Until recently, South Africa appeared to have been spared the rapidly escalating global trend towards increasing litigation for medical malpractice. Recent data, however, indicate that the country may be on the verge of a medical malpractice litigation 'storm', as the number and size of claims appear to be increasing rapidly. This is occurring in both the public and the private sectors. As an example it is worth noting in the public sector that apparently, according to its annual report, the Gauteng Department of Health and Social Development faced malpractice claims totalling R573 million in 2009 - 2010.1 The Department ascribes this to an increase in the size of the claims rather than their number. The largest payouts have been in obstetrics and gynaecology and orthopaedic surgery. Given that the Department has a fixed annual budget, claims of this size will inevitably reduce the quality of care in an already resource-strapped setting.

A healthy tension between the legal and medical professions probably serves to improve the quality of care and helps to reinforce and possibly define standards of care that are evidence-based.2 Patients have legitimate claims that need to be addressed. The question arises, however, whether the system is open to abuse, particularly when it comes to determining quantum in the assessment of damages.

Medical malpractice litigation in South Africa

There has been a very significant increase in both the size and frequency of claims in South Africa over recent years.

1. According to information provided by the Medical Protection Society (MPS):3 (i) it is currently assisting more than 895 members in South Africa who have ongoing negligence claims, while there are more than 1 000 open files that are potential claims awaiting assessment; (ii) of the outstanding claims, almost 1 in 5 is in excess of R1 million – this represents an increase of nearly 550% compared with 10 years ago; and (iii) the number of claims over R5 million has increased by 900% in the past 5 years, with several topping the R30 million mark.

2. According to the Health Professions Council of South Africa (HPCSA), between April 2008 and March 2009 about 90 doctors in South Africa were found to be guilty of unprofessional conduct, including cases of insufficient care, refusing to treat patients, misdiagnosis, practising outside of scope of competence, overcharging or charging for services not rendered.4

3. Statistics from the HPCSA also show that 44 doctors have been struck from the roll since 2005 due to unethical and unprofessional conduct.4

There is little doubt that South Africa is experiencing a dramatic increase in the number of claims made for medical negligence. Most claims relate to obstetrics and gynaecology and orthopaedic surgery, although others such as cosmetic surgery, which are less frequent, are potentially the most expensive. Although the form of fault for which medical malpractice liability may be incurred will usually be negligence, it may in certain circumstances take the form of intention.5 Malpractice liability may also include a range of other causes such as liability for breach of contract (e.g. in failing to perform an operation agreed upon) or liability for invasion of privacy by unwarranted disclosure of the patient’s medical details to outsiders.
South Africa has been slow in climbing on the litigation bandwagon. The question that arises is whether we are seeing at present is just a normalisation towards global trends, and whether the increase in litigation may be attributed to an increased public awareness of patient rights. Medical malpractice attorneys seem to target the public more deliberately than before, encouraging clients through the media to seek legal assistance when malpractice is suspected.

As indicated above, the specialty most affected by litigation is obstetrics and gynaecology. The 2011 annual MPS premium for obstetricians is R187 830. As one colleague put it: ‘I have to do several caesarean sections at the beginning of every month just to pay my malpractice premiums; this before I can start covering my practice overheads and taking something home to the family.’ Areas that provoke litigation include excessive use of oxytocics, shoulder dystocia, and failure to screen for conditions that can be detected antenatally (e.g. Down syndrome and spina bifida).

Next are neurosurgery and spinal surgery (surgical procedures performed on the spine and/or meninges), which are classed as ‘super high risk’ and for which the 2011 annual premium is R174 700. This is followed by gynaecology, trauma surgery and orthopaedic surgery, plastic and reconstructive surgery, bariatric surgery and fertility medicine, which are classed as ‘very high risk’ and for which the 2011 annual premium is R101 030.

