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Hyperbaric Medicine and the Law

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WITH THE ADVENT of the hyperbaric chamber, a new and potentially hazardous method of therapy has been introduced into clinical practice. The application of this method of therapy in clinical use may be classified, at least in some instances, as experimental. Although many authorities agree that hybaroxia may be useful in the treatment of certain diseases, facilities to carry out such therapy just have not been available. However, upon theoretic grounds hybaroxia may be useful in many diseases.

With the construction of such sophisticated facilities as the hyperbaric chamber now contemplated, it might be well to seek out possible legal pitfalls in the application of high pressure oxygen equipment in the treatment of suspected or proved diseases in the human.

A comprehensive discussion of the law as it applies to hybaroxia must include design, manufacture, installation, inspection, and use of the facility involved, also, the liability of the manufacturer, of the hospital, and of the physician. Legal literature reveals few cases in which these facets of the law have been discussed with special regard to the hyperbaric facility.¹ Therefore one is forced to review principles of the common law and to apply them to hybaroxia, or refer to statutory provisions.²

Permission of the Patient

One of the basic rights extended to everyone under the common law is freedom from intentional touching of his person.³ There are numerous unavoidable trespasses that are a product

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¹ Beatty v. Foundation Co., 222 N. W. 77 (Mich. 1928); Taylor v. List & Weatherby Const., 146 So. 353 (La. 1933); Maryland Casualty v. Gerlaski, 68 F. 2d 497 (5th Cir. 1934).

² Boycott, G. W. M. 35 J. Hyg. 318; 9 Zentralbl. f. Gewerbehyg. 250.

³ Prosser, Law of Torts 33 (3rd ed. 1964).

of modern life, such as unintentional touching in a crowded bus or elevator.⁴ When getting a haircut or having clothes fitted, the touching of the person is intentional, but permission to touch is to be implied. Somewhere beyond these areas, intentional touching becomes a battery. Meticulous care is exercised by hospital administrators and surgeons to obtain authorization to operate before the patient reaches the surgical theater. One could hardly imagine a more violent trespass to the sanctity of the person than an unpermitted contact of the surgeon's scalpel, of the anesthesiologist's syringe of pentol sodium, or of confinement in a hyperbaric chamber.

The grant of permission to intentional touching of the person constitutes a defense in actions against the physician. The case law on the duty of the physician to inform his patient concerning surgical or medical treatment may be extended to hyperbaroxia.

American Jurisprudence states that "the relation of physician and patient is a consensual one, and that in the absence of emergency or unanticipated conditions a physician or surgeon must first obtain the consent of the patient, if he is competent to give it, or of someone legally authorized to give it for him, before treating or operating on him."⁵ However, certain exceptions have been made to this general rule of law. Should such a rule be enforced strictly, it may only serve to endanger the very person it sought to benefit—the patient. There are many situations in the complex field of medicine today where express consent as executed in a formal and legalistic method employed in most institutions becomes impractical.⁶

Restatement of Torts, Section 62, provides that an invasion of an interest of personality of another who has not consented thereto does not give rise to liability if (1) the other is physically

⁴ *Wiffin v. Kincaid*, 2 Bos. & Pul. (N. R.), 471, 127 Eng. Rep. 713 (1807); *Coward v. Baddleley*, 4 Hur. & Nor. 478, 157 Eng. Rep. 927 (1859); *McAdams v. Windham*, 208 Ala. 492, 94 S. 742, 30 A. L. R. 194 (1922); *Gibeline v. Smith*, 106 Mo. App. 545, 80 S. W. 961 (1904); Note, 14 U. of Cinc. L. R. 161 (1940); *Wasmuth, C. E., Consent to Surgical Procedures*, 6 Clev-Mar. L. R. 235 (1957); *Wasmuth, C. E. and Oleck, Howard L., The Privilege of Consent*, 36 *Anesthesia and Analgesia*, 51 (November-December 1957).

⁵ 41 Am. Jur. 193.

⁶ *Jackovich v. Yocom*, 212 Iowa 914, 237 N. W. 444, 76 A. L. R. 551 (1931); *Mohr v. Williams*, 95 Minn. 261, 104 N. W. 12, 1 L. R. A. (N. S.) 439 (1905); *Schloendorff v. Society of New York Hospital*, 211 N. Y. 125, 105 N. E. 92, 52 L. R. A. (N. S.) 505 (1914); *Kennedy v. Parrott*, 243 N. C. 355, 90 S. E. 2d 754, 56 A. L. R. 2d 686 (1956).

or otherwise incapable of giving consent, or the consent of another having power to act for him cannot be obtained for any other reason, (2) an emergency has arisen which makes it actually or apparently necessary to invade the interest before there is an opportunity to obtain consent, (3) the invasion is or is reasonably believed to be so manifestly to the other's advantage that a reasonable man would give his consent if he had the opportunity to do so, and (4) the actor neither knows nor has reason to know that the other would not give his consent were there an opportunity to ask for it. The surgical operation in which untoward conditions are discovered making it necessary to extend the operation or to perform a different operation from that consented to is given as an example of invasion that does not give rise to liability.

Must the surgeon limit his operation to that operation that was specifically outlined to the patient? Or, may the surgeon, in order further to benefit the patient, extend the operation? The North Carolina Supreme Court in *Kennedy v. Parrott*, held that, under the modern view, the specific consent of the patient was unnecessary. In that case, the court held that the surgeon was authorized to extend the operation to any abnormal condition in the area of the original incision when this is necessary for the welfare of the patient and is the approved practice of surgeons generally. It stated:

While the law of contracts is applied as between a patient and his physician or surgeon, when a person consults a physician or surgeon, seeking treatment for a physical ailment, real or apparent, and the physician or surgeon agrees to accept him as a patient, it does not create a contract in the sense that term is ordinarily used. . . The patient selects, and commits himself to the care of the doctor because he is confident the doctor possesses the requisite skill and ability to treat . . . his physical ailment. . . The physician, after diagnosing the ailment, prescribes the treatment or the medicine to be administered; but the patient is under no legal obligation to follow the physician's instructions. Thus it is apt and perhaps more exact to say it creates a status or relation rather than a contract. . .

