S Ct 1237, 1244.
discovery device for the prosecutor, the secrecy surrounding may deprive the defendant of a similar advantage since neither the defendant nor his counsel has an absolute right to be present during the grand jury session. In addition, in many jurisdictions secrecy is invoked to deny the defendant a transcript of the proceedings.96

Recognising this fact, some states have taken steps toward liberalising pretrial disclosure of grand jury testimony.97

**Rights and rules applicable during the grand jury process**

Aside from its secrecy, the grand jury session differs from the regular jury trial process in terms of the rights accorded the defendant and other witnesses. Under various rationales, the Supreme Court has held that an individual's privilege against self-incrimination, right to counsel, right to appear and confront witnesses, and his prerogative to exclude hearsay can all be circumscribed in varying degrees in the context of a grand jury proceeding.98

The prevailing rule is that a grand jury witness may not be accompanied by counsel during his interrogation by the grand jury. It applies whether he is merely an ordinary witness or has become the target of the investigation.99 The reasons for this rule are as follows: (1) the grand jury is an investigation rather than a prosecution; (2) the counsel would disrupt the ex parte nature of the proceeding and cause delays; (3) the presence of counsel would breach the secrecy of the proceeding; and (4) the witness whose rights are abused has sufficient opportunity to exonerate himself at trial.100

**Grand jury composition**

The United States Supreme Court has repeated several times that the grand jury must be 'a body truly representative of the community'.101 The romantic image of the grand jury is that of a body of citizens who gather together to investigate the crimes of the community. In fact, grand jurors all too often follow the prosecutor's lead completely and return indictments whenever the district attorney requests them to do so.102 The grand jury has lately been

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98 Ibid 384–89.
100 See Whitebread Criminal Procedure 388; and see in general Steele 'Right to counsel at the grand jury stage of criminal proceedings' 1971 Mo L Rev 193, 203; ME Hixson Ibid note 86 at 315 et seq; Earl J Silbert 'Defense counsel in the grand jury — the answer to the white collar criminal's prayers' 1978 The American Criminal Law Review 293. In 1978, however, ten states had statutes or case law permitting counsel in the grand jury room under certain circumstances, eg to advise their clients of their rights: Mary Emma Hixson 'Bringing down the curtain on the absurd drama of entrances and exits — witness representation in the grand jury room' 1978 The American Criminal Law Rev 307 318.
102 See eg Morse 'A survey of the grand jury system' (pts 1–3), 1931 Ore L Rev 101, 217, 295 (1931).
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criticised as no longer being an independent body, but simply a rubber stamp of the prosecution.\textsuperscript{103}

The Supreme Court has also expressed some doubt concerning the independence of the grand jury:

The grand jury may not always serve its historic role as a protective bulwark standing solidly between the ordinary citizen and an overzealous prosecutor.\textsuperscript{104}

Grand jurors meet behind closed doors, are carefully guided by the prosecutor, and have almost unlimited power to demand evidence. State grand juries also have almost unlimited power to obtain information, to harass witnesses, and to indict, and they have sometimes abused this power. The potential for abuse is therefore great, and, according to Van Dyke, during the Nixon Administration a graphic demonstration of abuse was provided.\textsuperscript{105}

Van Dyke submits that the only way to guarantee that grand jury abuses do not continue to occur is to ensure that membership on grand juries accurately reflects the composition of the population at large.\textsuperscript{106} He is of the opinion that grand juries composed only of elite and influential citizens are particularly vulnerable to governmental abuse and that it is unlikely that such juries may be safely trusted to present the interests of less powerful groups in society.\textsuperscript{107}

Van Dyke states that when the grand jury first became a body separate and distinct from the trial jury, those selected to serve as grand jurors were wealthier and of a higher social class than their trial jury counterparts because their jurisdiction was broader and their potential power was greater and that this tradition remains intact.\textsuperscript{108}

Various justifications are given for this practice. Some commentators and judges have argued that because many grand juries perform both a watch-dog function (supervising governmental agencies) and an investigative function

\textsuperscript{103}United States v Provenzano 440 F Supp 561, 564 (SDNY 1977); 8 Moore's Federal Practice § 6.02(1), 6–22 (rev 2 ed 1985).

\textsuperscript{104}United States v Dionisio 410 US 1, 17 (1973). See also, Peter F Vaira 'The role of the prosecutor inside the grand jury room: where is the foul line? 1984 The Journal of Criminal Law and Criminology 1129.

\textsuperscript{105}Van Dyke 'The grand jury: representative or elite?' (1976) 37 The Hastings LJ 41–4.

\textsuperscript{106}A statement well known to present day politics in South Africa. See also Mark W Smith 'Ramseur v Beyer: The third circuit upholds race-based treatment of prospective grand jurors' 1993 Georgia Law Rev Vol 27 1993 621.

\textsuperscript{107}Van Dyke op cit 44.

\textsuperscript{108}Id.
(probing into abuses of power) the grand jurors must be sophisticated and well educated; otherwise they could be fooled by the officials they are supposed to investigate. 109

Another common justification given for the predominance of affluent and retired professionals in grand juries is that the time required of grand jurors is so great that only persons who are to some extent independently wealthy can perform the required task adequately. 110

According to Van Dyke neither of these justifications are persuasive because both problems could be easily solved by modest increases in the expenditures for grand juries. He suggests that the pay of grand jurors should be raised and then makes the proposal that any problems created by grand jurors who have trouble understanding the economic intricacies of local government can be solved by permitting each grand jury to hire its own attorney and investigator to assist the grand jurors in conducting its investigations. 111

In an interesting study Van Dyke found that in selecting grand juries the young, the poor and the non-whites are underrepresented because the selection is based on the voter registration list, which underrepresents these groups; because these lists are stored for four years at a time, thus discriminating against the most mobile of the population — ie the young, the poor and the non-white. Van Dyke submits that certain judges showed a readiness to excuse persons who differed slightly from the white, middle-class, middle-aged ideal if they presented even the slightest basis for being excused. 112

In San Francisco a United States District Court Judge ruled that 'persistent underrepresentation' of non-whites and women was 'sufficiently substantial to establish a prima facie case of unconstitutional exclusion'. 113

Van Dyke concludes by stating that grand juries have been given enormous power in the American legal system: the power to demand information from anybody, 114 the power to investigate anything, the power to indict any American. He states that this awesome power has been given to a body of citizens rather than to a panel of experts because they distrust bureaucracies and feel that persons in power tend to abuse that power. He feels that they are better protected by an anonymous group of citizens who cannot use their power to pursue any personal ambitions and who will drift back into society after their turn is over.

110 See Van Dyke, op cit, 44-5.
111 Ibid 45.
112 Van Dyke op cit 45-62. Many federal grand juries do not represent the community, but instead represent only the most established and powerful sectors of society — Ibid 62.
Van Dyke is of the opinion that if the grand jury is once again to act as a bulwark against governmental tyranny, random selection systems to protect against all official manipulation of grand jury composition must be adopted and the responsibility of ensuring the true representativeness of the grand jury should be taken more seriously.115

CONCLUSION
Critics frequently blame the grand jury’s failure on the passive, dependent role that the grand jury assumes when investigating criminal activity and prescreening guilt.116 Prosecutors direct the investigation. They determine who is subpoenaed, who are the targets and witnesses and what are the relevant charges. Moreover, they select, present and summarise the evidence and interpret the applicable laws. Some point to the fact that the grand jury is unable to conduct independent investigations inside the jury room and to sift through complex criminal statutes without relying on the prosecutor. Defence attorneys repeatedly complain of the lack of grand jury independence.117

The more cynical argue that the grand jury was never ‘independent’, shielding persons who shared the same political stances against governments who were unpopular to the grand jury and general populace.118

However, the grand jury remains one of the most effective methods in a criminal investigation for compelling the appearance of witnesses and the production of documents. Vaira is of the opinion that without the investigatory power of the grand jury, successful investigations of official corruption, large scale financial fraud, or organised crime would be dramatically reduced.119

The importance of the investigative role of the grand jury, however, must not be permitted to overshadow its role as an independent accusatory body. A balance must be maintained between the two roles. The key to the balance lies with the integrity and the professionalism of the prosecutor.120

The grand jury remains an important institution in the democratic values of the American people. Special Prosecutor Leon Jaworski, in his July 1974 brief before the Supreme Court in United States v Nixon,121 demanding President Nixon’s tapes and defending the action of the grand jury in naming Nixon a co-conspirator, described the grand jury as ‘this body of citizens, randomly

115Van Dyke op cit 62. These arguments sound very similar to those used in defending the jury system.
116Note ‘The grand jury as an investigatory body’ 74 Harv L Rev 590 at 592, 596.
118Ron S Chun op cit 1474.
119Peter F Vaira ‘The role of the prosecutor in the grand jury room: where is the foul line? 1984 The Journal of Criminal Law and Criminology 1129 1130.
120Ibid 1130. Prosecutors have an ethical obligation to preserve the status of the grand jury as an independent legal body: United States v Hogan 712 F 2d 757, 759 (2d Cir 1983).
selected, beholden neither to court nor to prosecutor, trusted historically to protect the individual against unwarranted government charges, but sworn to ferret out criminality by the exalted and powerful as well as by the humble and weak ... .

A place for the grand jury in the South African system?

'Trusted historically' in the quotation above is very important regarding the grand jury in the United States. This institution has for many decades been implanted in the American democratic, judicial system. It has not escaped strenuous criticism at times, though.

In South Africa the decision to prosecute and the prosecution itself has traditionally been left to the attorney-general and his staff. Although an attorney-general is appointed by the State President, in terms of the Attorney-general Act he is free from ministerial interference. On the whole, the courts are reluctant to comment on the discretion exercised by an attorney-general. The office of the attorney-general has always been seen as non-political and that is why (at the time of writing this article), the legal profession has been critical of the proposed new position of National Attorney-general, with a seat in Cabinet.

It has been shown that one of the main objections to and problems of the grand jury is its composition thereof. That is exactly one of the reasons why the reintroduction of the jury system is opposed in South Africa. To form a grand jury which will be acceptable to all in a multi-racial and heterogeneous South Africa will be practically impossible. The office of the attorney-general has historically been trusted in South Africa in the decision to prosecute and the prosecution itself. The investigatory and supervisory functions of the grand jury have traditionally been exercised by other organs of state, viz, the police and commissions of inquiry. Although much can be learnt from the principles concerning the grand jury the introduction thereof in South Africa in order to empower the population in general in the judicial process is not advocated.