How does this situation compare with litigation in other countries? It is generally recognised that the number of doctors sued may not necessarily be the best way of evaluating the situation. Nonetheless, a report published recently by the American Medical Association found that 42.2% of medical practitioners had been sued at some point in their career, with 22.4% being sued twice or more.6 The report provided data from 5 825 medical practitioners who had been surveyed across the USA and across medical specialties. The specialties with the highest incidence of claims were general surgery and obstetrics/gynaecology. Nearly 70% of practitioners in those specialties had been sued, with over 200 career claims filed for every 100 practitioners. More than 50% of obstetricians/gynaecologists had been sued before the age of 40, while 90% of general surgeons aged 55 and older had been sued. Paediatricians and psychiatrists had the lowest incidence of claims, although even among paediatricians, by the time they reached the age of 55, over half had been sued. Although the survey did show that only 5% of medical liability lawsuits ultimately ended up in court and that the medical practitioners involved won in 90% of cases, the costs incurred from a financial and personal (see below) perspective were high.

Achieving a balance between theory and reality

Although from a theoretical perspective, medicine practised on the basis of evidence-based norms and standards should ensure a high standard of care, several examples exist in which adherence to these norms and standards may simply not be achievable. An illustrative example is to be found in a study published by Klinger et al in 2005.7

The background to this study was the observation that episodes of hyperoxaemia and hypocapnia may occur unintentionally in severely asphyxiated neonates in the first few hours of postnatal life. The hypothesis is that hyperoxaemia and hypocapnia may aggravate pre-existing brain injury in this period, based on the recognition that hypoxic ischaemic encephalopathy (HIE) is a process evolving over hours to days (and possibly even weeks). The study was designed to determine whether hyperoxaemia and/or hypocapnia during the first 2 hours of life are associated with adverse outcomes ascertained at 24 months of age. Adverse outcomes were defined as death; severe cerebral palsy; and any cerebral palsy with blindness, deafness or developmental delay. This retrospective study was conducted on 244 term infants with HIE. 218 had known outcomes, of which 127 were adverse (64 deaths and 63 neurodevelopmental deficits). Multivariate analyses revealed an association between the adverse outcomes defined above and episodes of severe hyperoxaemia, severe hypocapnia or a combination of the two. From a statistical perspective, the association was strongest in cases of combined hyperoxaemia and hypocapnia. What was not determined in this study was the relationship between cause and effect, i.e. although hyperoxaemia and hypocapnia may have been the causes, they may equally have occurred as a consequence of HIE.

The question at stake here is that although this study demonstrated that hyperoxaemia and hypocapnia may increase the severity of brain injury after intrapartum asphyxia, Tracy et al. point out as follows: ‘Even with closely monitored ventilation, hypocapnia and hyperoxaemia occurred in 38% and 25% of preterm infants during transfer to the NICU.’ Does this open the door for litigation against paediatricians who treat neonates with HIE who subsequently develop cerebral palsy and in whom episodes of hyperoxaemia and hypocapnia have been documented in the first few hours of life? If hyperoxaemia and hypocapnia occur in one-quarter to one-third of infants despite closely monitored ventilation, can this in fact be avoided?

The question one has to ask is whether litigation in this setting may indirectly improve the quality of patient care. While this may be the case in an ideal world where the risk of litigation may promote higher standards of care through increased awareness and the provision of additional resources, it may be difficult to achieve in an under-resourced health care setting such as our own.

The principle that the plaintiff bears the burden of proof in medical negligence cases applies universally. If the evidentiary standards of proof in litigation are considered, specifically the standard of proof in civil cases which is that of a preponderance or balance of probabilities, it means that liability is decided on the basis of what is more likely to have occurred, or what carries more weight. In criminal cases, on the other hand, a higher burden of proof is required: an accused will be deemed innocent until proven guilty beyond reasonable doubt. In the example described above, constant monitoring of blood gases, acid-base balance, inspired oxygen levels and ventilator rates would be necessary to ensure that hyperoxaemia and hypocapnia, as the adverse outcome, do not occur. The feasibility of achieving this ideal (despite all intentions to prevent these conditions from occurring) in an under-resourced environment such as our own (particularly in the public sector) is questionable. Moreover, because medicine is not an exact science, medical practitioners mere human beings and not machines are often confronted not only with inherent risks and dangers associated with their profession, but with other factors beyond their control, such as practising in a poorly or under-resourced setting. To compound this problem, conflict-
ing judicial views exist on whether the location in which a medical practitioner practises should be a factor that should be considered in determining negligence. It has been suggested that a distinction be drawn between the subjective abilities (such as skill, education and knowledge) of the practitioner on the one hand and the objective circumstances in which she/he finds herself/himself in a specific location.