Prior to the advent of the modern hospital and before anesthesia had appeared on the horizon of the medical world, the courts formulated and applied a rule in respect to operations which may now be justly considered unreasonable and unrealistic. During the period when our common law was being formulated and applied, even a major operation

was performed in the home of the patient, and the patient ordinarily was conscious, so that the physician could consult him in respect to conditions which required or made advisable an extension of the operation. And even if the shock of the operation rendered the patient unconscious, immediate members of his family were usually available. Hence the courts formulated the rule that any extension of the operation by the physician without the consent of the patient or someone authorized to speak for him constituted a battery or trespass upon the person of the patient for which the physician was liable in damages.

However, now that hospitals are available to most people in need of major surgery; anesthesia is in common use. . . More and more courts are beginning to realize that ordinarily a surgeon is employed to remedy conditions without any express limitation on his authority with respect thereto, and that in view of these conditions which make consent impractical, it is unreasonable to hold the physician to the exact operation—particularly when it is internal—that his preliminary examination indicated was necessary. We know that now complete diagnosis of an internal ailment is not effectuated until after the patient is under the influence of the anesthetic and the incision has been made.⁷

When the patient is unconscious, and has not consented to such treatment, does hyperbaric therapy come within the purview of any consent that may have been given by the patient before his treatment? Cases in point are extremely few. However, there may be authority for the use of hybaroxia in the immediately postoperative period. The courts usually have held that consent for an operation has authorized a surgeon to take such additional steps as were necessary to repair or to correct conditions caused by the surgery.⁸ Admittedly, this is an extensive elaboration upon the original holdings of these cases, yet the principle at law remains identical.

In addition, it is generally recognized that emergency conditions in which immediate action is necessary for the protection

⁷ *Ibid*; see also: *Jackovich v. Yocom*, *supra*, n. 6; *King v. Carney*, 85 Okla. 62, 204 P. 270, 26 A. L. R. 1032 (1922); *Barnett v. Bachrach*, 34 A. 2d 626 (D. C. Mun. App. 1943); *Bennan v. Parsonet*, 83 N. J. L. 20, 83 A. 948 (1912); *Baxter v. Snow*, 78 Utah 217, 2 P. 2d 257 (1931).

⁸ *Preton v. Hubbel*, 87 Cal. App. 2d 53, 196 P. 2d 113 (1948): "The Law should encourage self reliant surgeons to whom patients may safely entrust their bodies and not men who may be tempted to shirk duty for fear of a law suit, and a surgeon is not required to perform every operation according to plans and specification approved in advance by the patient and carefully tucked away in an office safe for court room purposes"; *Higley v. Jeffrey*, 44 Wyo. 37, 8 P. 2d 96 (1932); *Barnett v. Bachrach*, *supra*, n. 6; *Kennedy v. Parrott*, *supra*, n. 6.

of life may justify an implication of consent to medical and surgical treatment where it is impractical to obtain actual consent from the patient or one authorized to consent for him. This principle has been applied to the situation where there is actual consent to treatment in some form, and in the course of such treatment the physician or surgeon is faced with unanticipated emergency conditions threatening the patient's life or health.⁹

Permission to place the patient in the hyperbaric chamber for the treatment of an emergency condition is implied. In modern case law, one can find adequate authority for the proposition that in the dire emergency, consent to treatment is implied.

Thus, we find the gradual changing of the old rule concerning consent, and a relaxation of the stultifying provisions, all brought about by the ever-increasing pace of medical and scientific programs. Today it may be stated that while consent to a surgical procedure must be given by the patient, once given such consent may be enlarged to include new and approved diagnostic and therapeutic medical technics. The case law is following the philosophy, as embodied in the ancient Latin maxim: *Ratio est legis anima; mutata legis ratione mutatur et lex*. (Reason is the soul of the law; the reason of the law being changed, the law is also changed.)

When the hyperbaric chamber is to be used as the primary course or mode of treatment, express consent of the patient must be secured. When the use of increased ambient pressures is used secondarily or incidental in the course of treatment, the necessity of express consent becomes less absolute when the patient is aware of such possible treatment. Whenever possible, however, the physician should inform the patient or the patient's relatives of the possible or contemplated use of the new facility and secure permission to use it.

Thus, we find authority for the use of hybaroxia in these situations: (1) where the patient expressly consents, (2) where the patient impliedly consents, (3) where the patient consents to a surgical operation and hybaroxia is necessary or may be necessary as an extension, (4) where the patient is unconscious and his condition requires the immediate use of such a therapeutic facility.

⁹ Mohr v. Williams, *supra*, n. 6; see also, 56 A. L. R. 2d 699 (1957); Valdiz v. Percy, 35 Cal. App. 2d 485, 96 P. 2d 142 (1939); Tabor v. Scobee, 254 S. W. 2d 474 (Ky. 1951); Hively v. Higgs, 120 Ore. 588, 253 P. 363, 53 A. L. R. 1052 (1927); Bennan v. Parsonnet, 83 N. J. L. 20, 83 A. 948 (1912).