122NY Times, July 2, 1974, at 20, col 6, quoted by Van Dyke, ibid, 38. The grand jury was also in the past abused by the government and its agencies to subpoena attorneys in order to obtain information about a client: see Matthew Zwerling 'Federal grand juries v attorney independence and the attorney-client privilege' (1976) 27 The Hastings LJ 1263.
125Richings 1977 SACC 143 144.
126November 1994.
127See, eg, the reaction of the Society of State Advocates, reported in Beeld of 26 November 1994.
128See the discussion in the text next to notes 102 et seq supra.
129Cf note 123 supra.
Epilepsy and driver’s licences*

M BLACKBEARD**

Vanaf 1989 het prof Strauss as my promotor opgetree by die skryf van my proefskrif getitl Epilepsy — Legal problems wat in 1994 voltooii is. Nie slegs was hy 'n uitmuntende promotor wat my op alle gebiede van die reg leiding gegee het nie, maar is hy steeds vir my 'n mentor. Sy wêreldwyse ervaring, ondervinding en kennis is vir enige student en kollega goud werd. Dit is vir my 'n besondere groot eer om onder sy uitmuntende leiding my doktorale studies te kon voltooii.

Introduction

The inability to drive a motor vehicle is for many persons with epilepsy a stumbling-block in the way of finding or retaining employment. Needless to say, in daily life the motor vehicle plays an important role. Apart from enabling a person to follow a normal occupation, it is also a source of relaxation, and a prohibition to drive a motor vehicle can have a marked effect on a person’s self-image and lifestyle. To prohibit a person with epilepsy from driving a motor vehicle, can have a serious and far-reaching effect on his or her life.

On the other hand, it is a great risk to allow some persons with epilepsy to drive a motor vehicle, as the safety of other road users must also be considered. Only a moment’s lack of concentration behind the wheel can cause an accident. We thus have to do with a risk-advantage situation. The risk a person’s ability to drive has for other road users has to be weighed up against the advantage the driver’s licence will have for the person with epilepsy. To create a balance between the two factors, various countries, for instance the Netherlands, require a two years’ seizure-free period before a driver’s licence may be issued to a person with epilepsy. Other countries, such as Austria, India and Japan, will not allow persons with epilepsy to drive at all. In the USA, it depends on the laws of each state whether a person with epilepsy may

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be issued a driver’s licence.\(^2\)

It has been determined that persons with epilepsy who have restricted licences, for instance to drive only to work, have committed more traffic offences and their accident percentages are higher than that of ‘normal’ drivers. This is not always due to the epileptic seizures, but also to the effect some of the medication has on their ability to concentrate. A problem that is often encountered is that the urge of persons with epilepsy to be independent and to drive is so strong that, even if the licence is refused, some of them would drive without a licence.\(^3\)

The circumstances under which a person with epilepsy is allowed to obtain a driver’s licence are discussed with reference to the USA, England and South Africa.

**The USA**

In the USA, each state has its own rules governing the eligibility of persons with medical conditions, to be issued with driver’s licences. For persons with epilepsy the most common requirements are that they should have been seizure-free for a specific period, and an evaluation by a doctor, about their ability to drive safely, is required. Some states also require that the person with epilepsy must periodically submit medical reports for a specific period or for as long as he is licensed.\(^4\)

The District of Colombia and 22 states require a one-year seizure-free period. In Alabama, for instance, a person with epilepsy may only obtain a driver’s licence if a medical report is submitted stating that he has been seizure-free for twelve months. The Medical Advisory Board of The Department of Public Safety will then review the medical information. The person with epilepsy must, for ten years, from the date of the last seizure, submit annual medical reports. The physician who submits these reports, records, examinations, etc, to the Director of Public Safety has civil and criminal immunity for providing the reports, records, examinations, etc. However, no mention is made in the legislation of the physician’s immunity from liability for damages arising out of an accident caused by a seizure.\(^5\)

In seven states a licence may be issued in a shorter period than one year as an exception to the rule. Requirements for this include inter alia a documental report of seizures experienced at night-time only, a prolonged period of the aura, etc. In Maine, for instance, there is a requirement of a one-year-seizure-free period before the date of the application which may be reduced to six

\(^2\)Goudsmit, Nieboer and Reicher *op cit* 365.

\(^3\)De Leede *Inleiding sociaal verzekeringrecht* (1981) 182; Goudsmit, Nieboer and Reicher *op cit* 365.

\(^4\)De Leede *op cit* 181, 197–201; Beresford ‘Legal implications of epilepsy’ 1988 *Epilepsia* 155.

\(^5\)Alabama Code, tit 32, par 6–45, as referred to in Epilepsy Foundation of America *The legal rights of persons with epilepsy* (1985) 88, hereinafter referred to as EFA.
months on the recommendation of a neurologist. The medical information submitted is reviewed by the personnel of the Motor Vehicle Division, and difficult cases are referred to the Medical Advisory Committee.  

Thirteen states require a seizure-free period of less than one year, which can vary from three to six months. In Connecticut, for instance, the Motor Vehicle Department requires that a person with epilepsy must be seizure-free for at least three months to be eligible for a driver’s licence. Persons who have been seizure-free for less than three months may also be considered on an individual basis, depending on the doctor’s report. If the person has been seizure-free for less than three years, a so-called SR-22 (Financial Responsibility Certificate) should be filed, and the person will be placed on medical probation. Periodic medical reports should then be filed with the Department of Motor Vehicles, usually every six months. The physician submitting these reports may not be held liable for damages arising from an accident caused by a seizure. Civil claims may also not be instituted against the physician.

Twelve states, Puerto Rico and the Virgin Islands, do not require any seizure-free period. These states usually require a doctor to state whether the person has the ability to drive carefully. Delaware, for instance, requires merely that a person with epilepsy must obtain certificates from two physicians, stating that their condition is under sufficient control to permit the safe operation of a motor vehicle. Such a certificate must be submitted annually. The Motor Vehicle’s Division will review the medical information. A physician providing such a certificate is not exempted from civil liability for damage arising from an accident caused by a seizure.

Three states require seizure-free periods of longer than one year, but they will all issue licences after a shorter period. In Pennsylvania, for instance, a person with epilepsy is not allowed to drive unless he has been seizure-free with or without medication for one year. An applicant between 16 and 18 years of age, who is applying for his first licence, must have been seizure-free with or without medication, for two years. In both instances the requirement of a seizure-free period may be waived upon the recommendation of the person’s neurologist. Requirements are, however, that a strictly nocturnal pattern of seizures has been established over the previous three years, or that such a pattern has been established over the previous five years or that the person has a specific prolonged aura, accompanied by sufficient warning. The medical information submitted is reviewed by the staff of the Department of Transportation and a medical consultant. The doctor who provides the medical information is exempted from civil or criminal liability for such

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6 *Maine Rev Stat Ann*, tit 29 par 533, as referred to in EFA 210–211.
7 *Connecticut Gen Stat* par 14–46(1) as referred to in EFA 125; Verborgt *Hoofdstukken over gezondheidsrecht* (1990) 203; Goudsmit, Nieboer and Reicher *op cit* 365; De Leeuw *op cit* 181.
8 *Delaware Code Ann* tit 21 sub-para 2707 (9–7) 2717 as referred to in EFA 131; Verborgt *op cit* 203.
9 *Pennsylvania Cons Stat* par 83 4 as referred to in EFA 344.
disclosure.10

Twenty-seven states will issue restricted licences for persons who do not comply with the main requirement for licensing in the state. The restrictions may include, inter alia, that the person may only drive during the day, to and from work or within a certain distance from his residence, or only in cases of emergency. If the ordinary licence requirements of the state are met, the restrictions are lifted. In Utah, for instance, a person with epilepsy must be seizure-free for at least three months prior to the date of application, whereafter a restricted licence may be issued. The restrictions may include that the person may only drive in certain areas, or certain times of the day. These restrictions are relaxed as the seizure-free period lengthens. After six months a person may drive a motor vehicle without any restrictions. Periodic submission of medical reports are required. Once the person has been seizure-free for a period of five years, and off medication for three years, he may obtain any type of licence.11

According to the policy of the United States Department of Transportation no person with an established medical history or clinical diagnosis of epilepsy, or with any other condition that possibly can cause loss of consciousness or any loss of ability to control the vehicle, may drive a commercial vehicle.12 California and Hawaii apply the federal standards for licensing persons with epilepsy to drive trucks which disqualifies anyone with a history of seizures.13

Most states do not have any legislation compelling physicians to report to the Department of Motor Vehicles should a person with epilepsy consult them. A few states, however, do require this. In New Jersey, for instance, a physician must, within 24 hours of determining that a person 16 years of age or older has epilepsy, report this fact to the Department of Motor Vehicles. Failure to do so is punishable by a fine of 50 dollars.14 In California physicians must immediately report to the local health officer individuals diagnosed as having ‘a disorder characterised by lapses of consciousness’. It includes a person of 14 years of age or older who experienced a lapse of consciousness or an episode of marked confusion during the preceding three years on one or more occasions caused by any condition which may bring about recurrent lapses. The local health officer must report these individuals to the State Department of Health, which in turn reports to the Department of Motor Vehicles.15 In Lopez v Hudgeons16 a physician who did not initially diagnose epilepsy, but

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10Pennsylvania Vehicle Code par 1518(A) as referred to in EFA 344.
11Functional ability in driving: guidelines for physicians' published by the Utah Department of Public Safety, as referred to in EFA 388.
12Goudsmit, Nieboer and Reicher op cit 367.
13As respectively referred to in EFA 110 and 157.
14New Jersey Rev Stat par 34:3-10 4 as referred to in EFA 287.
15California Health and Safety Code par 410 as referred to in EFA 113.
16171 Cal Rptr 527 (1981) as referred to in EFA 113.
later treated the person for epilepsy, was found not liable for not reporting the epilepsy.

The requirement that physicians should report persons with epilepsy to the licensing authorities is opposed by certain medical groups and voluntary health organisations, partly on the basis of confidentiality of the physician-patient relationship. The physician should, however, warn patients with epilepsy not to drive if seizures are uncontrolled. Should it be necessary for the physician to inform the authorities that a patient with epilepsy is an unsafe driver, protection is provided to him in some states. Failure to warn or notify, may be the cause for legal action against the physician. Lastly, some states have prohibitions against driving if the medication a person is using is changed or discontinued.\textsuperscript{17}

Spudis, Penry and Gibson\textsuperscript{18} proposed a system of classification for the use in judging limitations of drivers with epilepsy, which includes a variable time interval from the last attack to the return to driving, based upon the predicted likelihood of recurrence according to their classification scheme. This may be as short as four months for isolated seizures associated with a transient disease.

