

## Law notes

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### Patients' rights in surgery

Norway's new Patients' Rights Act, passed into law in July 1999, came into force on January 1st 2001 [1]. It is applicable in many fields of clinical activity, dealing among other things with the patient's right to be informed on his diagnosis and treatment, the right to a second opinion, the right to choose a hospital, the right to refuse a blood transfusion and the terminal patient's right to refuse further treatment.

Retrospectively analyzing cases seen at a department of vascular surgery in Tromsø (Northern Norway), Hanoa has examined some of the repercussions of this type of legislation for surgical practice [2].

*Right to care.* The Law, in its section 2(1), establishes the patient's right to both general and specialized care, subject only to the reservation that such care seems likely to be relevant and helpful, and that the costs of providing it will not be disproportionate to the effect which can reasonably be expected; the care must be provided within a period which can be considered reasonable having regard to the circumstances and needs of the case. Regulations under the Act provide more detailed specifications on the setting of priorities.

*Case 1:* A man of 64 had been suffering from bilateral intermittent claudication for some ten years, and had mild right-sided functional impairment following a cerebrovascular accident. Eight years previously there had been operative relief of subtotal stenosis of the external iliac artery. A year previously both superficial femoral arteries were occluded. Walking distance was no more than 100 metres because of the left-sided impairment, and this seriously disrupted his daily life. A femoropopliteal by pass was now carried out.

*The department was considered to have met the requirements of the Act regarding the right to necessary care, provided reasonably promptly, a standard which in this case must be considered to demand treatment within two months.*

*Right to participate in choice of treatment.* Under the Act a patient is entitled to take part in choosing between those alternative treatments which are accessible and reasonably justifiable.

*Case 2:* A man of 65 was found to be suffering from a large subrenal aortic aneurysm. Various alternative forms of repair were available, and decisions were also needed as regards the hospital which would carry out the operation and the possible desirability of a further period of observation. The patient, who was mentally fully competent, was consulted on all these matters, though he ultimately decided to leave the decisions to the surgeon.

*The consultation was considered to meet the requirements of the Law.*

*Right to be informed.* According to Article 3(2) of the Law, a patient shall be given such information as is needed to understand his condition and the possibilities for treatment which exist.

*Case 3:* A man of 66 had in the course of recent years undergone both coronary and other vascular surgery. He currently had intermittent claudication with a walking distance of 50 metres. With further surgery planned on the leg vessels, the patient posed a number of written questions to the surgeon

concerned, regarding treatment alternatives and possible complications, and requested a reply in writing.

*The Law does not create a right to receive information in written form. However, following receipt of the letter the patient was admitted for further investigation so that his various questions could be answered as fully as possible. (Further aspects of this case are considered below.)*

*Right to information when serious complications are incurred.* In its paragraph 3.(2)(i), the 1999 Law defines the right of the patient to be informed of any “injury or serious complication” suffered during treatment. He shall also be informed how to apply for compensation under the national Patient Compensation Scheme.

*Patient 4:* A man of 70 had been suffering from intermittent claudication for many years. Widespread arteriosclerotic changes were found at various levels. During surgical repair of the pelvic arteries, dissection of the arterial wall occurred; this itself was repaired with a graft, initially with success, but the graft became twisted and total occlusion on the left side followed. Patient was informed of the complication.

*While the hospital fulfilled its obligations under the Law, the question will always arise whether one may not risk raising false expectations regarding compensation in situations such as this where certain complications are not unlikely, particularly if the additional resulting impairment is not severe.*

*Patient 5:* A 75-year-old man with an infrarenal aortic aneurysm was treated with a graft. Four months later he developed left-sided intermittent claudication, which proved to be due to twisting of the left limb of the graft followed by occlusion. Medical and surgical treatment was given. The patient was fully informed of the complication, the treatment and the outcome.

*Again, occlusion of a graft is a well-known and to some extent predictable complication [3].*

*Right to reassessment.* Articles 2–3 of the Law deal with referral; though a patient has been assessed by his general practitioner, he has a right to re-evaluation by the specialist to whom he has been referred.

*Patient 3:* (continuation from above report) Among the written questions posed by this 66-year-old man was whether he could be re-evaluated by the National Hospital in Oslo. In this case he was informed that such re-evaluation was reasonable in view of the nature and severity of his condition.