Informed Consent

Recently, the doctrine of informed consent has been introduced into the medical malpractice action. By virtue of this doctrine, the physician is required to outline to the patient and/or the family the risks of the proposed treatment. This duty is an elaboration of the common law requirement of a negligence action, *i.e.*, the duty to exercise reasonable care and skill in the treatment of the patient. Ordinarily, the plaintiff, in a malpractice action, must plead and prove (1) the duty of care of the physician, (2) the breach of the duty of care, (3) that the breach of duty was the proximate cause of the injury, and (4) the damages. The duty to exercise care and skill is defined as that degree of care and skill exercised by the reasonable prudent physician in the same or similar locality. In cases involving informed consent, the courts have stated that a physician must explain to the patient the suggested treatment. In this short series of cases of informed consent the exercise of *ordinary care* has been determined to include an explanation of a method of treatment that, under the particular fact situation, requires such detailed description because of: (1) the methods inherent hazards, and/or, (2) its use constitutes the innovation of the method or technic into the treatment of a certain disease or dysfunction, and/or, (3) the experimental nature of the method of therapy, and, (4) the decision of the patient of an established method of therapy vis-a-vis the new experiment and hazardous method of therapy recommended.

In a review of the cases applying this doctrine, it becomes evident that the doctrine is reserved, or should be reserved, for cases involving new and hazardous technics.

In our opinion the proper rule of law to determine whether a patient has given an intelligent consent to a proposed form of treatment by a physician compels disclosure by the physician in order to insure that an informed consent of the patient is obtained. The duty of the physician to disclose, however, is limited to those disclosures which a reasonable medical practitioner would make under the same or similar circumstances. How the physician may best discharge his obligation to the patient *in this difficult situation involves primarily a question of medical judgment.* [Italics not in original publication.] So long as the disclosure is sufficient to insure an informed consent, the physician's choice of plausible courses should not be called into question if it appears, all circumstances considered, that the physician was moti-

vated only by the patient's best therapeutic interest and he proceeded as competent medical men would have done in a similar situation.¹⁰

In this same case the Supreme Court of the State of Kansas in clarifying its former opinion stated ". . . that the patient was entitled to a reasonable disclosure by the radiologist so that she could intelligently decide whether to take the cobalt irradiation treatment and assume the risks inherent therein, or, in the alternative, to decline this form of precautionary treatment and to take a chance that the cancerous condition in her left breast had not spread beyond the lesion which had been removed by surgery."¹¹

Thus, we find that the application of the doctrine of informed consent, in this case, was limited. Cobalt-60 teletherapy was a new technic to medical practice. Few patients had ever heard of such equipment or treatment. In addition, inherent in this technic were many hazards. The doctrine of informed consent was limited (1) to the application of new and hazardous technics and, (2) to the patient who must elect: (a) whether to undergo the new and hazardous treatment, or, (b) to decline the treatment and to take the chance that other more conservative and tried therapeutic technics would suffice.

The use of the hyperbaric chamber as a method of therapy fits precisely within the limitations of the doctrine of informed consent. Hybaroxia is a new technic being introduced into the practice of medicine, though the use of the principle is centuries old. Although considerable basic research has been carried on in the hyperbaric chamber, and although considerable clinical

¹⁰ *Natanson v. Kline*, 186 Kan. 393, 350 P. 2d 1093, 187 Kan. 186, 354 P. 2d 670 (1960); see also, *Hunter v. Burroughs*, 123 Va. 113, 96 S. E. 360 (1918); *Mitchell v. Robinson*, 334 S. W. 2d 11 (Mo. 1960); *Steele v. Woods*, 327 S. W. 2d 187 (Mo. 1959).

¹¹ *Natanson v. Kline*, *supra*, n. 10.

(Note: In this case a woman, suffering from cancer of the breast, had a radical left mastectomy performed, and then employed a radiologist to administer radiation therapy. Before treating the patient with radioactive cobalt the radiologist made an explanation of the risks involved. There was no immediate emergency at the time the treatment was administered, and the woman suffered injuries because of the treatment. The court held that the patient was entitled to a reasonable disclosure by the radiologist so that she could decide whether to take the cobalt irradiation treatment and assume the risks, or to decline this precautionary treatment and take a chance that the cancerous condition in her left breast had not spread beyond the lesion which had been removed. When the radiologist gave his patient no explanation whatever, on this state of the record, he failed in his legal duty to make a reasonable disclosure to her as a matter of law.)

research has been or will in the near future, be carried on in the hyperbaric chamber (whereby humans will be subjected to these conditions), in the minds of some authorities, the therapeutic advantages may be questionable. Still others, less familiar with the modern facilities, believe that the risk involved in therapy far outweighs the therapeutic advantages. Caution must be exercised, therefore, even in the discriminate use of the hyperbaric facility, particularly where hybaroxia is of limited or questionable advantage.

The public is familiar with situations similar to the physical forces involved in hybaroxia. Popular publications frequently contain elaborate discussions of skin diving and scuba diving. Many persons are acquainted with such terms as "bends," "rapture of the deep," and "caisson disease," though it is questionable whether this popular knowledge may be transferred to and related with the patient who is about to undergo hyperbaric treatment.

Therefore, outside of emergency situations, treatment in a hyperbaric facility must be discussed with the patient or the relatives. The nature of the chambers should be explained, the reasons why such therapy is advised, and some of its dangers. Sufficient information should be given, so that the patient's decision can be based upon a rational and comprehensive knowledge of the risks involved. It is recommended, therefore, that in the use of the hyperbaric chamber the patient and/or his nearest relative sign a consent that grants to the physician and to the hospital permission to utilize this method of therapy upon the person of the patient. The following form is suggested:

Hyperbaric Chamber Therapy (Consent Form)

This is to acknowledge and certify that Dr. (full name) has explained to me the nature of the condition or disease from which I suffer and, has outlined to me the usual methods of treatment. In addition, Doctor (last name) has suggested to me the possible advantages of treating this condition or disease by the use of increased air pressure and that this treatment is possible only within the hyperbaric chamber.

