

Medical Mass Screening Programs A Legal Appraisal

Marc A. Franklin

Follow this and additional works at: <http://scholarship.law.cornell.edu/clr>

 Part of the [Law Commons](#)

Recommended Citation

Marc A. Franklin, *Medical Mass Screening Programs A Legal Appraisal*, 47 Cornell L. Rev. 205 (1962)
Available at: <http://scholarship.law.cornell.edu/clr/vol47/iss2/3>

This Article is brought to you for free and open access by the Journals at Scholarship@Cornell Law: A Digital Repository. It has been accepted for inclusion in Cornell Law Review by an authorized administrator of Scholarship@Cornell Law: A Digital Repository. For more information, please contact jmp8@cornell.edu.

MEDICAL MASS SCREENING PROGRAMS: A LEGAL APPRAISAL*

Marc A. Franklin[†]

The lack of understanding between the medical and the legal professions has been a problem for both groups for many years.¹ After considerable effort to create greater understanding of the nature and the problems of each profession, it now appears that some improvement is taking place.² Further frank discussion should do much to hasten this improvement, but the facts on which such understanding can be based change as medical research opens new vistas. This article will consider the recent development of medical mass screening³ in order to acquaint the legal profession with its medical goals and limitations and to alert the medical profession to lurking legal considerations before the lawsuits arise and lead to new misunderstanding.⁴

* This article derives from a study financed by a grant from the Ophthalmological Foundation and the New York Association for the Blind (The Lighthouse). The Ophthalmological Foundation merged with the National Society for the Prevention of Blindness on July 1, 1961. I should also like to express my deep appreciation to Ross S. McConnell, M.D., LL.B., for his valuable assistance with the medical and legal problems raised throughout, and to Michael I. Ginsberg, third year student at the Columbia University School of Law, for his general assistance in the preparation of the original study and this article.

† See contributor's section, masthead p. 248, for biographical data.

¹ One provocative explanation is offered by Louisell & Williams, *Trial of Medical Malpractice Cases* § 1.03 (1960):

The professional education, training, and habits of thought—not to mention techniques and methods—of lawyers and physicians profoundly differ. The modern law curriculum is essentially a continuing Socratic dialogue. Medical instruction is largely didactic and authoritative. . . . The controversial method is the meat of the lawyer not only because he functions in an adversary system but because he has been nurtured in controversy from his first day in law school. The physician on the other hand has been conditioned to objective scientific inquiry and to him notorious contest, with its emotional overtones, is apt to be a disruptive element in the search for facts. While the lawyer typically sees challenge in open disputation, the physician may see in it only unnecessary insult, especially when his own or a brother physician's treatment of a patient is called into question.

These authors also suggest that the everyday experience of the two professions reinforces the difficulty; the attorney is engaged in adversary proceedings, while the physician is the unquestioned authority at his office, clinic, or hospital and is not conditioned to criticism. *Id.* at § 1.04.

² Among other improvements, the development of codes regulating interprofessional conduct and the creation of impartial medical panels to evaluate personal injuries and to testify at trial have helped reduce the antagonism. See generally, Louisell & Williams, *supra* note 1, at Ch. I.

³ The concept of mass screening is discussed in detail and defined in the text following note 10 *infra*.

⁴ As yet, there are no reported cases in the United States involving claims arising out of mass screening programs conducted for the public. The relatively few cases that do exist on the subject of screening have their origins in examinations given only to limited groups. This distinction may be significant. In one case, a hospital in its capacity as prospective employer gave the plaintiff a physical examination including a chest x-ray. The hospital failed to discover an existing tubercular condition and plaintiff's work assignment aggravated his condition. In discussing the relationship between the parties the court said:

Concededly, the hospital examines its employees primarily for its own benefit. This

The traditional physician-patient relationship characterized by personal and extensive consideration of the individual patient's condition⁵ gives rise to legal disputes well-known and understood by both professions. These disputes are usually complicated by disagreement about the specific facts of a case and proof problems, several of which are unique to malpractice cases and which make it more difficult for the plaintiff to prove liability than in ordinary negligence actions.⁶ These protections for the physician aside,⁷ the personal physician-patient relationship may lead to liability for lack of due care in either the diagnosis or treatment aspects of the case, or both.⁸ New diagnosis or

is something the person examined knows, and, hence, although there may be some reliance, it is in some lesser degree than in the case of a regular patient. Thus, whether, as a result of such examination, there is a duty to discover, as well as to disclose, any medical condition requiring treatment may be difficult to resolve. A similar question would arise in connection with entrance or other physical examinations given by many nonhospital employers, educational institutions, governmental organizations and others, where it is primarily the purpose of the examiner that is to be served, rather than that of the person examined.