In general, it appears that many states are moving away from a requirement of a fixed period of freedom from seizures prior to granting a driver’s licence, to more individualised evaluations permitting shorter periods before licensing. According to Schmidt and Wilder\textsuperscript{19} this will place an increased responsibility on physicians to evaluate whether the person with epilepsy will be able to drive safely. Further epidemiological studies are necessary to evaluate relative risks as more drivers are licensed through liberalised regulation and as drug management improves.

England

Until 1970 it was impossible for a person with epilepsy to obtain a driver’s licence. New regulations, however, changed the position, and from 1970 to 1982 a person with epilepsy could obtain a licence if (a) he had been seizure-free for a period of three years, provided he would not be a potential danger to the public, should he drive, and (b) if for the past three years, he only had seizures during his sleep. The licence had to be renewed each year.\textsuperscript{20}

Not only are attacks of unconsciousness due to epilepsy a possibility while driving, but so are drowsiness and sleep, which may be induced by anticonvulsant medication. The rate of accidents amongst licensed drivers with

\textsuperscript{17} Schmidt and Wilder ‘Epilepsy and the law: a commentary from the US perspective’ in Pedley and Meldrum (eds) Recent advances in epilepsy (1988) 254.

\textsuperscript{18} ‘Driving impairment caused by episodic brain dysfunction: restrictions for epilepsy and syncopy’ 1986 Archives for Neurology 558–564, hereinafter referred to as Spudis et al.

\textsuperscript{19} Op cit 255.

\textsuperscript{20} Vehicle and Driving Licences Act; Laidlaw and Laidlaw Epilepsy explained (1980) 75.
epilepsy is 1.3 to 2.0 times higher than their age-matched controls without epilepsy.\textsuperscript{21} Due to a voluntary reporting system, it was possible to investigate 1300 road accidents in Great Britain where damage was caused to property and/or persons due to loss of consciousness behind the wheel. Of these accidents, 38 per cent were due to grand mal seizures, and 12 per cent occurred during their first seizure. Of the persons who had an accident due to epilepsy, 70 per cent had not disclosed their epileptic conditions with regard to obtaining their drivers' licences.\textsuperscript{22} The law relating to drivers' licences was amended with effect from the 21st of April 1982 and defined the conditions under which a patient with controlled epilepsy may and may not drive. Firstly, any seizure first experienced after the age of five years prevents a person from obtaining a heavy goods vehicle (HGV) licence, or a public service vehicle licence. Seizures first experienced after the age of five are also an absolute bar for becoming a commercial airline pilot. Secondly, any person who has an epileptic seizure may not drive until they have had two seizure-free years, either with or without anticonvulsant medication. Thirdly, if a person's seizures only occur during his sleep, he may drive, provided that he has had no daytime seizures within the last three years, either with or without anticonvulsant medication. Fourthly, should a person with epilepsy with a driver's licence have his medication changed or withdrawn, he should inform the Driving Licensing Authority. A period of six to twelve months of no driving should follow such a change. Lastly, there is a statutory requirement that the driver's licensing authorities must be informed should patients have any medical condition which might impair their capacity to drive.\textsuperscript{23}

Section 92(1) of the Road Traffic Act (of 1988) now provides that an application for the granting of a licence must include a declaration by the applicant, in such form as the Secretary of State may require, stating whether he is suffering or has at any time (or, if a period is prescribed for the purpose of this subsection, has during that period) suffered from any relevant disability or any prospective disability. In terms of s 92(2), 'disability' includes disease, 'relevant disability' in relation to any person means any prescribed disability and any other disability likely to cause the driving of a vehicle by him in pursuance of a licence to be a source of danger to the public. 'Prospective disability' in relation to any person, means any other disability which (at the time of application for the granting of a licence or, as the case may be, the material time for the purpose of the provision in which the expression is used) is not of such a kind that it is a relevant disability, but by virtue of the intermittent or progressive nature of the disability or otherwise, may become a relevant disability in the course of time. A person with epilepsy will have to include a declaration in his application for a driver's licence that he is suffering or has suffered from epilepsy.

\textsuperscript{21}Fenwick 'Epilepsy and the law' in Pedley and Meldrum (eds) 249; Fritz 'Recommendations regarding driving after a single seizure' 1990 \textit{SAMJ} 493.
\textsuperscript{22}Taylor 'Epilepsy and driving' in Rose (ed) 533; Fenwick \textit{op cit} 249.
\textsuperscript{23}Fritz \textit{op cit} 493; Fenwick \textit{op cit} 249–250; s 92 of the Road Traffic Act.
If it appears from the applicant’s declaration, or if on inquiry the Secretary of State is satisfied from other information, that the applicant is suffering from a relevant disability, the Secretary of State must, subject to the following provisions of this section, refuse to grant the licence (S 92(3)). Should the epilepsy of a person cause him to be a danger to the public if he should drive a motor vehicle, he will not be granted a driver’s licence.

In terms of s 92(5) the Secretary of State must serve a notice in writing on that person and must include in the notice a description of the disability, where, as a result of a test of competency to drive, he is satisfied that the person who took the test, for instance a person with epilepsy, is suffering from a disability such that there is likely to be a danger to the public if he drives any vehicle, or if he drives a vehicle other than a vehicle of a particular construction or design.

A licence may be revoked if the Secretary of State is at any time satisfied on inquiry that a licence holder is suffering from a relevant disability or a prospective disability (S 93). The licence holder must forthwith notify the Secretary of State in writing of the nature and extent of his disability, if at any time during the period for which his licence remains in force, he becomes aware that he is suffering from a relevant or prospective disability which he has not previously disclosed to the Secretary of State, or that a relevant or prospective disability from which he has at any time suffered (and which has been previously so disclosed) has become more acute since the licence was granted. He is not required to notify the Secretary of State if the disability is one from which he has not previously suffered, and he has reasonable grounds for believing that the duration of the disability will not extend beyond the period of three months beginning with the date on which he first becomes aware that he suffers from it (S 94). A person with epilepsy will have to notify the Secretary of State should he develop epilepsy after qualifying for a driver’s licence, or should his epilepsy deteriorate causing him to be a danger to other road users.

South Africa

In terms of s 18(1)(f)(i) of the Road Traffic Act (Act 29 of 1989) a person will be disqualified from obtaining or holding a learner’s or a driver’s licence, if he suffers inter alia from uncontrolled epilepsy or any form of mental illness to such an extent that it is necessary that he be detained, supervised, controlled and treated as a patient in terms of the Mental Health Act. A person with controlled epilepsy may accordingly obtain a licence. But what is the difference between controlled epilepsy and uncontrolled epilepsy? The Act does not specify what is understood under uncontrolled epilepsy. One could, therefore, argue that a person with epilepsy is controlling his epilepsy if he previously had five seizures in one day, but now only has one seizure a day — he is now controlling it to remain only one seizure a day! It is submitted that this could never have been the intention of the legislature, but that ‘con-
trolled' epilepsy should be defined so as to include persons who have been seizure-free for a period of two years and longer, that no danger should then still exist to the public, and that in persons with nocturnal seizures only, the pattern must be established for three years to be considered as 'controlled' epilepsy, before a driver's licence may be issued.

Section 19(1) provides that no person may wilfully omit to disclose any disqualification to which he is subject to, in terms of s 18, for instance uncontrolled epilepsy, when applying for a learner's or driver's licence.

A provincial administrator may cancel or suspend a driver's licence if he is of the opinion that the holder is disqualified by virtue of any of the conditions described. He may request the holder to submit to an examination by a medical practitioner to determine his physical and mental fitness to drive a motor vehicle. The courts are empowered to order endorsement, suspension or cancellation of a driver's licence when a person is convicted of an offence relating to the driving of a motor vehicle or failure to stop after or report an accident. This includes instances where the offence was due to the person's epilepsy.

Bird suggested that the legal prohibition to drive a motor vehicle should be couched in general terms as referring to any disease or disability which would or might interfere with a person's driving ability, without any particular disease or disorder being specified. It is submitted that this recommendation is too vague because any person with epilepsy, even controlled epilepsy, may then be unable to drive, as epilepsy is a disease which might recur at any stage and interfere with a person's driving ability. It is indeed necessary to refer expressly to epilepsy in the Act and to define 'controlled' epilepsy, as persons with uncontrolled epilepsy could at any stage have a seizure whilst driving and therefore endanger the lives of other people on the road.

According to Fritz any doctor should instruct a patient who has experienced a first seizure not to drive for a period of six months. If an electro-encephalogram (EEG) or computed tomography (CT) is abnormal, he submits that a period of twelve months should elapse without driving.

Conclusion
In the USA, each state has its own regulations governing the eligibility of persons with epilepsy to obtain a driver's licence. Usually a person has to be seizure-free for a certain period of time which differs from less to more than a year. Some states even have no requirement of a seizure-free period. In other states a doctor's evaluation of the person's ability to safely drive a vehicle must accompany the application form, and should the application be successful, medical reports must periodically be handed in for a specified period or for as long as the person is licensed. Restricted licences may also be issued. A person with a history of epilepsy may not drive a commercial vehicle

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25S 30; Strauss  *Doctor, patient and the law* (1991) 144.
26S 55; Strauss  *op cit* 144.
27Epilepsy and the law in South Africa' 1970 *SAMJ* 1093.
at all.

In England a person with epilepsy must be seizure-free for two years before he will be considered for licensing. Furthermore, he should not be a danger to the public if he drives, and a licence will also be considered if he has only had night seizures for the past three years. Persons who had a seizure for the first time after the age of three are not allowed to drive a public service vehicle or a heavy duty vehicle.

In South Africa a person cannot obtain a learner’s or driver’s licence if he suffers from uncontrolled epilepsy or any form of mental illness that causes him to be detained, supervised, controlled and treated as a patient in terms of the Mental Health Act. A person with epilepsy may not omit to disclose his epilepsy when applying for a licence.

South African legislation does not prescribe a specific seizure-free period as is the case in some states of the USA, England and the Netherlands. Although it seems as though this is a far more equitable way of determining whether a person with epilepsy in his specific circumstances qualifies for a driver’s licence or not, it is unfair towards other road users whose lives may be endangered by the sudden seizure a person with epilepsy may experience. It is therefore submitted that a two-year seizure-free period should be recognised statutorily, for the protection of the community. The Road Traffic Act furthermore refers specifically to uncontrolled epilepsy. A person with controlled epilepsy may thus obtain a licence. It is, however, uncertain exactly what is understood under uncontrolled and controlled epilepsy. It could mean that a person with epilepsy who previously had five seizures on one day, but now sufficiently controls his epilepsy through medication and reduced it to only one seizure a day would qualify for a driver’s licence, as his epilepsy may be said to be ‘controlled’! However, this could not have been the intention of the legislature. It is submitted that ‘controlled epilepsy’ should be statutorily defined as to include a seizure-free period of two years, that the person with epilepsy should not be a danger to the public, and that with persons who experience only nocturnal seizures, a three-year period should be prescribed before they could qualify for a driver’s licence. A person that experienced a seizure for the first time, should as a general rule be instructed by his doctor not to drive for a period of six months, and if the person’s EEG or CT was abnormal, he should be instructed not to drive for a period of a year. It would be difficult to provide statutorily for this instruction, as it may be to the detriment of the doctor-patient relationship, and it would be difficult to police.