I, understand fully: (1) that the Hyperbaric Chamber is a large steel tank in which the air pressure can be increased to 45 pounds per square inch; (2) that I will be placed within this chamber in the care of competent nurses and/or physicians; (3) that all reasonable care and skill will be exercised in the operation of the facility; (4) that due to the use

of increased pressures that I am exposed to certain hazards such as:

- (a) increased risk of fire;
- (b) pain in the sinuses, ears, bones, teeth (due to the trapping of air while being compressed);
- (c) possible entrapment of air in the lungs upon decompression;
- (d) possible bubble formation in the blood and/or tissues upon decompression;
- (e) the toxic effects of nitrogen and oxygen under increased pressures.

However, in consideration of the possible benefits to be derived by myself in the treatment of the disease or condition from which I suffer, I hereby authorize and instruct Doctor (last name) and/or his associates to carry out this new and potentially dangerous form of therapy upon me.

Witness

Patient

Spouse or Relative

Witness

Relative

Some case reports suggest that a physician is under no duty to warn his patient of possible harmful effects of the treatment when he has reason to believe that the health of the patient will be adversely affected by such warning. However, it would be hazardous for the physician, contemplating the use of the hyperbaric chamber, to apply such a rule of law in the use of the latter facility.¹² It is a recognized exception to the rule of informed consent that the patient need not be informed of the added risk of the new and hazardous method of therapy when, in the judgment of the treating physician, such disclosure is not in the best interest of the patient.¹³

¹² Govin v. Hunter, 374 P. 2d 421 (Wyo. 1962).

¹³ Salgo v. Leland Stanford Jr. University, 154 Cal. App. 2d 560, 317 P. 2d 170 (1957): "A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment. Likewise the physician may not minimize the known dangers of a procedure or operation in order to induce his patient's consent. At the same time, the physician must place the welfare of his patient above all else and this very fact places him in a position in which he sometimes must choose between

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It is sometimes said that, when qualified physicians serving in the same or similar localities do not as a rule disclose the possibilities of danger to the patient, such consent and explanation is not necessary. Because of the recent decisions involving the necessity of disclosure of dangers to new and hazardous technics in the treatment of patients, this rule might not be applicable to such situations.¹⁴

The Supreme Court of Kansas stated:

... Anglo-American law starts with the promise of thorough-going self-determination; each man is considered to be master of his own body and he may, if of sound mind, expressly prohibit the performance of life-saving surgery, or other medical treatment, and while a doctor might well believe that an operation or form of treatment is desirable or necessary, the law does not permit him to substitute his own judgment for that of the patient by any form of artifice or deception.

It follows, therefore, that under ordinary circumstances a physician must acquaint his patient or someone properly acting for him of the diagnosis or treatment proposed and, having obtained the approval of his patient, must then proceed in accordance with proper and reasonable medical standards and with due care.¹⁵

Liability of the Physician for Malpractice

After the patient consents to a method of treatment, the physician owes the continuing duty to exercise reasonable care and skill. Moreover, the patient assumes the risks that are in-

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two alternative courses of action. One is to explain to the patient every risk attendant upon any surgical procedure or operation, no matter how remote; this may well result in alarming a patient who is already and duly apprehensive and who may as a result refuse to undertake surgery in which there is in fact minimal risk; it may also result in actually increasing the risk by reason of the physiologic results of the apprehension of itself." The others recognized that each patient presents a separate problem, that the patient's mental and emotional condition is important and in certain cases may be crucial, and that in discussing the element of risk a certain amount of discretion must be employed consistent with full disclosure of facts necessary to an informed consent. See also, *Mitchell v. Robinson*, *supra*, n. 10.

¹⁴ 79 A. L. R. 1028 2d (1961).

¹⁵ *Natanson v. Kline*, *supra*, n. 10. See also: *Roberts v. Woods*, 206 F. Supp. 579 (S. D. Ala. 1962). (Physician was not liable to the person for failing to advise her of all hazards involved in thyroidectomy, where patient's emotional state and concern over operation, as well as another operation to be

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herent in this method of therapy. However, the patient does not assume the risk of treatment that is performed negligently by the physician.

It is incumbent upon the plaintiff, in a malpractice action, to plead and to prove (1) the standard of care of other physicians within the same or similar locality and in the same or similar circumstances; (2) the breach of the standard of care, or, that the act complained of did not fit within the standards of care and skill as set down by the other physicians within the same or similar community; (3) that the negligent act was the proximate or direct cause of the damage that the patient suffered.

The defendant's conduct in a particular case is a pure question of fact. How he should have conducted himself is a pure question of law. But because the law has not undertaken to define exactly and specifically what a person should do in all possible circumstances, the question of what conduct amounts to due care in a particular case, and the question of whether the defendant's conduct does or does not equal such conduct, are usually not separated. The question of negligence, therefore, is a mixed question of fact and law.

It has long been settled that a defendant will not be held liable for consequences which are so far removed from the chain of causation that the causal connection becomes merely conjectural. Such consequences are called remote, in counterdistinction to near, or proximate, consequences. However, the defendant is *prima facie* liable at least for consequences which might have been foreseen by a prudent reasonable man in the position of the defendant, and a rule of legal cause holds him liable only for such consequences.

Therefore, in regard to a hyperbaric chamber, it is incumbent upon the institution and the physicians in charge of such or a similar facility to have established a standard of procedure.

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performed at the same time, would have made full disclosure detrimental); *Williams v. Menahan*, 191 Kan. 6, 379 P. 2d 292 (1963). (Doctor has no obligation to describe in detail all possible consequences of treatment, since to make complete disclosure of all facts, diagnoses, and alternatives or possibilities could so alarm patient that it would constitute bad medical practice); *Woods v. Brumlap*, 71 N. M. 221, 377 P. 2d 520 (1962). (Exception to the rule regarding disclosure of dangers of treatment in an emergency while the patient is in no condition to determine for himself, or where explanation of every risk may result in alarming a patient who is already apprehensive and who may refuse treatment in which there is minimal risk, which may be increased by disclosure).