Battistella v. Society of the N.Y. Hosp., 9 App. Div. 2d 75, 77-78, 191 N.Y.S.2d 626, 629 (1st Dep't 1959). The court then recognized that public mass screenings are for the benefit of the persons examined.

Another difference is that in the employer and other limited screening cases the person usually receives an extensive, albeit cursory, physical examination, whereas, as will be seen, public mass screenings generally stress a single procedure, though sometimes multiple screening procedures are offered to the public at the same time. This one procedure is chosen because it is apt for screening procedures, and not only because it is useful in telling about the physical condition of an individual. For these reasons, the limited screening programs present at best incomplete analogies to the problems discussed in this article.

⁵ The traditional relationship is discussed in detail in *Louisell & Williams*, *supra* note 1, at Ch. II.

⁶ The usual requirement that the plaintiff introduce expert testimony to show the prevailing standard of medical practice in the community and that the defendant failed to meet that standard differs in two ways from the required proof in a non-malpractice negligence case. First, the prevailing medical custom is accepted as the standard to which the defendant must adhere. In ordinary cases, the prevailing custom of persons in positions similar to that of the defendant may be admissible but is not controlling since it may, itself, be negligent. See *Morris*, "Custom and Negligence," 42 *Column. L. Rev.* 1147, 1163 (1942). The second difference is that in all but the most egregious cases of malpractice a lay jury is deemed incompetent to decide whether the physician acted properly without expert testimony to that effect. 2 *Harper & James, Torts* § 17.1, at 968 (1956). Moreover, even with expert testimony in support of his position, plaintiff may not be permitted to have the jury decide the question of malpractice if the defendant shows that plaintiff's expert follows a medical view with which the defendant does not agree, and that defendant's position is accepted by respectable, though minority, medical authority. See, e.g., *Gielskie v. State*, 10 App. Div. 2d 471, 200 N.Y.S.2d 691 (3d Dep't 1960), *aff'd* without opinion, 9 N.Y.2d 834, 175 N.E.2d 455, 216 N.Y.S.2d 85 (1961) and *DiFilippo v. Preston*, — Del. —, 173 A.2d 333 (1961).

⁷ It is not suggested that these additional protections are in any way inappropriate to the case of malpractice. One malpractice judgment against a physician may destroy his livelihood and his reputation, while a judgment against a negligent driver does not generally affect his social or economic status, though the plaintiff suffers the same injuries in both cases. See 2 *Harper & James, Torts* § 17.1, at 969 (1956).

⁸ Some courts have stated that negligence in the diagnostic phase of a relationship can never, without more, be the basis for liability, and that this negligence must be followed by improper treatment causing the injury. See, e.g., *Poor Sisters of St. Francis v. Long*, 190 *Tenn.* 434, 230 S.W.2d 659 (1950); *Huttner v. MacKay*, 48 *Wash.* 2d 378, 293 P.2d 766 (1956). But the cases do not appear to support the stated proposition. These cases may be explained on one of several bases: the plaintiff showed only improper but

treatment procedures affect only the specific fact question of whether in a given case the physician met his obligation.

In recent years, the medical profession has sought to develop means of dealing with disease at earlier stages. The entire field of preventive medicine is premised on the desirability and feasibility of preventing the onset of certain diseases.⁹ Also included are efforts to detect disease in individuals before it has progressed to the point at which the victim is aware of its existence, although this is not strictly prevention but rather control of incipient disease.¹⁰ Mass screening, one phase of this area, is the procedure with which this article is primarily concerned.