A provincial administrator may cancel or suspend a driver’s licence (including that of a driver with epilepsy). The courts are empowered to order endorsement, suspension or cancellation of a driver’s licence when a person is convicted of an offence relating to the driving of a motor vehicle or failure to stop after or report an accident. This includes instances where the offence was due to the person’s epilepsy.28

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28S 55; Strauss op cit 144.
On the rights of the foetus

A CARMI*

Definitions
Various definitions are used while discussing the doctors' and patients' duty of care towards the foetus during the pregnancy or even prior to conception.

Wrongful pregnancy; wrongful conception
This claim concerns a claim which is brought by the parents of a healthy but unwanted child, who was born in consequence of medical negligence (eg in performing sterilisation), for damages in respect of medical expenses involved in pregnancy, confinement and maintenance of the child.1

Wrongful birth
This claim concerns medical negligence, whether prior to conception2 or after conception (eg a failure to appropriately advise the mother of the risk of birth defects of the potential child).3 An action for wrongful birth is brought by the parents of an impaired child for the cost of the medical and other services required to treat their child's condition.4

Wrongful life
This claim for damages is brought by the disabled child. The essence of the claim is violation of an alleged right not to be born with defects, which in certain circumstances amounts to a right not to be born at all.5

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1LS Goldstein & MJ Zaremski Medical and hospital negligence (1992 Cumulative Supplement) 10:16; Sherlock v Stillwater Clinic 260 NW 169 (2ed 1977); Cataford v Moreau (3ed 1981) 114 DLR 585; Emeh v Kensington AHA [1948] 3 All ER 1044 (CA); SA Strauss Doctor, patient and the law (3ed 1991) 179, 197 (alternative definition: 175); Parents' right of claim for wrongful pregnancy has been acknowledged in many countries eg USA, Canada, England, Germany and Israel.

2Scbroeder v Perkel 432 A 2d 834 (1981). A New Jersey appellate court ruled that a couple could sue a condom manufacturer for wrongful birth where the device was defective and caused the wife to become pregnant. (However, the husband and the wife acknowledged in this case that the twins born as a result of the defective condom were normal and healthy. One may wonder whether the court should not have defined the cause of action as wrongful conception); 

3JPM and HM v Schmid Laboratories Inc 428 A 2d 515 (NJ Super Ct App Div 1981; EP Richards III, KC Rathbun Law and the physician — a practical guide (1993) 391; Goldstein & Zaremski supra n 1. Parents' right of claim for wrongful birth has been acknowledged in various countries eg USA, Canada, England and Israel, as well as in Germany; E Deutsch & HL Schreiber (eds) Medical responsibility in Western Europe (1985) 254.


5Strauss op cit 197 (196: 'A more unfortunate term could hardly been invented').
The issue of wrongful life has been widely discussed in the Israeli Zeitzoff case.\(^6\) A woman, before her marriage, requested genetic counselling, seeking to discover whether a certain hereditary disease known as 'Hunter' existing in her family, might affect her offspring in the future, because were this the case, she was determined not to bring (male) children into the world. The consultant doctor, as a result of negligence in performing the tests, or in the process of drawing conclusions from the tests, stated that no such risk existed. Based on this opinion the mother became pregnant and bore a son who suffered from the disease, which severely affected his physical and psychological development. A personal injury suit was brought inter alia in the name of the minor against the doctor and the institution at which she was employed.

The claim was dismissed by the District Court for two reasons: First, because 'this cause of action belongs to that type of claim which this court has neither the ability nor the power to establish, it being the function of the legislature to do so', and secondly, were the court 'to allow a cause of action against strangers only, the outcome would be that although we recognise the fact that the child was wronged, we could be freeing from responsibility those causing the wrong, that is the parents, and placing the responsibility for it upon strangers. This is an outcome against which the sense of justice rebels'. On the basis of this train of thought, the lower court decided to dismiss the minor's suit, hence the appeal in his name (Civil Appeal 540/82). Nonetheless, the learned judge declined to dismiss the claim of the parents in their own name, this forming the basis for the appeals of the doctor and the institution (civil appeal 518/82). The appeal in File 540/82 has been accepted by the Supreme Court, the appeal in File 518/82 has been dismissed, and the whole case has been returned to the lower court to be decided on the merits.\(^7\)

**Duty of care**

The rule that a human being has to accept life as given to him by nature,\(^8\) is replaced by a discussion concerning the doctor's duty of care towards the parents and the minor throughout the medical treatment. Parents are entitled to prevent the conception or birth of children suffering defects and to decide whether they want to have a child or not, and doctors owe a duty of care to parents to preserve that right.\(^9\)

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\(^6\)CA 518/82 Dr Rina Zeitzoff, Beilinson Hospital and The Health Fund of the General Workers Union in Israel v Saul Katz, Shmuel Katz, Nvadia Katz and Miriam Zakai; and CA 540/82 Saul Katz, Shmuel Katz and Nvadia Katz v Dr Rina Zeitzoff, Beilinson Hospital and The Health Fund of the General Workers Union in Israel 40(2) PD 85 (hereinafter Zeitzoff case).

\(^7\)Y Levi 'The fetus' right to be born' 49(3) Mikbtav Lehaver 9; S Gluck 'The fetus' right to be born' 49(3) Mikbtav lehaver 10; Same 48(2) Mikbtav lehaver 3.


\(^9\)Gieson op cit at 87, 249; Hartke v McKelway 707 F 2d 1544 (DC Cir 1983); James G v Caserta 332 SE 2d 872 (W Va 1985); Doiron v Orr (1978) 86 DLR 3d 719; Udale v Bloomsbury Area Health Authority [1983] 2 All ER 521 (CA); Barak op cit at 112; A Grubb 'Failed sterilization: is a claim in contract or negligence a guarantee of success? 1986 Cambridge IJ 197; A Grubb 'Failure of sterilization' 1985 Cambridge IJ 30.
In England, the doctor’s duty towards a foetus is prescribed by law.\(^{10}\)

One should not disregard the risk of imposing too heavy responsibility on the shoulders of the medical profession, as abortion may be improperly encouraged,\(^{11}\) the risk that the family system may collapse if children are entitled to sue their parents, and the difficulty of deducting the value of pleasure which the parents derive from bringing up children from the general compensation for suffering and pain.\(^{12}\)

A certain balance should be struck between conflicting interests. Sometimes the issue of abortion is not relevant.\(^{13}\) Most of the parents’ claims cover the costs of treatment and do not hurt or harm their children. And one should get to grips with the difficulty of evaluating damages rather than denying them.

There are more than 4000 human genetic diseases, 500 of them linked to a defect in a single gene. They include cystic fibrosis, sickle-cell anaemia, haemophilia and Tay-Sachs.\(^{14}\) The imposition of a duty of care is justified in cases of negligent and incomplete genetic counselling.\(^{15}\)

Negligent counselling comprises lack of full and comprehensive explanations,\(^{16}\) failure to inform women over 35 of the risk of giving birth to a child afflicted with Down’s Syndrome,\(^{17}\) and the availability of amniocentesis tests,\(^{18}\) failure to advice women of the possible adverse effects on the foetus of contracting rubella in the first trimester of pregnancy or of the correlation between the use of certain medicaments and birth defects in children.\(^{19}\)

Negligent treatment comprises also failure to establish that the parents are

\(^{10}\) Congenital Disabilities (Civil Liability) Act 1976. Where a medical practitioner is treating a pregnant woman, he owes a duty of care to the unborn child. If, as a result of his negligent treatment, the child is born disabled, he may be liable to the child. If negligent treatment of either parent before conception causes a child to be born disabled the doctor may be liable to the child. Consideration should be taken with respect to two provisos. First, there is no liability in respect of an act prior to the conception, if the parents were aware of and accepted the risk. Secondly, the doctor is not liable for harm to the child resulting from his treatment of the parent where such treatment accorded with the appropriate standard of care at the relevant time. RM Jackson & JL Powell Professional negligence (3ed 1992); JL Taylor (ed) Medical malpractice (1980).

\(^{11}\) Levi op cit 9.

\(^{12}\) Barak op cit 111.

\(^{13}\) Eg negligent counselling prior to the conception.

\(^{14}\) M Flight Law, liability and ethics (2ed 1993) 178.


\(^{16}\) Pratt v University of Minnesota Affiliated Hospital 403 NW 2d 865 (Minn App 1987).

\(^{17}\) Giesen op cit 249; Becker v Schwartz 413 NYS2d 895 (1978); Berman v Allan 404 A2d 8 (NJ 1979).


\(^{19}\) Jacobs v Theimer 519 SW2d 846 (Tex 1975); Harbeson v Parke-Davis Inc 656 P2d 483 (Wash 1983).
carriers of genetically-transmitted diseases,\textsuperscript{20} or negligent sterilisation.\textsuperscript{21} The genetic explanation must be correct\textsuperscript{22} so that the parents' consent be valid.\textsuperscript{23}

The imposition of responsibility on the genetic counsellors will raise various questions. For instance, a few test-tube babies were born with Down's Syndrome, and one may wonder whether the manipulation of genetic material in vitro or in vivo have caused chromosomal anomalies.\textsuperscript{24} There may indeed be some potential for future claims once such procedures will become routine.\textsuperscript{25}

Parents' claims
Do parents have a right to sue negligent doctors for bringing about the birth of a healthy child?

A Canadian court regarded such a claim as grotesque while dismissing it.\textsuperscript{26} A few American courts adopted a similar attitude,\textsuperscript{27} while others acknowledged such claims but limited the compensations to costs concerning the pregnancy and the birth only.\textsuperscript{28}

Judges refused to adopt certain defence arguments. Thus, courts dismissed claims of defendants for mitigation of damages by having an abortion.\textsuperscript{29} The argument of 'novus actus interveniens' was not accepted where the mother decided to refrain from abortion after the failure of a previous abortion.\textsuperscript{30}

The grant of child-rearing costs in these cases suits the traditional tort law

\textsuperscript{20}\textit{Naccash v Burger} 290 SE2d 825 (Va 1982).

\textsuperscript{21}\textit{Emeb v Kensington AHA} \textit{op cit} 1044.

\textsuperscript{22}Richards, K Rathbun \textit{op cit} 394. A physician who does not offer genetic screening because he is opposed to abortion has a duty to refer the patient to another physician who can carry out the necessary counselling and testing.