Such standard should take into consideration the strict rules concerning compression, duration of compression, conduct within the hyperbaric area, preparation of supplies for use in the hyperbaric area, maintenance in care of the hyperbaric facility and regulations for operation of the hyperbaric facility. In the preparation of such standard operating procedures, many excellent sources are available.¹⁶

Standard Operating Procedure

The properly prepared Standard Operating Procedure should anticipate all possible complications of increased ambient pressure.¹⁷ First of all, personnel must be certified for employment within this facility only after a complete physical examination including, but not limited to, hematologic studies and radiologic examinations of lungs and long bones. Routine periodic qualifying reexaminations must be a prerequisite for continuing employment. The prospective patient to undergo hybaroxia should be screened before admission to the hyperbaric chamber by having a complete medical history taken and a physical examination as well as preliminary roentgenograms of the chest and the long bones performed. The patient who presents the possibility of having trapped air within the lungs may suffer serious complications upon decompression. This complication serves to illustrate and to bring into proper focus the absolute necessity for adherence by the entire staff and personnel to the standard decompression tables as set down either in the *United States Navy Diving Manual* or those contained in the *New York State Regulations Concerning Work in Compressed Air*.

The effects of increasing barometric pressure may cause injury to the body because of the inability to equalize pressure between a closed air space and the ambient atmosphere.¹⁸ If an

¹⁶ U. S. Navy Diving Manual 1959, Navy Department of Washington, Navships 250-538; Submarine Medicine Practice, Bureau of Naval Personnel 1956, U. S. Government Printing Office, Washington 25, D. C.; Proceedings Second Symposium on Underwater Physiology 1963, National Academy of Sciences, National Research Council, Publication 1181, Washington, D. C.

¹⁷ Alt, F.: Pathologie der Luftdruckerkrankungen des Gehoerorgans, Verh. dtsh. Otol. Ges. 1897 6:49-61; Smith, Andrew H.: The effects of high atmospheric pressure, including the caisson disease (Brooklyn, Eagle Print, 1873); Friedrich, W., and Tauszk, F.: Die Erkrankung der Caisson arbeiter Wien, Klin. Rdsch. 10:233-235; 249-250; 267-268, 287-288; 323-324 (1896); Philip, M.: Des accidents aureculaires chez les travailleurs des Caissons. Gaz. heb. Sci. Med., 28:206-212 (1907).

¹⁸ Requarth, W. H. and Benson, R. E.: Compressed air illness with special reference to the middle ear, 9 Industrial Medicine 115 (1940); Almour, R.: The "blocked ear" of the caisson worker, 52 Laryngoscope 75 (1942).

air space within the body has a rigid or semirigid wall, it must be equalized by the free entry of air.¹⁹ Measures to prevent or to treat the conditions known as aerotitis media and sinusitis should be outlined. The question of consent for myringotomy arises, particularly in the unconscious patient. The prepressure myringotomy might be an assault upon a patient where a healthy portion of his body is operated upon to try to prevent a complication of the method of therapy.

Decompression Effects

Personnel operating the facility must be familiar with the diagnosis and treatment of decompression complications as (1) the bends, (2) pulmonary (chokes), (3) integumental, (4) central nervous system, (5) eye, (6) ear, (7) bone and joint involvement.

Inasmuch as the physician places the patient in a position of jeopardy, it is incumbent on him to have adequate facilities available to treat the complications of decompression. A recompression chamber capable of being pressurized to 90 p.s.i. must be immediately available.²⁰ In the event that a patient dies within the hyperbaric chamber or immediately after hybaroxic therapy, an autopsy should be performed if at all possible. When consent is not obtained from relatives, statutory authority, when available, may be invoked.

Res Ipsa Loquitur (The Matter Speaks for Itself)

To establish a prima facie case (or, to get the case to the jury) without the testimony of a medical expert, one may resort to the procedural effects of the rule of *res ipsa loquitur*, *informed consent* or *common knowledge*. When applied to a malpractice action, these procedural devices allow an inference at law to be created which requires consideration by the jury. Seldom have courts permitted the application of these procedural technics to medical malpractice actions. However, there is a trend in recent years, to liberalize former positions of the court. The increasing use of *res ipsa loquitur* exemplifies the growing recognition of

¹⁹ Haines, H. L.: Aero-otitis media in submarine personnel, 17 J. Acoust. Soc. Amer. 136 (1945); Harris, J. D.: Auditory acuity in severe aero-otitis media, 17 J. Acoust. Soc. Amer. 139 (1945).

²⁰ U. S. Navy Diving Manual, *supra*, n. 16.

the courts of special situations that arise from the particular relationship of patient and physician.²¹

The facts of the occurrence alone are sufficient to present a prima facie case . . . the results may be of such a character as to warrant the inference of want of care . . . *in the light of the knowledge and experience of the jurors themselves.*²²

This, unfortunately, is the trend of judicial philosophy in several jurisdictions today. In these areas, the courts have become more acutely aware of the need to protect an injured patient by inducing the physician to explain the reason for the injury or suffer the penalty of an adverse inference in the absence of such explanation. Contrariwise, many conservative jurisdictions limit the application of *res ipsa loquitur*.

A doctor's constant contact is with the frailties, idiosyncrasies, physical and mental weakness, and allergies of human nature. They may affect the condition, and yet are beyond his control.²³

The doctrine of *res ipsa loquitur* has been applied in malpractice cases where there have been injuries to healthy or hitherto unaffected areas of the patient's body occurring during the course of medical treatments.²⁴ However, the law regarding these injuries is not entirely clear.

The majority of jurisdictions apply the doctrine where the injury was of unusual character and where laymen could say it would not have occurred if due care been exercised. The doctrine has been applied particularly in instances where the patient was unconscious.