*An official commentary on the Act explains that the specialist to whom a patient has been referred is not legally obliged to carry out (or arrange for) a new diagnostic study in order to assess the patient.*

*Whether such further study is needed, or whether the specialist’s reassessment can be carried out on the basis of the existing documentation, will depend on the nature of the case.*

*Form of information.* According to para 3(5) of the 1999 Law, the information to the patient shall be provided in a manner appropriate to the patient’s needs, having regard for example to age, maturity, experience, cultural and linguistic background. The information shall be provided in a considerate manner.

*Patient 6:* A woman of 70 was referred to the emergency department for severe and acute ischaemia of the left foot with evidence of gangrene. The ankle-arm index was 0.5 on both sides. The duty surgeon ordered admission and angiography. The woman was mentally retarded but lived with her family and she had not been ruled mentally incompetent. She was informed as to her condition in a manner appropriate to her mental state but categorically refused admission. Although the hospital staff doubted whether the patient fully understood her situation it could do no more than send her home, and report back promptly to her primary care physician.

According to the Law's Art. 4(1), treatment can only be administered with the patient's consent, unless a legal exception applies. The Commentary on the Law notes for example that, under provisions of the earlier Law on Health Personnel, staff may continue existing treatment without permission if withdrawal of therapy could have serious consequences for the patient. Emergency help can be given even where consent cannot be obtained or has explicitly been refused. Art. 4(3)(ii) of the 1999 Patients' Rights Act rules that patient may be considered incompetent to give consent if there is mental retardation or senile dementia; in such instances, minor procedures can be undertaken without consent while major procedures can be carried out with consent of the patient's family, though even here care should not be provided if the patient objects.

In the case of the above patient, who was treated before the 1999 Law can into effect, the situation was not considered such as to justify overriding the patient's objections. Hanoa doubts whether the decision would have been any different under the new Law.

**Right to refuse necessary treatment.** Article 4(9) of the 1999 Law defines a right of the patient, under certain circumstances, to refuse even essential treatment. Strong personal conviction is a sufficient basis to refuse a life-saving blood transfusion or to continue a hunger strike.

*Case 7:* A man of 79 who had earlier undergone coronary surgery was now suffering from serious aortic and mitral stenosis with inoperable cardiac failure and chronic obstructive lung disease. The current indication for treatment was critical ischaemia of the left leg with ischaemic sores on the foot and pain at rest; the left external iliac artery was stenosed, and the stenosis was treated by grafting, but the left common iliac artery was also occluded by atheromatous plaques, and there was atheroma at other levels from the aorta downwards. There was considered to be an indication for thromboendarterectomy and grafting. The patient requested that an entry be made in the journal that he was a Jehova's Witness and did not wish to receive blood.

*In this case there was an evidently high risk of complications with any operation, and the refusal of transfusion comprised an added risk. Surgery was however undertaken successfully with only a small loss of blood.*

The same Article 4(9) gives a dying patient the right to refuse life-prolonging treatment. If the patient is incapable of expressing a view on the matter, health personnel should withhold treatment if the family request this *and* health staff themselves consider that this would be patient's own wish and should be respected.

*Case 8:* Another 79-year-old man was admitted for emergency treatment in connection with an abdominal aortic aneurysm with an immediate risk of rupture. On admission the patient was conscious, circulatory condition was stable and he wished to be undergo operation. He was already taking medication for a chronic obstructive lung disorder and prednisolon for temporal arteritis.

A tubular graft was inserted without complications but on the third postoperative day there was ventricular retention and respiratory insufficiency. Inotropic medication was prescribed, but circulatory failure, metabolic acidosis and oliguria followed, and patient was now mentally confused and unable to communicate. The family were informed and were aware that the condition was hopeless, and the medical staff considered that because of organ failure neither artificial respiration nor haemodialysis would be meaningful. The patient died in asystole.

**Right to choose a hospital.** The patient's right to choose the public hospital where he shall be treated is laid down in Art. 2(4) of the 1999 Law; he is not entitled to choose the grade of hospital to which he shall be admitted (e.g., local, regional or academic).