\textsuperscript{23}Richards & Rathbun \textit{op cit} 397.

\textsuperscript{24}1 Kennedy 'Let the law take on the test tube' \textit{The Times} 26 May 1984 6; 1981 \textit{New England J Med} 1525.

\textsuperscript{25}Giesen \textit{op cit} 89–90.

\textsuperscript{26}\textit{Doiron v Orr} 719, 723; JE Bickenbach 'Damages for wrongful conception: \textit{Doiron v Orr}' 1980 \textit{UWOLR} 493–503; See \textit{Cataford v Moreau} (1978) 7 \textit{CCLT} 241 (Que SC).

\textsuperscript{27}Supreme courts of Kansas and New York ruled that the birth of a healthy child does not reflect damage. The courts indicated the great importance which is attached by law and society to human life, and held the social and emotional aspects of raising children superior to economic difficulties: \textit{Byrd v Wesley Med Ctr} 699 P2d 459 (Kan 1985); \textit{O'Toole v Greenberg} 477 NE 2d 445 (NY 1985). On the other hand: \textit{Macomber v Dillman} 8 Med Liab Rptr, 849 (Me 1986) where a doctor was found liable for negligent sterilisation which brought about the birth of a child. The doctor was obiged by the Supreme Court of Maine to cover the costs of the birth but not the expenses of upbringing of the child. A similar claim was dismissed by a court in Nevada: \textit{Szekeres v Robinson} 715 P2d 1076 (Nev 1986).

\textsuperscript{28}Giesen \textit{op cit} 244. An appeal court in Pennsylvania awarded compensation to a woman who gave birth to a healthy child following a negligent treatment of her tubes by a doctor. The mother received also the expenses for bringing up her child: \textit{Mason v Western Pennsylvania Hospital} 428 A 2d 1366 (Pn Super Ct 1981).

\textsuperscript{29}Emeb v Kensington AHA \textit{supra}.

\textsuperscript{30}Giesen \textit{op cit} 247.
principles.\textsuperscript{31} However, a more sympathetic attitude is shown in cases of defective newborns, where mothers were compensated for suffering and pain, loss of earning, and even costs of bringing up their children.\textsuperscript{32}

There are divergent judicial opinions concerning the question whether costs of raising healthy children should be awarded.\textsuperscript{33} German courts award such costs\textsuperscript{34} to mothers and even to fathers,\textsuperscript{35} except in certain cases.\textsuperscript{36} In New Zealand the courts acknowledge the mother’s right to be compensated for pregnancy and birth, but not for raising the child.\textsuperscript{37} Similar attitude is shown by American and Canadian courts.\textsuperscript{38} South-African courts award compensation for raising the child,\textsuperscript{39} while the majority of the American courts will regard the costs of child-rearing too speculative and remote.\textsuperscript{40}

The value of life

The above mentioned issue encompasses questions of the very essence of life, and who has control over it, questions of belief and religion and the necessity and power to interfere with the acts of creation, questions of habits and outlook on life, questions of public welfare both in its wider and more narrow sense, questions of intrusion into the most intimate areas of family relationships, questions of the relationships between the generations and between parents and their children, and parents between themselves.\textsuperscript{41}

The issue furthermore includes, \textit{inter alia}, the question whether it is possible to compare a suffering existence with non-existence? Can it be said that an impaired life is worse than non-existence, or perhaps that life is always preferable to any alternative of non-existence? Can one complain about an act of negligence when that very same act, in addition to causing the plaintiff to be born disabled, also gives him life itself? Is the plaintiff who requests to be restored to the condition of non-existence (but also cutting off the branch on which his case is built), in such a position that if the prior condition is

\textsuperscript{31} Giesen \textit{op cit} 245.

\textsuperscript{32} Emeb \textit{v Kensington} AHA supra; Giesen \textit{op cit} 244.

\textsuperscript{33} Giesen \textit{op cit} 246; AC Reichman ‘Damages in tort for wrongful conception — who bears the cost of raising the child?’ 1985 \textit{Sydney LR} 568–90.

\textsuperscript{34} Giesen \textit{op cit} 246.

\textsuperscript{35} Giesen \textit{op cit} 247, 248: A physician whose negligence causes a woman to undergo pregnancy and childbirth against her will may also be liable for non-pecuniary damages on the basis of interference with life-processes and pain suffered at birth, even if the pregnancy is entirely normal.

\textsuperscript{36} Giesen \textit{op cit} 248.

\textsuperscript{37} \textit{XY v Accident Compensation} (1984) NZACR 777 (IIC).

\textsuperscript{38} McNeal \textit{v United States} 689 F2d 1200 (4 Cir 1982); \textit{Hartke v McKelway} 526 F Supp 97 (1) DC 1981); \textit{Becker v Schwartz} 400 NYS 2d 119 (1977) modified, 46 NY 2d 401, 386 NE 2d 808, 413 NYS 2d 895: A physician failed to inform a woman over 35 of the increased risks in her age group of giving birth to a child afflicted with Down’s Syndrome and the availability of the amniocentesis tests; \textit{Paris v Checks} 400 NYS 2d 110 (1977); Maggard \textit{v McKelvey} 627 SW 2d 44 (Ky Ct App 1981).

\textsuperscript{39} Strauss \textit{op cit} 197.

\textsuperscript{40} Goldstein \& Zaremski \textit{op cit} 10-17.

\textsuperscript{41} Barak \textit{op cit} 108, while quoting Judge Zeiler.
restored and the damage disappears, the plaintiff himself will also disappear? Does man have a right not to be born? Is it possible to assess, in monetary terms, the suffering of a minor who claims that he would prefer not to have been born to life? Is it desirable to recognize the doctors' responsibility towards minors and their parents or might this just add to the number of unwanted abortions? Is it proper to recognize the minor's claim against his parents or might this harm the family establishment and one's right to decide whether or not to bear children? Are we to recognize responsibility for every disability or are we to differentiate between serious defects (for example brain damage or blindness) and 'legal' (for example, illegitimacy) or 'social' (for example, unfair discrimination) ones? And if we say that tort responsibility is to be recognized, whose function is it to create this responsibility? Is it preferable for the judicial system to establish responsibility in these situations through judicial lawmaking or is this function to be left to the legislature?42

'Life is dear, life is a present of God, a difficult life is preferable to no life', and other similar sentiments, create an axiom that cannot be shunned, according to which life is something known to us, which we understand, and usually take to be good. On the other hand, 'non-existence' involves a lack of life, and since life is considered to be something positive, we are not able to compare it with something unknown to us, and the only thing we are sure of is that it lacks life.43

An English court indicated that if difficulty in assessing damages is a bad reason for refusing the task, impossibility of assessing them is a good one:44

How can a court begin to evaluate non-existence? The undiscovered country from whose realm no traveller returns? No comparison is possible and therefore no damage can be established which a court could recognize. This goes to the root of the whole cause of action.

Judge D Levine added in the Zeitzoff case:45

At first glance, someone who was privileged to see the sun rise and the blue of the sky, who has felt the intensity of the experience of life and has tasted its treasures, is in a position preferable to that of someone denied all this. In general, life itself has a certain exalted value, a certain sanctity. It is a privilege which should not be relinquished or destroyed, and he that received life

42Barak op cit 109; Ben Porat op cit 89, 90.
43Barak op cit 116. Giesen op cit 250: The law is not equipped to make a comparison between life in an impaired state and non-existence. Gleitman v Cosgrove 227 A 2d 689 (1967) 692: 'This Court cannot weigh the value of life with impairments against the non-existence of life itself. By asserting that he should not have been born, the infant plaintiff makes it logically impossible for a court to measure his alleged damages because of the impossibility of making the comparison required by compensatory remedies.' Turpin v Sortini 643 P 2d 954 (1982) 961, 963: '... it is simply impossible to determine in any rational or reasoned fashion whether the plaintiff has in fact suffered an injury in being born impaired rather than not being born.'
44McKay v Esser Area Health Authority (1982) 2 All ER 771, 782 (CA) and at 787. (A claim for wrongful life contrary to public policy as a violation of the sanctity of human life).
45Judge D Levine in Zeitzoff case supra 125.
should be happy.

Judaism has adopted that view, and has always elevated and exalted the great value of human life. Life is the holiest asset, and its protection overrides any other holiness. "Nothing overrides the protection of life, except idol worship and adultery and murder only".

The same attitude has been adopted by the judiciary in the USA and Germany. However, the sanctity of the life principle does not always attain merit. Some courts and legislatures have been willing to make the determination that nonexistence is preferable to life with disabilities. As evidence of this trend, living-will statutes have been enacted in many states allowing an individual to request that no extraordinary lifesaving methods be used to save that individual if recovery is beyond hope. In a more closely analogous situation, judicial decisions have allowed parents to decide when extraordinary life-sustaining measures should be removed from their injured child.

Judge Ben-Porat adopted a similar attitude in the Zeitzoff case.

The minor’s claim for wrongful life
The discussions with regard to wrongful conception and wrongful life necessitate the consideration of the minor’s right to claim. A wrongful life action is brought by or on behalf of a defective child who alleges that, but for the defendant’s negligent treatment or advice to his parents, the child would not have been born.