In some instances involving injuries to a patient from the use of a mechanical device under the management or control of the physician or surgeon it has been recognized that the occurrence or the injury raises a presumption or inference of negligence on the part of the defendant, or, renders the doctrine of *res ipsa loquitur* applicable. However, the conditions requisite for the application for the doctrine of *res ipsa loquitur* are (1) the accident must be of a kind that ordinarily does not occur in

²¹ *Cho v. Kemplar*, 177 Cal. App. 2d 342, 76 A. L. R. 2d 774 (1960); *Ybarra v. Spangard*, 25 Cal. 2d 486, 154 P. 2d 687, (1944); 93 Cal. 2d 43, 208 P. 2d 445 (1949).

²² *Cho v. Kemplar*, *supra*, n. 21.

²³ *Morgensen v. Hicks, et al.*, 110 N. W. 2d 563 (Iowa 1961).

²⁴ *Ybarra v. Spangard*, *supra*, n. 21.

the absence of someone's negligence, (2) it must be caused by an agency or instrumentality within the exclusive control of the defendant, and (3) it must not have been due to any voluntary action or contribution on the part of the plaintiff.²⁵

Most laymen who are familiar with scuba diving or underwater construction work can appreciate the hazards inherent in a hyperbaric chamber. The very thought of enclosing a patient in a steel tank and increasing the pressure within the tank might lay very heavily on a juror who suffers from claustrophobia. Should the plaintiff's attorney use the leverage of the doctrine of *res ipsa loquitur* or the doctrine of common knowledge to get his case to such a juror, the outcome of the decision might depend wholly upon such a juror's vote.

In addition, the plaintiff's attorney may classify the use of the hyperbaric chamber as an experimental method of treatment. This introduces into an already complex legal picture the still unsettled question of clinical research. According to the basic law of negligence, it is the duty of the treating physician to use that degree of skill and care, and therefore methods and techniques, as would a reasonable prudent practitioner use in the same specialty and in the same community under the same or similar circumstances.²⁶ However, this is not interpreted so strictly as to preclude the use of new methods of therapy:

Although it is the duty of a physician or surgeon to keep up with the advancement made by his profession, it is also his duty to refrain from trying experiments on his patients. It is incumbent upon him to conform to the mode established by his school of practice for the treatment of given conditions, and if he departs therefrom he does so at his own peril. Where only one course of treatment would be approved by physicians or ordinary skill, the adoption of any other course may evidence want of ordinary negligence, skill, or care. This does not, however, limit him to the most generally used of several approved modes; and the use of another mode known and approved by the profession is in exercise of proper care. A physician may adopt new methods as they are approved by the profession. This qualification gives to the profession the opportunity to make progress after the experi-

²⁵ *Cavero v. Franklin Gen. Benevolent Society*, 36 Cal. 2d 301, 311, 223 P. 2d 471 (1950); see also *Ybarra v. Spangard*, *supra*, n. 21.

²⁶ *Wasmuth, C. E.: Physician's liability when using new or experimental drugs*, 31 *Cleveland Clinic Quarterly* (April 1964); see also: *Wasmuth, The use of experimental drugs and technics*, 43 *Anesthesia and Analgesia* 2 (1964).

mental stage in the development of a new method is passed, but it does not authorize the trying of untested experiments on patients; and if an experiment is tried on a patient, it is at the financial risk of the physician rather than of the patient.²⁷

Therefore, the law recognizes that medicine is a progressive science. In determining the degree of care and skill which the law exacts of physicians and surgeons, due regard must be paid to the state of the advancement of the science at the time of the treatment. The treatment is to be measured by the standards existing at the time in question and not those that may have existed in the past. Therefore, it may be stated that the physician is not bound to use any particular method of treatment and, if among physicians of ordinary skill and learning, more than one method of treatment is recognized as proper, it is not negligence for a physician to adopt any of the such methods. The fact that some other method of treatment exists or some other physician or surgeon might or would have used or advised another and different treatment does not of itself establish negligence or improper treatment. However, the method followed and adopted if a proper method, the physician must use ordinary skill and care in treating his patient.

Manufacturer's Liability

According to the common law, the manufacturer or seller of a product is liable in a negligence action only to the person who can establish privity of contract. Stated in another way, the seller of a product is responsible for injuries caused by the product only to the person to whom he has sold it.²⁸ However, privity of contract has been disregarded in many cases, and as a result we have several exceptions to the general rule. The first one was the "inherently dangerous product" exception, and, soon to follow, food and drugs were excluded.²⁹ Of more recent origin is the "imminently dangerous product" exception to the privity requirement. Justice Cardozo in the case of *MacPherson v. Buick Motor Car Company* stated:

²⁷ *Miller v. Toles*, 183 Mich. 252, 150 N. W. 118 (1914); see also: *Hodgson v. Bigelow*, 335 Pa. 497, 7 A. 2d 338 (1939).

²⁸ *Winterbottom v. Wright*, 10 M. and W. 109, 152 Eng. Rep. 402 (1842).

²⁹ *Thomas v. Winchester*, 6 N. Y. 397, 57 Am. Dec. 455 (1852).