Finally, it is well recognised that malpractice claims often do not involve medical error or negligence. As noted by Kane: Claim frequency should not be used as an estimate of the error rate or malpractice rate in medicine ... the majority of claims are dropped and an even larger percentage are closed without payment. A review of closed claims showed that no injury had occurred in 3 percent of claims, and that in another 37 percent, there had been no error. The same paper showed that in terms of compensation for medical errors, the system "gets it wrong" about equally on both sides. Twenty-seven percent of claims involving errors were uncompensated and, on the flip side, the same percentage of compensated claims did not involve an error. Earlier research that matched claim level data with hospital records also suggested similar inaccuracies. In that work, the authors found that less than 15 percent of patients who suffered a negligent injury filed a claim, and that negligence had occurred in only slightly over 15 percent of filed claims.

### Indemnity insurance for health professionals in South Africa

Regulations relating to indemnity insurance for registered health care practitioners were published in the Government Gazette on 30 August 2010 under the Health Professions Act. The regulations would make it compulsory for medical doctors, specialists, dentists and psychologists ‘registered and practise in the category “independent practice” to “obtain a professional indemnity cover”. It appears that annual registration will be dependent on providing proof of indemnity cover.

These new regulations were due to come into effect at the beginning of 2011. However, recognising that there are several critical issues that still need to be addressed, the HPCSA placed a moratorium on the implementation of the regulations. Some of the reasons for this moratorium include the following:

1. **Current providers of indemnity cover need to be registered** in terms of section 7 of the Short-Term Insurance Act. None of the current providers in South Africa are registered as required. Although the regulations make provision for a 4-month grace period between their publication (30 August 2010) and registration by the providers, this is unlikely to be sufficient.

2. **The extent of the insurance cover required (minimum and maximum amounts)** is not stipulated.

3. **No provision is made for run-off cover**, i.e. to cover practitioners once they retire. For example, the High Court in London has recently given permission for a 35-year-old man with cerebral palsy to claim for damages arising from alleged negligence at birth.

4. **Cover provided by current providers is considered to be too expensive for many doctors.**

Fortunately, these regulations were recently quietly revoked by the Department of Health after discussions between the HPCSA, the South African Medical Association (SAMA), the MPS and the Financial Services Board. Why these seriously flawed regulations were published without consulting those to whom it would have applied, is not clear.

If enacted, these regulations would only have applied to practitioners in ‘independent practice’. Practitioners employed by the state would have fallen outside their scope. The state provides indemnity for doctors working in its hospitals as is established under the common law doctrine set out in v Minister of Health, as well as in Treasury Regulations. The present position is that state hospitals must, except in cases of gross negligence, assume vicarious liability for the acts or omissions of their employees and will indemnify those employees against such claims. In terms of the new State Liability Bill of 2009, which will replace the State Liability Act, the state will be vicariously liable for the negligent conduct of the practitioners it employs (the Bill was published for public comment in General Notice 689 in GG 32289 of 1 June 2009). Coetzee has suggested that the introduction of contingency fees, allowing the poor access to legal redress for obstetric mistakes made in state hospitals, is ‘a great threat to the survival of state healthcare in South Africa, as the large amounts that are awarded to claimants could cripple the healthcare system’. However, although this diminishes the resources required for the state to meet its health care responsibilities, if a patient is entitled to compensation, it is necessary to find a way to fund this.

It has, however, been argued that the new proposed Protection of (State) Information Bill, published in Government Gazette No. 32999 of 5 March 2010, may curb access to medical records held by the state. As the bill now stands, the medical records and other information could be classified ‘confidential’ by officials to hide negligence or other inconvenient truths. Cases such as the recent tragic death of 29 neonates at East London’s Cecilia Makiwane Hospital in March would be hidden from public scrutiny. Eastern Cape health MEC Sicelo Gqobana himself expressed concern that hospital authorities had failed to report the deaths to him. Swart maintains that ‘[i]f even an MEC was initially kept in the dark, would there not be a temptation in future to classify such records as “confidential”, thus denying public access to such information?’.  