In England, and in the USA claims by the infants themselves for wrongful

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46Aboth chapter 5 29.
47Ketubot 19 1.
48Berman v Allan, 404 A2d 8 (NJ 1979) 12, 13: 'Whether it is better never to have been born at all than to have been born with even gross deficiencies is a mystery more properly to be left to the philosophers and the theologians.' Becker v Schwartz 386 NE 2d 807, 812, 1978: 'To recognize a right not to be born is to enter an area in which no one could find his way.' Gleitman v Cosgrove supra 711; Elliott v Brown 361 S2d 546 (1978) 548; Dumer v St Michael's Hospital 233 NW 2d 372 (1975) 379.
49Giesen op cit 89, quoting a decision of the German Supreme Federal Court: 'Man has to accept his life as it is given to him, and he has no right to its being prevented or destroyed.'
50Life is so terrible; it would be better never to have been conceived. Yes, but who is so fortunate? Not one in a thousand'. Nozick Robert Anarchy, state and utopia (1974) 337.
51Goldstein & Zaremski op cit 10:18.
52Ben Porat op cit 96.
53Giesen op cit 84.
54Goldstein & Zaremski op cit 10:16. GJ Annas Judging medicine (1988) 103: 'The wrong actually being complained of is the failure to give accurate advice on which a child’s parents can make a decision whether not being born would be preferable to being born deformed.'
life have been regarded with disfavour. Various reasons justify this kind of attitude. Some decisions hold that an unborn child has no existence apart from his mother, and that it therefore has no right of action for personal injuries inflicted upon it, prior to its birth, by the wrongful act of another.57 Others argue that the foetus has no right of action because he is not regarded as a person,58 or that life itself is a compensable injury.59 They also warn that 'too careful' advice might be offered by genetic counsellors.60

On the other hand, there has been a trend recently, toward recognising such actions.61 It is, for example, perfectly consistent with amniocentesis followed by abortion: both actions argue that no life is preferable to life with certain physical or mental defects. Further, since many defective newborns will never have the mental or physical ability to commit suicide, and may not have parents or others who can provide for their well-being, permitting them to sue for damages suffered on their own behalf is both rational and humane.62

Concerning previous decisions, that there was no way to comprehend non-existence, thus making it impossible to calculate damages based on a comparison of non-existence to a defective existence, the fact is that we permit

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61 Judge Goldberg in the Zeitzoff case supra 129.
62 Goldstein & Zaremski op cit 10:18. Park v Chassin 80 App Div 2d60, 400 NYS 2d 110 (1977): Mrs Park, the plaintiff, gave birth to a baby who lived for five hours. The cause of death was a hereditary kidney disease that had a high probability that future children of this couple would be born with it. Immediately following the birth, the Parks entered genetic counselling with the intention of determining whether another child born to them would be at risk for the same disease. The defendant, Dr Chessin, stated that the chances were 'practically nil'. Mrs Parks gave birth to another baby born with kidney disease and who died shortly after birth. The Parks brought a cause of action against Dr Chessin, alleging that the defendant's advice was the proximate cause of the injury. The court held that there was a viable cause of action on behalf of an infant for wrongful life. Public policy consideration gives the parents a right not to have a child; the breach of this right may also be tortious to the fundamental right of a child to be born as a whole, functional human being. American courts even went so far as to allow recovery of damages in the case of pre-natal injury to a foetus where the foetus was not born alive, provided that it was viable at the time of the injury. Chrisafogeorgis v Brandenburg 55 Ill 2d 368, 304 NE2d 88 (1973). Strauss op cit 197. See Amadio v Levin 501 A 2d 10085 (Pa 1985).
63 Annas op cit 101.
courts to make similar distinctions and measurements, for example, in wrongful death cases.\textsuperscript{63} Further, imposition of the duty of the child may foster the societal objectives of genetic counselling and prenatal testing, and will discourage malpractice.\textsuperscript{64} The issue of unwanted birth has become more and more relevant due to the ever-widening scope of legal duty in respect of the increasing range of foreseeable plaintiffs for an increasing variety of foreseeable damage.\textsuperscript{65}

The Zeitzoff case

Judges Barak and Ben-Porat presented two systems of reasons which motivated them as well as judges D Levine and S Levine to acknowledge the minor’s right of claim. Barak contends that the minor has a right, if he is born alive, to live without defect caused by medical malpractice. The damage caused by the malpractice and for which the doctor is responsible, is not the actual granting of life (since the minor has no right to non-life) but in granting a defective life. Therefore, in essence, this damage is established not by comparing defective life to non-life but in the comparison between a defective life and a non-defective life.\textsuperscript{66}

Ben-Porat contends that the physician’s duty of care exists also towards one who at the time of the negligent act did not yet exist and was not yet even conceived because expected damages should be avoided.\textsuperscript{67}

The assessment of damages, owing to the very essence of damage, requires a comparison between the condition the plaintiff would be in were it not for the negligent act and his condition as a result of it. The only interpretation possible in this case is, in her opinion, a comparison between nonexistence (were it not for the negligence) and an impaired existence, the result of the negligence.

Ben-Porat contends that the physician who is responsible for the child’s existence must compensate him in monetary terms, in such a manner as to minimise as much as possible the effect of his disability. She does not make a comparison between the defective child and a child born healthy and whole, but asks to maximize the existing potential, so that the child will function better, and suffer less, in his disabled condition.

On the other hand, the partially disabled minor will not have, in her opinion,\textsuperscript{68}
any tort claim. He received, as a result of the counsellor’s negligence, an almost full life. Recognition of the existence of damage to the minor in the described situation is contrary both to public policy and the principle of the sanctity of life. If the minor was born with a relatively slight physical disability, it is not to be said that compensational damage was caused as a result of the negligence since through this he received life.64

Judge D Levine adopted Ben-Porat’s view, while Judge S Levine supported Barak’s view.

Claims of minors versus parents

The question whether parents are responsible towards their foetus for negligently causing harm to him, arises in those legal systems which impose liability on genetic counsellors.

According to one view, withholding of necessary prenatal care, improper nutrition, exposure to mutagens and teratogens, or even exposure to the mother’s defective intrauterine environment caused by her genotype could all result in an injured infant who might claim that his right to be born physically and mentally sound had been invaded.

The most fundamental objection is that there is no ‘right to be born physically and mentally sound’, and should not be. Such a ‘right’ could almost immediately turn into a duty on the part of potential parents and their care-takers to make sure no ‘defective’, different or ‘abnormal’ children are born.65

Authority

Due to the complexity of the present dilemma, one may wonder whether all these questions should be dealt with by the legislature or by the judiciary.

Four out of five judges in the Zeitzoff case preferred the judicial involvement. Judge Zeiler of the District Court stated that this course of action belongs to that category of claims which it is neither the function of nor in the power of the courts to establish, this task being the function of the legislature, if it is deemed fit and correct by it to grant a right to claim in such a course of action.

Judge Barak did not agree. The court put into use the old principle of negligence, which was applied to new factual circumstances. The present reform is limited and compact, and includes only an extension of the known

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64Ibid 97, 99, 104. See Giesen op cit 83; DE Carroll ‘Parental liability for preconception negligence: do parents owe a legal duty to their potential children?’ 1986 Cal Western LR 289-316. Annas op cit 106, refers to a hypothetical case in which the parents have been warned of the probability of having a handicapped child, and yet decided to go ahead with the pregnancy. In such a case the parents might be obliged to compensate their offspring for the pain and suffering which they have wrought upon the minors.

categories of responsibility. As the principle is already contained in the law of negligence itself, liability should be established according to the existing precedents.70

**General**

The modern legislation and judicial decisions in the field of medical law are important, interesting, exciting, and sometimes unexpected and surprising. This phenomenon does not reflect the ordinary, typical routine by which behavioural norms are crystallised.

The quick and complicated scientific and technological developments set up advantageous though risky situations, which were not anticipated and which need immediate response. The state authorities which are not ready to offer such a response prefer to leave the decision to the judiciary. However, the judiciary too is not prepared or trained in order to cope with these dilemmas, so that the establishment of new norms may be founded on personal views of individual judges, and found to be arbitrary. Sooner or later the state will have to set multi-disciplinary organs which will comprise of skill and training in order to collect and draw up the data to be used by the legislature or by the courts.

Meanwhile, one should commend the valuable contribution of a few researchers in the modern field of medical law. Their contribution is not only substantial for the collection of background materials for the decision-makers, but also as a source of recommendations for guidelines and norms.

Of course, some of these guidelines may fail in the course of time, because one cannot always anticipate the judicial response to new situations. The wrongful-life issue constitutes a classic illustration of this phenomenon.

In the USA courts initially held that doctors would not be found liable for negligence in such cases.71 Later, the judicial outlook changed, and doctors were held liable in some cases.72 George Annas, one of the leading proponents of patients' rights in the States, admitted in a later publication:

> My conclusion, in a previous column about the New York cases, that "the issue of wrongful life" is dead in the courts, now seems premature.73

In England, for many years it was held on policy grounds that a birth of a child could in no circumstances constitute a compensable damage, either to the

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70 Goldberg *op cit* 127. Barak *op cit* 118–121. Ben Porat *op cit* 98. Note: On the state of the fetus in criminal law, see: Cr c (Tel Aviv) 480/85 *State of Israel v Dolberg* 1987 (2) PM 446. Flight *op cit* 182.


72 Strauss *op cit* 175.

73 Annas *op cit* 102; B Kennedy 'The trend toward judicial recognition of wrongful life: dissenting view' 1983 *CULA LR* 473 494; Skegg 'Consent to medical procedures on minors' 1973 *MLR* 370 375.
parents or the child itself.  

In a later English decision, damages were awarded in respect of the birth of a child with congenital defects after a failed sterilisation, for the mother’s pain and suffering during birth and subsequent sterilisation, the pain and suffering and loss of amenities by reason of the need to care for the child, the layette, the mother’s loss of future earnings and the cost of maintaining the child.

In the 1980 edition of his book *Doctor, patient and the law*, Prof SA Strauss, a prominent leader in the field of medical law, stated as follows:

> It is questionable — to say the least — whether a South African court would be prepared to allow parents to sue for damages where a normal child is born in consequence of contraceptive failure, abortion failure or sterilization failure that is attributed to the negligence of a doctor. My guess would be that our courts will view the birth of a normal child, whatever the “pre-history” of the infant, as an event which would call for the popping of champagne corks, rather than for the issuing of a summons!

In the third revised edition of the same book, Prof Strauss was cautious, stating: ‘It is still an open question whether our courts will uphold a claim for “wrongful life” in the narrow sense’. Later decisions by South African courts justified that modification.

These and other prominent researchers should, however, offer their opinion, guidelines and even legal forecast: their recommendations are of great value and constitute a fundamental component of modern medical law.

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74 G Carter ‘Legal responses and the right to compensation’ 1976 British Medical Bulletin 89-94; P Can Atyah’s accidents, compensation and the law (5ed 1993) 61; Giesen *op cit* 243; Udale *v* Bloomsbury Area Health Authority (1983) 2 All ER 522 (QBD).

75 *Emeb v Kensington AHA* supra 1044; *Tbake and Another v Maurice* (1986) 1 All ER 497 (CA).

76 Strauss *op cit* 163: ‘In my opinion there is no principle in South African law which would allow the parents to sue for damages in respect of the loss of a potential child, except for damage which the mother herself might have suffered to her own body in consequence of the injury. We do not recognize in our law anything comparable to a right of “ownership” of children. A person can only bring an action for damages resulting from the wrongful death of another, if he can prove that the wrongdoer by his deed has caused him (the plaintiff) pecuniary damage. Thus a child who is dependent can claim damages from the man who killed his father, but the father would only be entitled to claim in respect of the death of his child if he (the father) was financially dependent on the child. To put it in crude terms: I am entitled to claim damages from the man who wrongfully killed my dog, but I do not ordinarily have a claim for the killing of my child.’