Screening has been defined as

the *presumptive identification* of unrecognized disease or defect by the application of tests, examination, or other procedures which can be applied rapidly. Screening tests sort out apparently well persons who probably have a disease from those who probably do not. A screening test is not intended to be diagnostic. Persons with positive or suspicious findings must be referred to their physicians for diagnosis and necessary treatment.¹¹

The essence of screening is its reliance on a single medical procedure to which every screenee is exposed. The specific procedure is selected for its medical effectiveness as a method of detection and the feasibility of its rapid application to numerous persons. There can be only minimal personalization of the routine; screening can be effective only if it relies on predetermined standards of presumptive normalcy that will be accurate for the vast majority of the population. Thus, screening is quite different from the traditional concept of diagnosis. Diagnosis is personalized; the question is what ails the particular patient, and he may undergo several different procedures to find the answer. In screening, on the other hand, one procedure is applied rapidly to many persons. Those whose screening results indicate possible disease are advised to follow the screening with diagnosis and, if necessary, treatment.

not negligent diagnosis (Huttner, *supra*) or even a correct diagnosis would not have helped the plaintiff because the condition could not have been treated (Long, *supra*). In still other cases, the negligence of the diagnosing physician may not have been deemed the proximate cause of the plaintiff's injury, because the negligence of the treating physician was deemed superceding in the particular facts. Cf. *Bugg v. Security Ben. Ass'n*, 153 Kan. 522, 112 P.2d 73 (1941). These cases are all consistent with the general principle that if a negligent diagnosis is shown to have caused injury to a plaintiff, the defendant will be liable. See, e.g., *Smith v. Mallinckrodt Chem. Works*, 212 Mo. App. 158, 251 S.W. 155 (1923) (plaintiff hurt by delay based on negligent diagnosis that he was well); *Greenwood v. Harris*, 362 P.2d 85 (Okla. 1961) (needless operation resulted in scars).

⁹ See Levin, "Screening for Asymptomatic Disease, Principles and Background," 2 J. Chronic Diseases 367 (1955).

¹⁰ Broadly conceived, preventive medicine has two branches: prevention of occurrence of disease and prevention of progression of disease. Hilleboe & Larimore, *Preventive Medicine* 1 (1959).

¹¹ Breslow & Roberts, "Introductory Statement on Screening for Asymptomatic Disease," 2 J. Chronic Diseases 363, 365 (1955). (Emphasis in original.)

Mass screening will certainly not be feasible for every disease. For screening to be successful, the disease must have at least one distinctive sign or symptom detectable very early by a rapid and inexpensive procedure. Mass screening is most valuable when it seeks a disease that may be easily cured or controlled if discovered early, but is severe, incurable, or uncontrollable, if allowed to progress to the stage at which the victim himself is aware of its presence.

Perhaps the most familiar of these public screening programs is the chest x-ray,¹² but they have also been used increasingly in efforts to detect glaucoma,¹³ diabetes,¹⁴ cancer,¹⁵ and other diseases.¹⁶ To clarify much of the following discussion of the legal problems of screening, it will be helpful to explore in some depth a specific disease and its screening program that may serve as a continuous illustration throughout this paper. Glaucoma has been chosen because it presents a readily understandable, though rather complex, example of the medical and legal problems involved.¹⁷

Glaucoma is characterized by an abnormal elevation of the pressure within the eye.¹⁸ Unless this elevation is controlled, a progressive deterioration of tissues essential to vision will occur and will produce irreversible and total blindness. Although there are several types of glaucoma, consideration of the two most common varieties will suffice here. The acute variety of primary glaucoma (also known as closed angle glaucoma) is epitomized by sudden, very painful increases in pressure in the anterior chamber of the eye. The victim is immediately aware that something is wrong and will probably see a physician who will be able to detect and usually control the condition by simple treatment. Thus, acute glaucoma really presents no preventive medicine problem because the victim is aware of the condition early enough to avert serious damage.¹⁹

¹² Although chest x-rays are traditionally associated with tuberculosis screening, they also prove valuable in detecting other chest defects including lung cancer. See Anderson, "The Future of the Miniature Chest X-ray in Screening for Asymptomatic Disease," 2 J. Chronic Diseases 418, 422-25 (1955).

¹³ Foote & Boyce, "Screening for Glaucoma," 2 J. Chronic Diseases 487 (1955); Ryan, "Glaucoma—A New Challenge to Occupational Medicine," 1 Archives of Environmental Health 278 (1960).