One of the models proposed for indemnity cover involves a rearranging of the funding structure, such as in the State of Wisconsin where practitioners were only required to purchase cover up to $1 000 000 per claim and $3 000 000 in a year, with claims above that level being covered by a statutory fund. Another model is to introduce no-fault schemes or no-fault elements to the overall scheme. For example, in Florida the Birth-Related Neurological Injury Compensation Association was introduced, a no-fault compensation scheme that covers injuries which leave an infant permanently and substantially mentally and physically impaired. Countries with a common-law system, such as Australia, the USA and the UK, rely on the tort system to handle negligence cases, including medical malpractice. Australia reviewed medical indemnity insurance in 2003 and recommended measures aimed at stability and affordability of premiums in this market. In contrast to these, schemes based solely on causation exist in several countries, most notably in Nordic European countries (Sweden, Denmark,
Norway, Finland) and in New Zealand. These countries typically have a cap on claims. Hybrid fault or no-fault models also exist in some countries, such as France, where a no-fault system is in place for injuries resulting in incapacity of at least 25%.

The MPS in South Africa adheres to the principle of uncapped discretionary cover on an ‘occurrence basis’. With regard to the discretionary principle, the MPS claims that ‘we can find no case in our long history where MPS has allowed a patient, who has suffered proven harm as a result of negligence by an MPS member, to go uncompensated. MPS also has no caps on the amount that will be paid out’.40 This does however mean that there is no contractual duty for the MPS to pay a claim, as every claim is considered on its own merit. According to the MPS, this approach allows for greater flexibility in dealing with claims, and avoids the exclusions, provisos and duties of the policyholder that would form part of a normal insurance policy. Therefore, although an insurance company would be contractually bound to pay, this would only apply if the claim complied with all the conditions and requirements of the policy.

With regard to ‘occurrence cover’, MPS members have the right to request assistance for all claims that are made regarding incidents that occurred in the membership year, i.e. in the year for which the annual subscription was paid, irrespective of when the claim is made.43 This covers practitioners who may decide to leave the profession, move overseas or retire. It also negates the need for run-off cover.

The Consumer Protection Act

The introduction of the Consumer Protection Act,41 signed by the President on 24 April 2009, has widened the scope of legal liability that health care practitioners and health care establishments may incur. Its purpose is to promote broad-based public good, and to protect the public from exploitation and harm. It has been characterised as a ‘Bill of Rights for consumers aimed primarily at protecting the vulnerable’.42 The Act came into operation on 31 March 2011.43

How does this affect health practitioners? The Act provides in section 61 that the producer or importer, distributor or retailer of any goods is liable for any harm (e.g. death, injury or illness) caused wholly or partly as a consequence of supplying unsafe goods; a product failure, hazard or defect in any goods; or inadequate instructions or warnings provided to a consumer in respect of any hazard arising from or associated with the use of any goods, irrespective of whether the harm resulted from any negligence on the part of the producer, importer, distributor or retailer. If more than one person is liable for the harm or loss, they may be jointly and severally held liable.44 A practical example illustrating the effect of this provision that introduced strict or no-fault liability is where a cardiologist correctly fits a pacemaker into a patient’s heart (e.g. an endocardial implantation), which fails prematurely. Whereas a patient previously had to prove that the premature failure of the pacemaker was the result of negligence on the part of the manufacturer of the pacemaker, he or she now only needs to prove that the pacemaker failed prematurely and that he or she suffered harm or loss as a result of this. Moreover, the patient need not institute a claim against the manufacturer of the pacemaker, but may claim damages from anyone in the supply chain, which includes the cardiologist as the person who supplies the pacemaker to the patient.45 No transaction with a supplier (such as a medical practitioner) may be subject to a term or condition that purports to limit or exempt the practitioner from liability for any loss directly or indirectly attributable to the gross negligence of the practitioner or a person acting for the practitioner.46

The no-fault provisions of this Act will lead to an increase in medicolegal litigation. Since the claimant can sue anyone in the supply chain and hold them liable for harm and cost, and since the health professional who delivered the care is the most easily (and usually the only) identifiable person in the supply chain, she/he can be held strictly liable for the cost of the damages that may follow. This applies, among other things, to defective prostheses, blood products, implants, pacemakers and medication for which a claim may be brought if damage results.42 It is alarming when one considers the law suits that could be filed for defective medication without having to prove any negligence; evidence of harm/loss would be sufficient.