*Case 9:* A 33-year-old woman had been examined as an out-patient because of varices of the right leg; it was decided that she should be operated as a day-patient. There is a close collaboration in the area between the regional hospital at Tromsø and the local hospital in Harstad, and the patient was informed that she was likely to be treated at Harstad. Shortly afterwards she wrote pointing out that she had no family in Harstad and that it would be more convenient if she were operated in a certain city in southern Norway where she had relatives. The hospital agreed that, since the hospital in the latter place had the same grade as that at Harstad she should be able to opt for treatment there.

*Case 10:* A woman of 73 was admitted to the regional hospital from a local hospital with the provisional diagnosis of intestinal angina. Angiography confirmed the diagnosis, with a 50% stenosis of the vessels. The condition is a rare one with which few hospitals have experience. It was considered that treatment in a regional hospital was justified and that the patient had the right to choose the most suitable one.

*Right to designation of a responsible physician.* Norway's similarly recent Law on Specialist Services, in its Art. 3(7), provides a basis for designating a particular physician to accept responsibility for the treatment of an individual hospital patient.

*Patient 3 (continued):* As noted above, this 66-year-old patient put a number of questions to the health service and requested a written answer. One of these questions related to the patient's experience hitherto at the regional hospital where he had been dealt with by different physicians and students; he now asked whether there was not one particular physician designated to have primary responsibility for his case, and with whom he could maintain contact.

*This enquiry reflects the need of a patient to have a single medical contact point within the hospital to which he is referred. The current law indeed requires that such a physician be designated, and that the patient be informed what this physician's role will be.*

In the light of the above cases, Hanao suggests that in many respects the new Law on Patients' Rights only confirms good current practice, at least in hospital surgical departments. Some provisions of the law – notably those relating to the choice of hospital, the right to a second assessment and the right to refuse blood transfusion – are essentially new. To ensure that hospitals do indeed conform in all respects to the new Law it will be particularly necessary to record the basis on which decisions are taken and to keep very exact patient records.

## References

- [1] A. Syse, *Pasientrettighetsloven med kommentarerer (The Law on Patients; Rights, with Commentary)*, Gyldendal Akademisk, Oslo, 2001.
- [2] R. Hanao, Karkirurgiske pasienter og pasientrettighetsloven, *Tidsskr Nor Laegeforen* **122** (2002), 290–292.
- [3] J. Lundbom, S. Hatlkinghus, J. Wirsching et al., Endovascular treatment of abdominal aortic aneurysms in Norway: the first 100 patients, *Eur. J. Vasc. Endovasc. Surg.* **18** (1999), 506–509.

## Protection of trial participants; enforcement of regulations; employees as trial volunteers

In April 2001 Ellen Roche, who was a 24-year-old employee of the Johns Hopkins Asthma and Allergy Center, agreed to take part in a physiological investigation at the Center in which hexamethonium bromide was to be given by inhalation to examine pulmonary function. Of a small series of volunteers who

originally joined the study, three including Ms Roche continued into the phase where hexamethonium was administered. One of the subjects developed a cough within two days which persisted for eight days. Three days after Ms Roche inhaled the same substance, she developed severe pulmonary symptoms; she was admitted to an intensive care unit but died with Adult Respiratory Distress Syndrome and following multi-organ failure.

The Office of Human Research Protection, following an immediate site visit, ordered the suspension of all federally supported research projects at the Johns Hopkins Medical School and its associated institutions. The suspension order was only lifted after a programme of corrective action to ensure appropriate protection of trial subjects had been submitted and approved [1].

The events were also reviewed by an internal committee [2] which identified a number of protocol violations. The drug had in fact been administered to two subjects in a non-approved manner and admixed with sodium bicarbonate, which was in violation of the protocol. Despite the fact that it constituted non-approved treatment, it had not been the subject of an "Investigational New Drug" application to the Food and Drug Administration. The complication experienced by one other trial subject was not reported to the Institutional Review Board.

The Roche family brought a legal action against the Johns Hopkins University which was settled out of court.