¹⁴ Reynolds, "Screening Methods for Diabetes Mellitus," in Hilleboe & Larimore, Preventive Medicine 541 (1959); Wilkerson, "Screening for Diabetes," 2 J. Chronic Diseases 464 (1955).

¹⁵ Levin, "Cancer Detection and Screening," in Hilleboe & Larimore, Preventive Medicine 505 (1959); Dunn, "Screening for Cancer," 2 J. Chronic Diseases 450 (1955).

¹⁶ For the several other conditions for which screening is conducted, see the entire Symposium on Screening for Asymptomatic Disease, 2 J. Chronic Diseases 363-490 (1955).

¹⁷ It is also the medical problem with which I am most familiar. See introductory note, *supra*.

¹⁸ See generally for a discussion of the medical aspects of glaucoma, Sugar, *The Glaucomas*, passim (2d ed. 1957).

¹⁹ Also, acute glaucoma is quantitatively less significant than the chronic variety.

The chronic simple variety of primary glaucoma (also known as wide or normal angle glaucoma), however, is characterized by a very gradual increase in the intraocular pressure that may take ten years or more from onset to the first impairment of vision.²⁰ No sudden pain episodes occur and the victim is unlikely to be aware that he has chronic glaucoma until his vision starts to wane, by which time it may be too late to save much, if any, of it. The disease can generally be held in check when discovered, but since the damage already done is irreparable, early detection is vital. Most important, a rapid, inexpensive medical procedure exists that will detect most of the incipient cases of chronic simple glaucoma and is ideal for mass screening.²¹

The procedure relies upon the fact that elevated pressure characterizes most chronic glaucoma.²² Several instruments, called tonometers, have been developed to measure this pressure by a procedure called tonometry.²³ The traditional tonometer operates on a gravity principle. The person being tested lies on a cot or bed. After a few drops of anesthetic have taken effect,²⁴ the patient is told to look straight up. The tonometer is placed very gently on each eye for an instant and a weight is allowed to rest free on the surface of the cornea. The resistance to the descent of the weight is measured on a scale yielding an approximation of the internal pressure of that eye.

Several factors, however, combine to make accurate measurement difficult. First, there are mechanical problems. The instrument is very delicate and must be held perfectly vertical; it must not be pressed on the eye but allowed to rest freely on the surface. There are also biological problems. If the screenee is nervous and squeezes his eyelids or eye muscles, the measurement will be unduly high. Also, the very act of measuring pressure will cause its own changes in the pressure. The normal person's reaction to the weight of the instrument has been estimated and on that basis professional groups have erected conversion

Acute glaucoma is estimated to constitute only 10 or 15% of the total of the two varieties. See Ryan, "Glaucoma—A New Challenge to Occupational Medicine," 1 Archives of Environmental Health 278 (1960), Glaucoma Program Guide 5 (N.Y. State Dep't of Health, Chronic Diseases & Geriatrics Monograph No. 3, 1959).

²⁰ The ten-year estimate appears in Leydhecker, "The Technique and Organization of Mass Screening for Glaucoma," 51 Am. J. Ophthalmology 248, 249 (1961).

²¹ Because of the much greater incidence of chronic glaucoma among people over 40 than those under 40, most screening programs strive to attract the former population group.

²² This is not true of a variety of chronic glaucoma known as low-tension glaucoma. See text accompanying note 26 *infra*.

²³ Tonometry is discussed in detail in Sugar, *The Glaucomas* Ch. VI (2d ed. 1957).

²⁴ The currently-used anesthetics take effect within 30 seconds and last for 15 to 20 minutes. This leads to a problem that is discussed in the text following note 55 *infra*. All persons receiving eye anesthetics are warned not to rub their eyes for a certain period lest some tissue be rubbed off without the person realizing it.

tables that give meaningful equivalents to the scale readings on the instrument. However, some persons do not react normally to the measuring process. Their reflex action may alter the secretion of fluids in an unusual way or their muscles may become unusually distended or elastic. These persons are said to have atypical scleral rigidity, which will cause inaccurate conversions of their scale readings.