Section 5(3) of the Consumer Protection Act provides that a regulatory authority, such as the HPCSA, may apply to the Minister for an industry-wide exemption from some of the provisions of the Act on the basis that those provisions overlap or duplicate a regulatory scheme administered by that authority in terms of other national legislation, e.g. the Health Professions Act. Given that the HPCSA already has the authority to take disciplinary steps against doctors found guilty of professional misconduct, it is likely that application for exemption would succeed and that the HPCSA should already have done this. However, it is questionable whether the HPCSA could accept this additional burden, given that they are already working at full capacity.

What are the consequences of an increase in litigation?

First, there is a move away from compassion-centred care towards so-called defensive medicine. A recent international MPS case-book survey indicates that 73% of more than 3 000 MPS members indicated that they practise defensively.47 Practitioners have begun to see their patients as a medical liability risk. As a result, many additional tests are done in anticipation of potential legal action,48 and their necessity is debatable. This has also resulted in a marked increase in certain procedures such as caesarean sections (even when the element of convenience is taken into consideration). Medical services of limited or questionable value are rendered with the purpose of avoiding adverse outcomes or persuading the legal system that the standard of care was met.49 This in turn drives up the costs of health care and may even expose patients to unnecessary risk.

Second, the emotional consequences that a practitioner experiences as a result of a malpractice suit45 cannot be underestimated.47 This can have the same emotional impact as a major illness, loss of a loved one or a severe career setback,50 and often involves the stages of grief as described by Kübler-Ross. This is particularly difficult to assume when the practitioner believes that the best treatment possible was administered under difficult circumstances.51 It is well recognised that practitioners are sued despite practising within the standard of care.52 Reported clinical manifestations of the effect of malpractice suits on practitioners include irritability, headache, insomnia, difficulty with concentration, clinical depression and suicide.53

Third, health care practitioners may lose their enthusiasm for their profession and may shy away from certain specialties.
Would-be health care practitioners might also be discouraged from entering the profession.\textsuperscript{31}

Fourth, the notion that medicine is a noble profession is sometimes undermined, and this may have a negative impact on patients' perception of their doctors.

**Recommendations**

In an article by McLennan et al.,\textsuperscript{33} a number of recommendations were made regarding litigation related to cerebral palsy. Although these recommendations refer to obstetric practice, many are applicable on a broader front. The discussion that follows is based in part on these recommendations.

**Better self-policing by the medical profession**

Peer review and improved communication between medical staff, particularly with regard to liability, are important. In addition, as suggested by Coetzee,\textsuperscript{7} practitioners should participate in continuing professional development activities to ensure that they are up to date with current developments, although the real benefit of CPD, if not undertaken with specific aims in mind, is debatable. Furthermore, they should be adequately trained for any procedure they might wish to utilise in their practice. The use of ultrasound by obstetricians appears to be a problematic area, as extensive training and skills are required. There appears to be a proliferation of practitioners using ultrasound machines without adequate training. Patients should be informed of the level of the practitioner's personal skills, and should be given the choice to obtain a more expert opinion if there is any doubt about a diagnosis.

**Establishment of special health courts and policing by the medical profession of those offering expert opinion**

Using medically trained judges for medical malpractice suits would ensure that judgements are based on sound medical/scientific principles rather than on the apparent credibility of expert witnesses. Likewise, assessment of the real credibility of expert witnesses should include peer review and possibly registration with an accrediting body.

**Dispute resolution**

The use of an arbitrator, ombudsman or independent counsellor to resolve medicolegal issues has been suggested to reduce legal involvement.

**Creation of a no-fault system for resolving disputes over birth outcomes**

A patient compensation pool that is funded through surcharges or premiums\textsuperscript{51} could be more efficient and fairer that the current malpractice system. In practice, minor injuries are over-compensated because they are cheaper to settle than to defend, whereas major injuries may be under-compensated because of the difficulties in estimating rising costs/life expectancy, etc.