*This remarkable train of events in a prestigious institution raises various questions. One relates to the use of staff employees in clinical studies. It is axiomatic that a "volunteer" should be precisely that, and not subject to any form of coercion, e.g., such as might be inherent in the belief that participation in trials might be conducive to career development; the internal committee indeed spoke of a subtle culture of coercion within the centre. Similar questions have been raised earlier as regards the use of students as trial participants in university studies, or industry employees in clinical trials undertaken by the pharmaceutical industry. Involvement of prisoners in drug trials was understandably abandoned for similar reasons some twenty years ago.*

*A second question relates to the authority of an Institutional Review Board (IRB); in this case the Board was not informed when the experiment deviated from the protocol, let alone had it given permission for such a deviation. There is too often – in many countries – a tendency to dismiss the procedures associated with an institutional review board as mere formalities and to assume that an investigator is unlikely to expose his trial subjects to risk. Boards are not always active or competent nor do they always have adequate means to enforce their authority. It may be noted that in the U.S., a year prior to these events at Johns Hopkins, the Federal Department of Health and Human Services announced a number of measures to strengthen IRB's as well as planned legislation to empower the FDA to impose substantial fines for protocol breaches – up to \$250,000 per clinical investigator and \$1 million per institution [3]. While that initiative was developed in order to cope with the rising tide of gene transfer experimentation, it could be of great significance for other forms of study involving human subjects.*

*A third relates to the obligation to report non-therapeutic studies to a national authority (in this case the FDA). Universities not uncommonly carry out studies involving the administration of pharmacologically active substances for research purposes and may fail to realize that – even if these are not given to test their therapeutic potential – it may nevertheless constitute (and indeed should constitute) a form of experimental exposure bringing the study within the provisions of national regulations designed to protect experimental subjects.*

## References

- [1] Johns Hopkins University: Letter to Office of Human Research Protection, dated 21st July 2001.
- [2] See <[http://www.hopkinsmedicine.org/press/2001/JULY/report\\_of\\_internal\\_investigation.htm](http://www.hopkinsmedicine.org/press/2001/JULY/report_of_internal_investigation.htm)>.
- [3] Anon, Clinical Research: Shalala Announces Plan to Strengthen Federal Oversight of Human Subjects Trials. Health Law Reporter (BNA), 9 (May 25th, 2000) at 800.

## USA: Medical errors viewed as a system failure; liability of Health Management Organizations

*Petrovich v. Share Health Plan*, 719 N.E.2d 756 (Ill. 1999).

Inga Petrovich, a native of Illinois, was a member of a Health Management Organization (HMO) known as Share Health Plan of Illinois, which was part of the health care coverage provided by her employer. In September 1990 she consulted the primary health care physician Dr Kowalski because of continuing pain involving parts of her mouth, tongue, throat and face. She was referred to an ear, nose and throat specialist, Dr Friedman, who recommended that she should be further examined using magnetic resonance imaging (MRI) or a computed tomography scan (CT) to the base of her skull. In accordance with procedure, the matter was referred back to her primary care physician who was the designated “gatekeeper” of the Share Health Plan and responsible for evaluating the necessity of tests in the light of their costs before arranging for them to be performed. He ordered an MRI which was performed the following month, but requested only a scan of the “brain” and not of the base of the skull. No abnormalities were visible on the resultant scan, as examined by Dr Kowalski. The symptoms however persisted, and early in 1991 Ms Petrovich went back to Dr Kowalski who now diagnosed oral cancer. She underwent extensive surgery followed by irradiation.

Concluding that her cancer had not been diagnosed in a timely manner, Ms Petrovich now brought a legal claim for medical malpractice against the two physicians and at the same time (on the basis of vicarious liability) against Share Health Plan. Share argued in its defence that the cost containment function accorded to it as a Health Management Organization entitled it to special consideration. The Court of first instance, considering this defence, granted Share summary judgement, but the Court of Appeal reversed this finding and the Illinois Supreme Court similarly held that the plaintiff was entitled to a trial on the issue of vicarious liability, based on apparent and implied authority. The Supreme Court went on to rule that traditional theories of liability had to be considered applicable in such matters in order to ensure justice and provide a counterbalance to the goal of cost-containment. It further emphasised the utter dependence of members of HMO’s on these organizations: to quote the judgement: “Share, like many HMO’s, contracted with plaintiff’s employer to become plaintiff’s sole provider of health care, to the exclusion of all other providers. Share then restricted plaintiff to its chosen physicians. Under these facts, plaintiff’s reliance on Share as the provider of her health care is shown not only to be compelling, but compelled”.