Another impediment to accurate measurement is that one's pressure varies in the course of the day—whether he is normal or has glaucoma. Apparently these cycles, called diurnal fluctuations, are such that a reading in the afternoon or evening may be lower than one taken in the morning. This daily variation is greatest in those who have glaucoma.²⁵ Also, it appears that a large amount of liquid in the body or nervousness of the screenee will raise the measurement to some undetermined extent. However, even if these difficulties did not exist, some fifteen to twenty per cent of the chronic simple glaucoma cases would still not be detected by tonometry because the increased pressures, though abnormal in the victims' body systems, do not reach the danger figure set for the public at large.²⁶

Glaucoma provides a concrete example of the difference between diagnosis and screening. The screening procedure calls only for tonometry. When that test yields positive or suspicious findings, the screenee is referred to a physician for diagnosis. The physician may do several tonometries with different instruments and weights²⁷ and at different times of the day; he may test the patient's visual field to see if there has been any impairment; he may perform several provocative tests—procedures that will induce certain reactions in glaucoma victims but other reactions in people who have not got the disease.²⁸ In other words, the follow-up would conform to the accepted ophthalmological procedure for glaucoma diagnosis.²⁹

Thus informed about the nature of glaucoma and its screening program, we may consider some of the major legal problems inherent in

²⁵ Four different types of diurnal fluctuation have been reported; until recently, it had been thought that the peak was reached only once a day in the morning and that the afternoon and evening yielded lower tensions. The presence of four types, some with double peaks, suggests that the error from this source may be less than originally feared. See Sugar, *supra* note 23, at 177-78.

²⁶ See Sugar, *supra* note 23, at 53.

²⁷ The weight used may be one of three sizes: 5.5 gm, 7.5 gm, or 10 gm. The first two are most commonly used. Atypically high scleral rigidity will have less adverse effect on a measurement done with a heavy (10 gm) weight, but the 10 gm weight is a less accurate one for testing the vast majority with normal scleral rigidity.

²⁸ For a full discussion of diagnostic procedures for glaucoma including discussion of the provocative tests, see Sugar, *supra* note 23, at Ch. XIII.

²⁹ Of course, not every procedure need be done in every diagnosis. The follow-up need be only as complete as original diagnosis would require to confirm or negate the presence of the suspected disease.

mass screening. These fall naturally into three categories: choice of the screening procedure, execution of that procedure, and problems arising from test result notification.

CHOICE OF SCREENING PROCEDURE

The first category involves the problem of choosing a legally permissible screening procedure.³⁰ Since no presently conducted screening program appears so hazardous or contrary to public policy as to be subject to strict liability or to being enjoined, the question is whether the specific procedure proposed is unreasonably dangerous so as to make its use negligent.³¹ The answer to this question requires consideration of three factors: the likelihood of harm caused by the specific activity; the severity of injury if it should occur; and the interests that would be sacrificed if the specific act were not undertaken. The first two of these factors must then be set against the third, balancing the dangers of the specific activity against its benefits to see which outweighs the other.³²

³⁰ This article proceeds upon the assumption that the group doing the screening is not protected from tort liability by any immunity—either governmental, charitable, or based on a valid exculpatory agreement. For a recent state-by-state compilation of the status of governmental and charitable immunity, see Louisell & Williams, *Trial of Medical Malpractice Cases*, Ch. XVII (1960).

It should also be noted that, in the absence of such immunity, it is no defense that the screening program was being conducted without charge to the public. See *Union Carbide & Carbon Corp. v. Stapleton*, 237 F.2d 229 (6th Cir. 1956), in which the jury found that the defendant had given chest x-rays as part of its periodic medical examination of its employees, had found tuberculosis in the plaintiff at numerous times, had noted it on his card, but had failed to inform him of it. The fact that the service was free and did not have to be given at all did not exonerate the defendant from liability so long as the plaintiff could reasonably expect to be told of a discovered defect.

It should also be noted that, although this article is primarily concerned with liability only to screeners for the negligence of the screening group, this may not be the actual limit of liability. In *Wojcik v. Aluminum Co. of America*, 18 Misc. 2d 740, 183 N.Y.S.2d 351 (Sup. Ct. Erie County 1959), the tubercular wife of an employee was held to have an action against her husband's employer under allegations that the defendant negligently failed to inform her husband that his chest x-ray might indicate a tubercular condition. The court considered it reasonably foreseeable that an employee who was not aware of a contagious condition would spread it to his wife.