**Legislative intervention to reduce the impact of litigation**

As suggested by Coetzee,\textsuperscript{7} 'the law around litigation will have to be amended in some way to prevent a catastrophe in healthcare'. In the USA, for example, more than 30 states have implemented caps on damage awards. But the legality of the caps or the statutory ceiling on damages in medical malpractice of some states, including Illinois and Georgia, was recently successfully challenged.\textsuperscript{54,55}

**Other measures**

Confidential counselling services provided by an external psychologist at the expense of the providers of indemnity\textsuperscript{50} could reduce the negative impact of litigation on health care practitioners. Collegiate support and mentoring are also important. The MPS has recently set up a free counselling service, and to date this service has provided assistance to many of its members.\textsuperscript{3}

With regard to the implications of the Consumer Protection Act, it will be important to work with reputable suppliers and if possible to get them to provide indemnity on their products.

Finally, a long-term goal should be better education of the public.

**Conclusion**

The fear of litigation has become a deterrent in some countries for practitioners to assist people involved in accidents on the side of the road, given the likelihood that the affected/injured party may sue the medical practitioner if the outcome is less than optimal. A doctor who comes to the rescue of a patient in an emergency situation assumes the duty to complete what he or she has started and the duty to exercise reasonable skill and care in performing the intervention.\textsuperscript{56} A similar situation prevails regarding medical emergencies on flights. This results in a conflict between professional obligations based on an acceptance of the Hippocratic Oath or its equivalent and reluctance to get involved. In addition, our then Appellate Court ruled in Minister van Polsie v Ewels\textsuperscript{50} that an omission to act might result in delictual liability if the juristic convictions of society would require such omission to be wrongful. In the same way, as a society becomes more litigious, there is a tendency for practitioners to shy away from those medical specialties that are most frequently affected, for example obstetrics,\textsuperscript{53} and talented individuals may even be deterred from entering the medical profession at all.

Statistics published by the World Health Organization (Table I) have revealed large variations between countries and regions with regard to the number of doctors and nurses/midwifery personnel per 10 000 population.\textsuperscript{58} From a regional perspective, the lowest numbers are found in the African region, with 2 physicians and 11 nursing and midwifery personnel per 10 000 population. The highest numbers are found in the European region, with 32 physicians and 79 nursing and midwifery personnel per 10 000 population. The figures for South Africa are 8 physicians and 41 nursing and midwifery personnel per 10 000 population. With regard to litigation, it is well appreciated that the standard of medical care will be affected as demands on the health care system increase. This is particularly true in the state sector in South Africa at present, but it also applies to the private sector. In regions where there are a limited number of specialists serving a large population, experienced individuals may be stretched to the limit of their capacity and beyond. This is compounded by the fact that junior doctors are often forced to work without supervision. It would be interesting to assess the relationship between health care resources and malpractice litigation at a global level.
Table I. Global, regional and country-specific health workforce data (World Health Statistics 2009, WHO).

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<tr>
<th>Country</th>
<th>Density per 10 000 population (2000 - 2007)</th>
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<td>Maximum</td>
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<td>Median</td>
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<td>Botswana</td>
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<td>Egypt</td>
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<td>Kenya</td>
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<td>Lesotho</td>
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<td>Mozambique</td>
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<td>South Africa</td>
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<td>Zimbabwe</td>
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<td>Other developing countries</td>
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<td>New Zealand</td>
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Patients do have legitimate claims, and these need to be fairly dealt with. In 2003 it was estimated that the average lifetime cost for a person with cerebral palsy was US$921 000. In addition, litigation has in the main been reserved for those who can afford the legal fees. However, as Coetzee points out, ‘while assisting the HPCSA, I have been aghast at some of the obstetric errors that led to asphyxiated newborns and possible later cerebral palsy. I have come to realize that it is an unfair society that does not allow the poor to be compensated for suboptimal care.’ The principle of contingency, in which the attorney will not require legal fees from the claimant but only gets paid on winning the case, provides legal recourse for medical malpractice to the entire population, particularly those who cannot afford legal costs. Most attorneys will, however, only take a case on contingency if there is a reasonable chance of success, and human nature being what it is, the greater the potential reward, the higher the incentive to win. Alternatives such as legal aid and pro bono work should be considered for the indigent.

The replacement of compassion-based medicine by defensive medicine not only raises the cost of health care (up to one-third of costs may be related to defensive practices), but may redirect the focus from the patient’s immediate needs to an imagined and hypothetical court case, which in turn may affect the quality of the care that is delivered.

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