If the nature of a thing is such that it is reasonably certain to place life and limb in peril when negligently made, it is then a thing of danger. Its nature gives warning of the consequences to be expected. If to the element of danger there is added knowledge that the thing will be used by persons other than the purchaser and used without new tests, then, irrespective of contract, the manufacturer of this thing of danger is under a duty to make it carefully. That is as far as we are required to go for the decision of this case. There must be a knowledge of a danger, not merely possible but probable. It is possible to use almost anything in a way that will make it dangerous if defective. That is not enough to charge the manufacturer with a duty independent of his contract. Whether a thing is dangerous may be sometimes a question for the court and sometimes a question for the jury. There must also be knowledge that in the usual course of events the danger will be shared by others than the buyer. Such knowledge may often be inferred from the nature of the transaction. But it is possible that even knowledge of the danger and of the use will not always be enough. The proximity or remoteness of the relation is a factor to be considered. We are dealing now with the liability of the manufacturer of a finished product, who puts it on the market to be used without inspection by his customers. If he is negligent, where danger is to be foreseen, a liability will follow.³⁰

The "imminently dangerous product" exception is based upon the broad ground that an article, although not inherently dangerous, may become so when put to its intended use. Therefore, the manufacturer or the seller owes to the public a duty to employ reasonable care, skill, and diligence in its manufacture.³¹ Thus, if a product contains a defect that renders it dangerous when applied to its intended use in the usual and customary manner, it has become an imminently dangerous product.³²

There are numerous exceptions to the rule of privity which are well-founded in the law. These exceptions include explosives, poisons, food, drugs, and other inherently dangerous products. There is little in the law concerning the application of the doctrine to medical devices. In this particular situation, medical

³⁰ *MacPherson v. Buick Motor*, 217 N. Y. 382, 111 N. E. 1050, L. R. A. 1916 F. 696 (1916).

³¹ *Gorman v. Murphy Diesel*, 42 Del. 149, 29 A. 2d 145 (1942); see also, *Hunter v. Quality Homes*, 45 Del. 100, 68 A. 2d 620 (1949).

³² *Goullon v. Ford Motor*, 44 F. 2d 310 (6th Cir. 1930); *Borg Warner Corp. v. Heine*, 128 F. 2d 657 (6th Cir. 1942); *Miles v. Chrysler Corp.*, 238 Ala. 359, 191 So. 245 (1939).

equipment is purchased by the hospital or by the physician for use upon a patient. If the patient has been injured by faulty medical equipment, can he reach the manufacturer of the equipment on his implied or expressed warranty? The core of the question is whether the manufacturer or seller may be held liable for injury caused by such a product to one other than the purchaser of the product. It is clear that there can be no recovery for injury caused by medical equipment when the product was not actually harmful or defective at the time when the manufacturer or seller was responsible for it.³³ However, if the manufacturer knew or should have known that the product might cause injury, then the manufacturer has the duty to notify and to advise the physician or the ultimate consumer of these dangerous propensities of the product.³⁴ Thus, we find ample authority to establish that the manufacturer of hyperbaric chambers and equipment are responsible not only to the institutions to whom they sell the equipment but also ultimately to the patient who is treated within the hyperbaric chamber. Should any defective construction be found, liability becomes absolute.

Hyperbaric Chamber Construction

The installation and utilization of the hyperbaric facility for the administration of oxygen to patients under increased atmospheric pressures presents several medical and legal problems.³⁵ Before 1905, boiler explosions had been regarded either as an inevitable evil or "an act of God." In 1908, the State of Ohio passed legislation entitled the *Ohio Board of Boiler Rules*, which was patterned after the Massachusetts statutes.³⁶ Other states

³³ *Nelson v. Swedish Hospital*, 241 Minn. 551, 64 N. W. 2d 38 (1954); *Markulics v. Maico*, 74 Cal. App. 2d 66, 168 P. 2d 35 (1946); *Blissenbach v. Yanko*, 90 Ohio App. 557, 48 Ohio Ops. 203, 107 N. E. 2d 409 (1951); *Smith v. American Cystoscope Makers*, 44 Wash. 2d 202, 266 P. 2d 792 (1954). Contra: *Bowles v. Zimmer Manufacturing Co.*, 277 F. 2d 868, 76 A. L. R. 2d 120 (7th Cir. 1960); *Lindroth v. Walgreen Company*, 407 Ill. 121, 94 N. E. 2d 847 (1950); *Walstrom Optical Co. v. Miller*, 59 S. W. 2d 895 (Tex. 1933); *Orthopedic Equipment Co. v. Eutsler*, 276 F. 2d 455, 79 A. L. R. 2d 390 (4th Cir. 1960).

³⁴ *Harmon v. Plabao Laboratories*, 218 S. W. 701 (Mo. 1920); *LaFrumento v. Kotex Co.*, 131 Misc. 314, 226 N. Y. S. 750 (1928); *Cleary v. John Maris Co.*, 173 Misc. 954, 19 N. Y. S. 2d 38 (1940); *Poriser v. Wappler Electric Co.*, 147 Misc. 317, 260 N. Y. S. 35 (1932).

³⁵ *Wasmuth, Carl E.; Homi, John*, *Hyperbaric Oxygen chambers*, 13 Clev.-Mar. L. R. 436 (Sept. 1964).

³⁶ *Chuse, Robert*: *Unfired Pressure Vessels*, Dodge Corporation (4th ed. 1960).

began to formulate rules and regulations to control the manufacture as well as the operation of boilers. As regulations differed from State to State and often conflicted with one another, manufacturers began to find it difficult to construct vessels for use in one State that would be accepted in another one. Because of this lack of uniformity, an appeal was made in 1911 both by manufacturers and by the users to the Council of the American Society of Mechanical Engineers to correct the situation. After three years of study, the first American Society of Mechanical Engineers *Rules for Construction of Stationary Boilers and for Allowable Working Pressures* was adopted in 1915.³⁷

Subsequently, the boiler manufacturers, with the chief inspectors of the states and cities that had adopted the ASME code, formed the National Board of Boiler and Pressure Vessel Inspectors for the purpose of presenting the ASME code to governing bodies of all states and cities.³⁸ It is now possible for an authorized shop to build a boiler or pressure vessel that will be accepted anywhere in the United States or Canada after it has been inspected by an inspector holding a National Board Commission.³⁹ Therefore, it is customary for users of pressure vessels to order ASME code vessels. This insures that such vessels will be designed, fabricated, and inspected in compliance with a safe standard as well as an accepted standard.⁴⁰ The State of Ohio requires unfired pressure vessels to comply with Section VIII of the ASME code; in addition, however, the shop inspectors must have a commission from the State of Ohio as well as from the National Board.⁴¹

According to the regulations, repair or alteration of ASME code vessels may be made in any shop that manufactures ASME code vessels, or in the field by any welding contractor qualified to make repairs on such vessels. Recognizing the broad application of welding in repair work, The National Board of Boiler and

³⁷ Fish, E. R.; Objectives of the ASME Boiler Code Committee, National Board Bulletin (October 1944).