³¹ As to the situations in which strict liability or injunctions may be invoked against activities, see 2 Harper & James, *Torts* 932-36 (1956). As the following paragraphs in the text demonstrate, tonometry is a most safe procedure.

If all of the risks of a specific procedure are fully and openly announced to potential participants in advance, there would be no liability to these persons for injuries caused by inherent dangers in the procedure. The explanation might be framed in terms of the plaintiff having "assumed the risk." Cf. *Murphy v. Steeplechase Amusement Co.*, 250 N.Y. 479, 166 N.E. 173 (1929). Perhaps a more meaningful expression of the reason for nonliability is that the duty of the defendant can be satisfied not only by making the procedure reasonably safe, but also by fully disclosing the then existing risks in the procedure. Thus, in this sense, it may be said that the defendant is not liable for the injury because it fulfilled its duty of making full disclosure and has, therefore, not been negligent. See 2 Harper & James, *Torts* § 21.2 (1956). The problems of making full advance disclosure of tonometry's dangers are discussed in the text following note 62 infra.

³² See *L. Hand, J., in United States v. Carroll Towing Co.*, 159 F.2d 169 (2d Cir. 1947) and in *Conway v. O'Brien*, 111 F.2d 611 (2d Cir. 1940). See also 2 Harper & James, *supra* note 31.

Taking tonometry as the specific example, how would this balancing procedure operate?³³ Recent medical reports indicate that significant physical injuries are suffered by about two people in every 10,000 screened.³⁴ Almost all of these injuries are probably inherent in the procedure and are not the result of negligence at some later specific step of the execution.³⁵ What other harm may be caused by tonometry screening? One may be that the two to four false positives found in every 100 screenees³⁶ are hurt by having to pay some physician for a complete diagnosis when they did not in fact have glaucoma. They may also be hurt by anxiety incurred by the initial warning that they might be positives. As will be seen later, most of these false positives probably result from the choice of tonometry as the method of screening and are not attributable to specific negligence at a later stage.³⁷ The false negatives, perhaps one in 100 screenees,³⁸ may also be said to be hurt by screening if they are lulled into a false sense of security about their conditions and delay to their detriment in seeking treatment.

³³ Empiric knowledge of the tonometry procedure provides several quantitative yardsticks though, of course, the final balancing is not a matter of mathematics. See, e.g., L. Hand, J., in *Moisan v. Loftus*, 178 F.2d 148 (2d Cir. 1949).

³⁴ This figure is derived from the following reports of anesthetic reactions from tonometry: Screening for Glaucoma (U.S. Pub. Health Serv., Pamphlet No. 666, 1959) reports seven mass glaucoma screenings involving 52,094 screenees. Correspondence has revealed that no more than ten of these people suffered any anesthetic reactions. Another report of a survey of 4,000 screenees reveals no anesthetic reactions. Ryan, "Glaucoma—A New Challenge to Occupational Medicine," 1 *Archives of Environmental Health* 278, 280-84 (1960). Ryan also reports that he had correspondence with leading tonometry experts who reported having done some 175,000-200,000 tonometries with a total of 14 allergic reactions. These totals suggest 24 anesthetic reactions in some 230,000-255,000 tests—a rate of about 1 in 10,000.

The incidence of corneal abrasions was determined as follows: Ryan reported no injuries in his survey of 4,000 screenees. His correspondents who had done the 175,000-200,000 tonometries were said to have reported 16 corneal injuries. Ryan, *supra* at 278. A German source reports ten "erosions" in a survey of 10,000 subjects. Leydhecker, "The Technique and Organization of Mass Screening for Glaucoma," 51 *Am. J. Ophthalmology* 248, 251 (1961). All these figures combine to suggest corneal injury in about 13 cases in 100,000. Combining the anesthetic and the corneal injury figures yields a figure of 23 in 100,000 or 2.3 in 10,000. Correspondence with the major medical malpractice insurers has revealed only one claim for injury alleged to have been caused by tonometry.

All of the reported injuries have been minor. See note 39 *infra*.