77 Strauss *op cit* (3ed 1991) 176: ‘The principle that prenatal injury to a foetus which is subsequently born alive and as a child is defective on account of the injury, can lead to delictual liability on the part of the person who negligently injured the foetus, has been recognised both in American decisions and in South Africa. That there is a sound jurisprudential basis for these decisions cannot be denied. There is no reason why this principle should not be extended to injury before conception, provided that the requisite causal connection can be proved’.

78 Strauss *ibid* 176, 197; Bebrmann and another *v* Klugman 1988 WLD (unreported); Edouard *v* Administrator of Natal 1989 (2) SA 368 (D); Administrator of Natal *v* Edouard 1998 (3) SA 581 (A).
Medical experimentation: international rules and practice

ERWIN DEUTSCH *

Medical experimentation: definition and types of experiments
Definition
Experimentation has to be distinguished from treatment. Treatment is never to be regarded as experimental solely because doctor and patient are not sure about the success. Medical treatment concerns the person, a complex being, so that expectations cannot be absolute. The medical trial therefore is not the opposite of success, but has to be assessed in the light of standard treatment. Standard treatment is any medical measure that is commonly used by physicians and specialists in treating illness. In contrast, the trial or experimentation concerns a medical intervention that aims to lead to a new standard of treatment. Treatment here is used in the broadest sense: It is not just treatment in the narrow sense of the word, but encompasses diagnosis and preemptive matters as well, such as inoculation, disinfection, etc. Research, trial and experimentation are used to describe the same phenomenon. Treatment and trial may sometimes work together in the same medical measure. Sometimes they are of equal importance, sometimes it is necessary to know whether the emphasis is on treatment or experimentation.
There is still a question mark as to whether the principal investigator or the single investigator can undertake the trial only if he has some objective criteria or if he entertains the subjective belief that the trial will be of advantage to the patients and/or science. Probably there have to be a few objective criteria on the one hand and some kind of subjective belief in the superiority of the new method on the other. An old English case and a recent American one show the range of experimentation.

In Slater v Baker & Stapleton1 the patient brought an action upon the case against a surgeon and an apothecary. They were employed to cure the broken leg of the plaintiff. The defendants broke and disunited the callous of the plaintiff's leg after it had set. The Court gave judgment for the plaintiff, recognising the possibility that the surgeon had wanted to try out a new

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1German Supreme Court case BGHZ 20, 61, the court distinguished whether the medical measure aims at the restoration of the health of the patient or is directed more particularly to research purposes. The Report of the Cervical Cancer Inquiry (1988) seems to be ambivalent in this respect: On p 63 the question is merely 'whether it had a research component'. On p 69 suddenly 'the principal of primacy of aim' becomes important.

295 English Reports 860 (1767).
medical instrument. However, it is not permitted to break an already broken, but set bone again without the consent of the patient.

The plaintiff in *Carmichael v Reitz* had suffered pulmonary embolisms and thrombophlebitis after taking Enovid. During the proceedings another doctor, for purposes of proof, again tried Enovid on the patient. The same symptoms as before appeared. The patient now sued for damages. As far as the test was concerned the court gave judgment for the defendant company. The plaintiff had acted at her own peril.

**Types of experimentation**

We distinguish between two basic types of experiments: the therapeutical trial and the purely scientific research. Experimentation is therapeutical if it is used for the purpose of furthering the health of the experimental subject. The purely scientific experiment does not in any way improve the health of the experimental subject. As far as therapeutical research is concerned there is the distinct possibility to weigh the advantages against the risks for the patient concerned. With scientific experimentation it is very hard to compare the advantage for the public with the risk for the subject. Hence in this field minimal dangers only are accepted.

A controlled clinical trial is a medical undertaking, that is done with regard to a certain result and which is assessed with that in mind. Usually at least two groups of experimental subjects are formed: the test group and the control group. The test group gets the new treatment; the control group is receiving the standard therapy or, in minor matters, gets a placebo, which means that it is not treated at all. Placebo-controlled clinical trials are commonplace in matters of sleep disorders and pain-relief. In serious matters placebo-controlled experiments can be conducted only where there is no effective standard treatment. Sometimes there is more than just one test group. The trial is blind, if the patient or the experimental subject does not know whether he or she belongs to the test group or the control group. The research is double blind if the doctor, who is treating the patient, is in the dark as well. Sometimes even the principal investigator does not know who belongs to which group. We talk of crossover, if during the trial the subjects are moved from one group to the other. To get a statistically valid result it is usually necessary to randomise the patients or experimental subjects.

Randomisation is there to counteract artificial results. Randomisation particularly works to discourage persons with identical backgrounds to enter just one group. Usually randomisation follows special rules established by clinical statistics. The types of experimentation can be gathered by the following two cases.

**Karp v Cooley**

The widow of a deceased patient sued the famous heart surgeon Cooley, who

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493 F 2d 408 (US Court of Appeals 1974).
had tried to save the critically ill patient after unsuccessful open-heart surgery. Cooley had removed the heart and installed a pump, previously used only on dogs, in its place. A few days later the artificial heart had been taken out and a transplant was made. Cooley had obtained the patient's written consent for this procedure. One day later the patient had died of renal failure. The Court gave judgement in favour of the defendant and it was decided that there had been no negligence on the part of the surgeon. Moreover, the patient had knowingly agreed to the use of an artificial heart.

Rice and Beri-Beri, Preliminary Report
on an experiment conducted at the Kuala-Lumpur Lunatic asylum

In a psychiatric institution in Kuala Lumpur the chief of service divided his inmates into two groups. One group was given uncured rice and the other got white rice. Of the 120 inmates who lived on the cured rice 34 developed Beri-Beri and 18 died. The group that ate only uncured rice consisted of 123 patients. Only two developed Beri-Beri and could have developed it before becoming inmates of the asylum. The trial established once and for all that Beri-Beri is an illness resulting from vitamin deprivation.

Typical contents of a research protocol
A controlled clinical study is undertaken on the basis of a research protocol. The research protocol is itself based on the following statements: At the outset there is an outline of the standard of the science today, followed by the question raised by the research protocol, this itself followed by the result of a possible pilot study and finally the expected result. The research protocol then usually goes on to name the criteria for inclusion and exclusion of subjects and the whole system of selecting subjects. It is necessary to make a statement concerning the overall number of experiments subjects and the anticipated reasons for abandoning the trial early. If they are not expressly stated the study is assumed to be discontinued if one of the original elements has changed considerably. Moreover the overall setup of the study has to be disclosed. If it is a multi-centre study all the participation institutions and doctors have to be named. This is even more important if it is an international study. The information given to the subjects and their consent has to be documented. In a country such as Germany, compulsory accident insurance has to be taken out in the case of the testing of pharmaceuticals. In other countries the Government has to give its approval or at least be notified before the trial is started. Normally an ethics committee has to review the research protocol and to accept it or at least not to object against it. Often special rules for the termination of the study are adopted. In longer studies, especially in multi-centre or multi-national studies, a special committee is established with jurisdiction over the study as far as the prolongation or the termination of the study is concerned. The position of the principal investigators and the rights and obligations of the contributing investigators have to be determined. Most important is the part about the risks, benefits and expectations of the study.

51907 The Lancet 1776 ff.
Here the work of the ethics committee starts. Even the consenting patient should not be put at an unreasonable risk that outweighs the possible benefits for himself or other patients. This is for instance the case if a chronically ill patient is to undergo a prolonged wash-out period before the trial starts or if in phase IV-studies the trial is undertaken for marketing purposes in the first place.

International legal and ethical instruments

The starting point: the Prussian directive of 1900

There are no international treaties concerning clinical trials. The development has not been going that way. Medical experimentation is regulated typically by instruments whose legal qualifications are sometimes in doubt. The development over the last century has been that experimentation is regulated mostly by national or international directives. The first regulation on a national basis we know of was issued on 29 December 1900 in Berlin. The Prussian Minister of Health directed the university clinics to conduct experiments with patients only after having obtained their informed consent. Experimentation with incompetent patients or children were not allowed. All experimentation had to be approved by the heads of the department. This directive was due mostly to a public scandal created by articles in illustrated papers of the time. These concerned, among others, trials in German university clinics at the end of the 19th century with patients in the final stages of venereal diseases, without obtaining their informed consent. Since the publication in the popular press found their counterparts in scientific journals there was no use denying them. There is an interesting similarity between the first scandal concerning human experimentation at the turn of the century in Germany and the Metro article by Coney and Bunkle entitled ‘An “Unfortunate Experiment” at National Women’s’ (June 1987). On both occasions publication in widely read illustrated papers forced the authorities to react. In Prussia there was no use denying therefore the directive came into being.

The 10 points of Nuremberg

In 1947 an American military tribunal sitting in Nuremberg and composed of...
three state judges issued their verdict in the so-called Medical Case.\textsuperscript{10} The judgment rested on 10 points which the court used to distinguish between lawful and unlawful experimentation. The 10 points obviously originated with the court, but in reality probably were for the greater part, formulated mostly by the medical adviser to the prosecution, Leo Alexander.\textsuperscript{11} Unfortunately, because the 10 points were not discussed in open court some of them later seemed open to severe criticism. Therefore in the fifties an American committee proposed an amendment of no less than 5 of the 10 points of Nuremberg.

The Nuremberg Code followed the Anglo-American approach of affording precedence to the patient’s will \textit{vis-à-vis} his interests. Therefore it stated categorically that experimentation has to be performed with the informed consent of the experimental subject. Moreover the experimental subject has to give consent, a rule which seemed to rule out experimentations on mentally ill patients or children. Very valuable is the rule concerning the right of the patient have the experimentation discontinued at any time. Today the right to withdraw consent is no longer conditional on specific reasons as in the Nuremberg code and the experimental subject may withdraw at any time without furnishing reasons. There was also the equally valuable ban against experimentation that somehow could result in major injury or death of the experimental subject. Less fortunate was the basis of the 10 points of Nuremberg merely addressing purely scientific experimentation. One rule has even been described as bizarre.\textsuperscript{12} It is No 5 allowing the experimentator to take a greater risk if he is participating in the study. Nowadays we know that particularly high risks are often run by the principal investigator only. If he steps in often there is more risk than the average experimental subject would tolerate. Nowadays the 10 points of Nuremberg seem to have been superseded by the two Helsinki Declarations issued by the World Medical Association.

\textit{United States v Rose}\textsuperscript{13}

Professor Rose had furnished doctors at concentration camps with typhus vaccines. At the concentration camp of Buchenwald two groups were treated. One group had been inoculated against the disease, the other was not. In all, there were 729 experimental subjects of which at least 154 died. If the inmates had been given information at all, they had been told that the experimentation was harmless and they would be given better rations. Professor Rose was

\textsuperscript{10}United States v Rose Trials of war criminals before the Nuremberg Military Tribunals volume 1, 2 'The medical case' (1949). Cf Alexander ‘Medical science under dictatorship’ 1949 New England Journal of Medicine 43.