The Supreme Court referred sympathetically to a submission made in the case by the Illinois Medical Society that HMO’s in the state were “operating in a manner which convolutes the decision-making process regarding health care”, *inter alia* by requiring a “determination of medical necessity” of a proposed procedure or treatment; in effect, the Society pointed out, an HMO was delegating its cost-containment task to the physician. In the Court’s view, the HMO exercised a measure of control over Drs Kowalski and Friedman which was sufficient to “negate their status as independent contractors”. The case was therefore remanded to the trial court on the matters of both apparent and implied agency.

*Notes:* Although this case as cited here relates only to the law in one State of the US, it reflects an emergent trend to challenge some aspects of “managed health care”. Although that concept is not exactly defined, it involves an effort now being made in many parts of the world to introduce a cost-control element into basic health care, coupled with a degree of privatization; the risk is clearly that where health care coverage is actively seeking to limit costs and deliver profits to investors this will be achieved at the expense of the patient. An HMO such as Share does not employ practising physicians, but it employs a network of independent practitioners and specialists, and members of the scheme are obliged to use physicians within this network. Moreover the primary physician has a “gatekeeper” function which is an important element in seeking to contain costs by eliminating less necessary or unnecessary routines. An HMO can seek to argue that the physicians in its network remain independent agents, using their own best judgement, and that it therefore does not have vicarious liability for their acts or omissions, but the rules imposed by the system clearly can constrain them in various ways.

It seems clear that, if the facts are as the trial court summarized them, Share required the specialist Dr Friedman to refer his recommendation for an MRI back to the primary health care physician rather than ordering an MRI himself. It would certainly appear that Dr Kowalski was in error in ordering an MRI of “the brain”, rather than of the base of the skull, but if the Share procedures had allowed the specialist himself to order the diagnostic tests which he considered necessary there would have been less chance of the error being made.

This case does not stand alone in opening the door to litigation against HMO’s where their way of working exposes patients to avoidable injury. In *Jones v. Chicago HMO* [1], which similarly went to the Supreme Court of Illinois, a mother who had enrolled her family for health care with an HMO, which had solicited membership in a door-to-door promotional campaign, sought paediatric help by phone for her three-year-old daughter. The child was suffering from fever, constipation and excessive crying. The district paediatrician designated by the HMO was not available, and an assistant prescribed castor oil. The paediatrician rang back later in the evening but did not modify the advice already given. When the mother took her daughter to an emergency unit the next day she was found to be suffering from bacterial meningitis. As a result she became permanently disabled.

Bringing an action for institutional negligence against the HMO, Ms Jones argued that it had assigned to her family a paediatrician who was serving too large a population to provide proper care, and that its procedures required a telephone consultation even before an appointment could be made or a patient taken to the emergency room.

The Court indeed found that the paediatrician was supposed to serve 4,527 patients, well in excess of what he could reasonably hope to do adequately, and was indeed only available on a half-time basis. As in the *Petrovich* case above, the Court considered that holding an HMO accountable for injury in such cases provided a necessary counterbalance to the drive within such organizations to reduce costs and increase profits.

A more general conclusion which can be derived from these two cases and others like them is that in cases of medical error Courts can and should be willing to trace back the cause, where necessary, to faults in the system within which a physician works. Liability for those faults may be of greater importance than the personal liability of the physician who made the ultimate error.

## Reference

- [1] *Jones v. Chicago HMO*, 730 N.E.2d 1119 (Ill. 2000).

**England: New adverse drug effects; duty of agencies protecting the public health interest**

*Amanda Claire Smith vs Secretary of State for Health. High Court, London, March 2002; Morland J.*

In March 1986 the Committee on Safety of Medicines, which was in effect the British Drug Regulatory Agency, determined that aspirin (acetylsalicylic acid) was a contributing factor in the development of Reye's syndrome, a disorder which can occur in childhood, particularly when aspirin is used for the treatment of fever, and which can cause severe neurological damage or death. Following its decision, the Committee and its supporting staff at the Department of Health were occupied for a number of weeks in planning a public statement on the matter, and in negotiating with the many producers of aspirin-based products with respect to the form and financing of a public announcement and the steps to be taken as regards the labelling and future formulation of these products. A warning to the public was ultimately issued on June 10th. During the intervening period, the girl Amanda Claire Smith, who was then six years old, developed chickenpox and was given aspirin by her mother to relieve the symptoms. She developed Reye's syndrome as a result of which she suffered severe and permanent neurological damage and became permanently dependent on institutional care. Through her mother she now brought an action for damages against the Secretary of State for Health.