³⁸ Greene, Arthur M., Jr., History of the ASME Boiler Code (American Society of Mechanical Engineers, 1955).

³⁹ Myers, C. O., The National Board and Its Functions in Jurisdiction and Uniformity. Proceedings of Eighteenth General Meeting (National Board of Boiler and Pressure Vessel Inspectors, 1948).

⁴⁰ Myers, C. O., The National Board Inspection and Stamping, National Board Bulletin (April 1956).

⁴¹ The National Board Inspection Code. The National Board of Boiler and Pressure Vessel Inspectors (1954).

Pressure Vessels Inspectors has approved a set of rules called *The Recommended Rules for Repair of Power Boilers and Unfired Pressure Vessels by Welding*.⁴² These, combined with rules for riveted repairs, are intended to apply only to used vessels and pressure vessels. Many states have adopted these rules as part of their boiler and pressure laws. However, before repairs are made on any ASME code boiler, the method of repair must be approved by an authorized inspector. The inspector will examine the vessel, identify the material to be welded, and compare it with the material to be used in repair. He will then make sure that the welding contractor or shop has a qualified welding procedure for the material being welded, and that the welder who does the job is properly qualified to weld that material.

The operation of a hyperbaric chamber is also subject to the many restrictions set down in city or state regulations relating to ownership, operation, and building of hospitals. In Ohio (Section 2919.18, Ohio Revised Code) the Board of County Commissioners is granted the authority to inspect a public or private hospital within its jurisdiction. Again, under Section 3703.01 of the Revised Code, the Department of Health is directed to inspect all public or private institutions such as sanitariums and hospitals and to condemn all unsanitary or defective plumbing, or order such changes in the method of construction in drainage and ventilation, as well as in arrangement of the plumbing appliances, as are necessary to insure the safety of the public health. However, the Department, by virtue of the same statute, shall not exercise any authority in municipal corporations or other political subdivisions in which ordinances have been passed or resolutions or regulations have been adopted and are being enforced by the proper authorities regulating plumbing or prescribing the character thereof.

Section 4103.06 (Ohio Revised Code) provides that when a person desires to manufacture a special type of boiler, the design of which is not covered by the rules of the Industrial Commission, he shall submit drawings and specifications of such a boiler to the Commission, which may permit its installation. As an example, in several jurisdictions, the code demands adequate ventilation of the operating theaters and prohibits recirculation of air. This one factor may exert considerable influence upon con-

⁴² "The National Board of Boiler and Pressure Vessel Inspector Organizes," *Power* (February 15, 1921).

struction of chambers. In this jurisdiction, it is obvious that one must examine many separate and varied provisions of the state and municipal codes in order to determine whether an intended facility fulfills all statutory requirements.

Hyperbaric Chamber Operation—Hospital Liability

As there are no current statutory or code regulations for the operation of a hyperbaric facility within the hospital, one may look to administrative regulations promulgated by the Department of Labor of the State of New York.

There are bills before Congress to amend the Food, Drug and Cosmetics Act in order, among other things, to assure the safety, efficiency, and reliability of therapeutic, diagnostic, and prosthetic devices. If passed, the Food and Drug Administration will apply to devices the same regulations now prevailing for approval of new drugs.

Under Section 505, manufacturers would have to file an application for the approval of every new product before manufacturing and marketing, stating:

(1) Investigators reports whether device is safe and effective,

(2) Details of construction and principles of operation,

(3) Methods and controls of manufacture,

(4) Samples of the device,

(5) Specimens of labeling.

In effect, HR 6788 and S 2580 which embody these provisions, seek to provide for preview of all new medical devices, and subjects them to the similar screening as new drugs.⁴³

Of interest is the first appeal from a decision of the Food and Drug Administration contesting the supremacy of Article III Section 8 of the "...Commerce among the several states" clause of the United States Constitution over the Fifth Amendment— "...nor be deprived of life, liberty, or property, without due process of law," provision of the Fifth Amendment. This is an effort to strike down the recent amendments to the Pure Food and Drugs Act upon a constitutional challenge. The Industrial Code, Rule No. 22 entitled "Work in Compressed Air" is set

⁴³ Wasmuth, Carl E.: Physician's Liability When Using New or Experimental Drugs, 31 Cleveland Clinic Quarterly 61 (1964).

down by the State of New York, Department of Labor. These regulations delineate the responsibilities of the owner, and regulate the general operation of such pressure facilities, including the work periods, rest periods, and decompression time. These rules also contain special provisions in regard to such matters as regulating the compressors, lighting, fire prevention and first-aid.

In addition, the National Fire Protection Association Committee on Hospitals has codified specifications relative to compressed gases as well as ventilation in the operating room. It is readily apparent that the operation of the hyperbaric facility comes within the purview of many statutes, regulations, and administrative rules dealing with varied aspects of the problem. It is suggested that the Committee on Hospitals of the National Fire Protection Association, or the Hyperbaric Committee of the National Academy of Sciences, set down a model code for the operation and maintenance of hyperbaric facilities. Should any legal action be instituted against a physician or hospital, the evidentiary weight and sufficiency of such a code would be most helpful in defense.