\textsuperscript{12}Ladiner-Newman Clinical investigation in medicine (1963) 140 f. For criticism of the 10 points of Nuremberg see Moore ‘Therapeutic innovation: ethical boundaries in the initial clinical trials of new drugs and surgical procedures’ 1969 Daedalus 502, 515.

\textsuperscript{13}Trials of war criminals before the Nuremberg Military Tribunals (1949) Vol 2 264.
Erwin Deutsch

convicted because of war crimes and crimes against humanity. Since he had openly criticised the experimentation this was taken as proof that he knew about the illegality of the procedure.

**United States v Stanley**

In 1985 a sergeant in the American Army volunteered for a research programme to test the efficacy of protective clothing during chemical warfare. Without his knowledge he also became part of a programme in which LSD was administered, which led to hallucination and loss of memory. The experimental subject learnt of the second trial only in 1975. Though the courts clearly expressed disapproval of this secret experimentation his claim was dismissed because a member of the Army is not allowed to sue his employer.

**Halushka v University of Saskatchewan**

Halushka was a student who, for a fee of $50, had agreed to act as a research subject at the university hospital. He had been told that a new pharmaceutical product was to be tried out on him and that a catheter would be inserted into a vein. He had signed away all responsibility of the university and the physicians. During the trial a new anaesthetic agent 'Fluoromar' was used and the catheter was even advanced towards his heart. For a short time the experimental subject suffered a complete cardiac arrest, but after 90 seconds open heart massage was applied and his heart started beating again. Halushka sued the university and doctors. The judge held that experimentation was justified only if there had been informed consent. The consent given was invalid because of the incomplete information concerning the new drug used and the catheter advanced to the heart. An experimental subject was entitled to at least the same information as that given to a patient.

**Declaration of Helsinki (1962–1964)**

In the first half of the sixties the World Medical Association issued the Declaration of Helsinki concerning biomedical research on human beings. The declaration was supposed to replace the Nuremberg code which had obvious shortcomings. At the same time the World Medical Association changed the emphasis from the freely given consent to the more paternalistic approach: that the advantages should outweigh risks. Informed consent then appears as the second requirement for medical research. In some cases of clinical research combined with professional care personal consent was not required, allowing therapeutic experimentation on unconscious patients. It distinguishes between purely scientific research and therapeutic experimentation. In both cases a balance between advantage and risk on the one hand and informed consent on the other is required. This becomes evident in two cases, a German and an American one.

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15 52 Western Weekly Reports 608 (Court of Appeals Saskatchewan 1965).
German Federal Supreme Court February 2, 1956, BGHZ 20, 61:
A German soldier had been treated at the Heidelberg University Hospital during the war because of an injury that had caused an aneurysm of the fumaroles. A few times an arteriography had been performed using Thorotrast. Despite an occasional warning in the late thirties that Thorotrast might have severe long-range side effects, the Greek chief of service decided to try it out on many soldiers to dispel the cloud hanging over Thorotrast. The soldier suffered cirrhosis of the liver. successfully sued Heidelberg University. The Court concluded that the arteriographies amounted to research, at most, since the health of the soldier was in no way furthered by doing more than one arteriography. Since the soldier had not been informed and had not given his consent to the experimental procedure, but nonetheless had been under military orders and could not have refused, he was awarded a substantial sum not as damages, but as compensation for having sacrificed his personal rights by acting as experimental subject while under command of the army.

Fiorintino v Wenger
A fourteen-year-old boy underwent an operation to have a scoliotic condition corrected. The orthopaedic surgeon employed a method which he had developed himself five years ago and that had not been generally recognised. Up to that date 35 operations had been performed employing his method. One patient had died and four serious mishaps had occurred. The operation on the boy did not prove successful. The court gave judgment for the plaintiff. The surgeon had not informed the parents of the fact that a new and unorthodox method was being used and that there had been a particular risk.

Revised Declaration of Helsinki (1975–1989)
In 1975 the Helsinki Declaration on Biomedical Experimentation was totally revised by the World Medical Association in Tokyo. A group of Scandinavian doctors headed by Povl Riis from Copenhagen, had submitted a draft to the assembly in Tokyo. The so-called Revised Declaration of Helsinki of 1975 is the most modern international instrument to deal with medical research. It is universally accepted because it makes the necessary distinction between therapeutical research and purely scientific experimentation; it insists on a medically acceptable benefit-risk ratio; it requires the informed consent of the subject; it establishes ethical committees and finally it requires publishers of learned journals to assess the ethical propriety of medical research papers submitted. One of the hotly debated issues in Tokyo concerned the establishment and function of ethics committees. The draft had proposed that the committee should have the power to review, allow or deny the application. The European delegations on the other hand were successful in changing the role of the ethics committee from review to advice. The section concerning ethic committees now reads: 'The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a

17227 N E 2d 296 (New York Court of Appeals 1967).
specially appointed independent committee for consideration, comment and guidance.\textsuperscript{18} The institution of ethics committees came into being mainly as a result of certain occurrences in the United States. One was the publication of the famous article by Beecher in 1966 concerning ethics in clinical research.\textsuperscript{19} This paper proved that at least 12 research protocols out of a 100 clinical trials, documented in the very same journal, had been ethically questionable. Two other cases have helped to bring the human subject protection committees or institutional review board into being.

\textit{Hyman v Jewish Chronic Disease Hospital} \textsuperscript{20}

In 1963 the Sloane-Kettering Institute for Medical Research in New York approached the Jewish Chronic Disease Hospital in Brooklyn. The aim was a medical test to establish whether chronically ill patients had the same ability to reject foreign tissue as healthy persons. The test was unrelated to their normal therapeutic program. 22 chronic patients had live cancer cells injected. They had been asked whether they agreed to participate in a test that was to test their immune reaction. They did not know that it was a purely scientific experimentation and that live cancer cells were to be used. The court found that a director of the hospital corporation was entitled as a matter of law to an inspection of the records of the hospital to investigate into the propriety of experimentation on patients.

\textit{Syphilis in the deep South} \textsuperscript{21}

Since 1929 Salvarsan had been used in the southern states of the United States to treat syphilis. In 1932 a programme was launched by public health agencies that, for the next four decades, studied the results of untreated syphilis in contrast to medication. The patients in the study group did not receive Salvarsan or (later) Penicillin. The survivors instituted civil proceedings and were paid 10 million dollars by the Government in 1974. The function of the ethics committee is to safeguard the rights of the patient and/or experimental subject. In the second instance the committee should protect the researcher who sometimes violates the rights of the patient in his desire to establish a new treatment or to achieve a goal in scientific research. Finally, even the institution where the research is to be performed, should be protected by the deliberations of the ethics committee. At present it is still questioned how far an ethics committee is entitled to look into the scientific validity of the research protocol. Sometimes it is simply assumed that the committee has to review everything including the scientific design of the study.\textsuperscript{22} Many ethics committees concern themselves mostly with ethical and legal questions. But it is generally agreed that an experimentation without scientific merit is also unethical. On the other hand an ethics committee should not act as a scientific committee and interfere if the research protocol is questionable only if there

\textsuperscript{18}Revised Declaration of Helsinki \textsuperscript{12}.
\textsuperscript{19}Beecher 'Ethics and clinical research' \textit{1966 New England Journal of Medicine} \textit{1354}.
\textsuperscript{20}206 N E 2d 338 (Court of Appeals, New York 1965).
\textsuperscript{21}\textit{Newsweek} (20.7.1981).
\textsuperscript{22}As in the Report of the Cervical Cancer Inquiry (1988) \textit{14}.
could be other ways and means of achieving the results.

Medical experimentation: more or less

The medical treatment of today is based on experimentation of yesterday. To ensure the steady progress of medicine, it is necessary to undertake medical research on a broad range. Medical experimentation should be assisted and not unduly burdened. The latter would be the case if unnecessarily stringent rules would apply to medical experimentation. In biomedical research the role of the lawyer is mostly concerned with consent and procedure. I will therefore look into the conclusions and recommendations of the report of the Cervical Cancer Inquiry in New Zealand. The highly impressive report by Judge Silvia Cartwright invites discussion and dissent in three respects.

(a) Findings and recommendations 5.b (ii) 'General information and therapeutic or non-therapeutic research should be offered to all patients whose permission is sought for inclusion in a trial. Their written consent must be sought on all occasions when interventions, clinical or non-therapeutic research is planned'. The unqualified language of the second sentence seems to preclude medical research on unconscious persons and the mentally ill. Especially with regard to research in the field of cardiovascular illnesses the wording should be qualified to allow clinical experimentation with assumed consent on unconscious persons. The Revised Declaration of Helsinki allows this type of clinical research in II.5: 'If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee'.

(b) 'Written consent'. There is no legal precedent that the consent of the patient or experimental subject should be given in writing. On the other hand, a statute can specify that consent has to be given in writing. In the absence of a statute, written consent can help to establish evidence that the patient has agreed. In the daily practice of medical experimentation it has been shown, however, that a checklist given to the doctor and used by him in informing the patient verbally is at least as useful as a written consent form. In a conversation with the patient the physician can establish whether the patient really understands what the experimentation and its procedures are about. If the patient then still agrees, he may do so in writing, orally or just by taking part in the experimentation. All this means that consent is second in importance only to information. If the experimental subject, after having been informed, participates freely in the trial, there will be no delictual liability, even if the consent has not been given in writing.

(c) '... that lay representation on ethical committee approximate one half of the membership.' Ethics committees started out with the peer review system, where other doctors and researchers reviewed researched protocols. Now the community review model is preferred: researchers and physicians are joined

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by one, two or at the most three members not involved in research or treatment. To require that one half of the ethics committee be composed of laymen unnecessary in the extreme. Judge Cartwright refers to the modern trend towards increased lay participation in ethical assessment and mentions a recommendation in Australia according to which a woman, a man, a minister of religion, a lawyer and a medical graduate without research experience shall function as lay members of an ethics committee established by the medical research council. But what would be the task of these venirepersons? Research protocols are often lengthy and very technical. They sometimes venture into intricate statistics and are occasionally framed in a foreign language. It usually takes a researcher to understand a research protocol. Lay members may, after a period of adjustment, be able to understand the less complex research procedures. But to promote lay members from their watchdog function to the role of overseer of scientific experimentation is hardly advisable. Lay members are there to guard against the danger of a ‘closed shop’ of scientists. It is of no use to give the lay members voting power to inhibit experimentation. Especially if the ethics committee has first to enquire whether the study is scientifically valid, as the Report states, the lay members are inexpedient. Let us not limit medical experimentation too much. Medical research today is the medical treatment of tomorrow.