For the plaintiff evidence was presented that, had the Committee for Safety of Medicines issued a prompt statement regarding the risk of Reye's syndrome, her mother would not have used aspirin and the injury would have been avoided. Reye's syndrome had left her with brain damage, spastic quadriplegia, epilepsy, and a life expectancy of 40 years or less.

For the defence it was argued *inter alia* that a poorly prepared statement to the public would not have achieved its purpose, that in view of the massive number of products concerned the only reasonable means of correcting the market situation was to come to a voluntary agreement with the industry on product withdrawal, and further that the agreement with industry had provided a financial basis for it to fund an adequate advertising campaign to convey a balanced message to the population. Witnesses suggested that more rapid action would have been ineffective and irresponsible, and could have caused confusion or even panic, leading for example to the abandonment of aspirin for other indications as well.

Giving judgement for the defendant, Mr Justice Morland said: "I have reached the clear conclusion that no fault is established against the Secretary of State, the secretariat of the medicines division of the Department of Health, or the Committee on Safety of Medicines, who in my judgment acted throughout rationally and in good faith reaching decisions and implementing them carefully and expeditiously in the interest of the public at large and children in particular, having regard to the risk of very serious injury to young children from taking aspirin when feverish".

He said that the postponement of a public warning until June 1986 was "reasonably justifiable", adding that "the risk was that without that postponement the prospect of full positive cooperation from the industry, which in the event achieved so much, might be lost". In his view it was right to delay until the drug industry was fully on board to ensure the right message was given. The fact that the Aspirin Foundation, representing manufacturers, was an integral part of the campaign in June 1986 was what made it so successful, the judge said. A decision had to be taken that balanced the real risk of grave or fatal injury to two or three children as the result of the delay against the reasonable expectation of the undoubted benefit of a "coherent, coordinated, comprehensive campaign". The campaign included the withdrawal of paediatric aspirin with the full weight of the Department of Health, the Committee on Safety of Medicines, and the industry behind it, thus giving a clear, definitive, unambiguous message



to both professionals and the general public. “In my judgement” he added, “it would be unfair and unreasonable to condemn the decision, essentially a discretionary/policy one, as faulty or negligent”.

Reye’s syndrome was first described in 1963, and by 1965 Giles in the UK noted that at least 15 of 31 cases of the syndrome which he had seen had been treated with aspirin. A controlled study by Starko in the USA showed that aspirin had been used significantly more often in children developing Reye’s syndrome than in healthy controls. Publicity accorded to this finding led to a strong and progressive decline in the use of aspirin in childhood fevers in America, and with it a marked fall in the incidence of Reye’s syndrome in that country. A series of controlled studies in the years that followed produced strong evidence of the association of Reye’s syndrome with the use of aspirin. In 1980 the U.S. authorities first advised caution in the use of aspirin in childhood fevers. By 1982 there were much stronger warnings from the U.S. Surgeon General, an FDA Workshop and other bodies, but in that same year the British Committee on Safety of Medicines considered that there was too little evidence to take action in the United Kingdom. In 1984 *the Drugs and Therapeutics Bulletin* in Britain itself issued a warning to the medical profession. In 1985, following a strong statement by the Institute of Medicine in the US, the US authorities requested (and subsequently compelled) manufacturers to introduce warning texts and undertook public education on the matter. In early 1985, however the British C.S.M. again concluded that the evidence was insufficient to justify measures. Finally, in March 1986, it decided that action must be taken. By that time, action had also been taken in Western Germany, Austria and Norway, though not in Australia or Ireland.

It is striking that in this case the claimant’s case was based almost entirely on the slowness of the action ultimately taken between March and June 1986, and not to any significant extent on the fact that a number of other countries had taken their essential decisions earlier. This may reflect the fact that there had been some genuine concern among experts in Britain that the complication experienced might not in fact be exactly the same as that described in the United States, e.g., since it was occurring in a somewhat different age group. However, it is unclear why the matter was dealt with so ponderously by the Committee on Safety of Medicines, as if acetylsalicylic acid was an entirely irreplaceable drug for the relief of childhood fever; it was well documented that paracetamol was fully capable of replacing it and did not carry the same risks.