³⁵ The fact that tonometry may cause a certain number of injuries not attributable to negligence, and that the procedure is ultimately determined to be a permissible one, does not mean that there will be no liability for negligence at individual steps in the procedure. These possibilities of specific negligence at some points in the procedure are discussed in detail throughout. See 2 Harper & James, *supra* note 31.

³⁶ The latest rate of false positives appears to be about two to each true positive, according to recent experience with New York City screening programs. False positives are explained in detail in the text at note 76 *infra*.

³⁷ See note 35 *supra*.

³⁸ It is estimated that tonometry detects more than half of the screenees who have chronic glaucoma. Thus, for every true positive there is less than one false negative. This is an outside margin of error since tonometry may detect two of every three chronic cases or more depending on the referral standards chosen. See text following note 50, *infra*, and Becker, "Annual Review, Glaucoma 1956-1957," 58 *Archives of Ophthalmology* 862, 896 (1957).

So much for the likelihood of harm. How serious are the injuries likely to be, should they occur? All the reports of physical injuries caused by tonometry suggest that the injuries that do occur are extremely minor, and not one permanent injury of any severity is known.³⁹ The injury caused to the false positives seems trivial except for the possibility of psychic injury due to anxiety. But even this may not be especially serious since the error will probably be discovered as soon as the person sees an ophthalmologist.⁴⁰ The extent of injury to false negatives would be reduced by the warning that they should not rely on the test result for more than two years since the disease may strike at any time. Few persons should suffer more than two years' delay as false negatives—and this is not necessarily a long period in the course of chronic simple glaucoma, which takes ten years to manifest itself.⁴¹

Against these dangers, what benefits does tonometry offer? First, and foremost, it does detect two true positives in every 100 persons over the age of forty who are screened.⁴² This is a high yield and demonstrates the potential value of the program on a long range basis. Lastly, tonometry is presently the only feasible method of mass glaucoma detection. It may well lead to the saving of millions from permanent and total blindness.⁴³ Moreover, any screening program alerts the public to the dangers of a particular disease and also shows how easy it is to avoid its dread consequences. It may well be argued that even the false negatives and false positives have realized a benefit from the screening by virtue of learning of the nature of the disease and of the necessity of the two year retest; they might have known nothing of the disease before the screening program.

Balancing these various factors, it seems that tonometry is a legally permissible procedure; its benefits appear to outweigh its dangers.⁴⁴

³⁹ See Ryan, "Glaucoma—A New Challenge to Occupational Medicine," 1 Archives of Environmental Health 278, 284 (1960). Correspondence with the major medical malpractice insurers disclosed one claim of a minor nature based on physical injury suffered from tonometry. Correspondence also disclosed that the anesthetic reactions reported in the screening of 52,094 persons in note 34 *supra*, were all minor.

⁴⁰ See the full discussion of the problem of false positives in text following note 84 *infra*.

⁴¹ See note 20 *supra* and the full discussion of the problem of false negatives in the text at note 78 *infra*.

⁴² The figure is derived from recent New York City screening experience and has varied between one and two—running closer to two. There is probably some self-selection in any screening program offered to the public. In the case of glaucoma, this is thought to offset the false negatives and leads to the conclusion that some 2% of the population over age 40 has chronic simple glaucoma.

⁴³ It is estimated that in the United States, there are more than 1,000,000 victims of chronic glaucoma, and that glaucoma causes more than 15% of all blindness. David, "Symposium, Community Projects for the Early Detection of Glaucoma," 30 Sight Saving Rev. 4 (1960).

⁴⁴ This is the final judgment that must be made by a court in the light of what a reasonable man in the position of the screening group would have thought at the time

A group undertaking a given procedure that may be justified in itself need not undertake to provide the most elaborate system that money can buy. The only requirement is that what is actually undertaken be reasonably safe when its dangers are compared to its benefits. Under this analysis the tonometry screening program would appear to be a reasonably safe undertaking and is the only way to achieve the desired objective of mass screening.

Assuming that tonometry is a permissible screening method, what type of tonometry should be used? Of the two major types in current private use, applanation tonometry is much more accurate in measuring the intraocular tension than the impression method described earlier, of which the Schiøtz tonometer is by far the most common and representative.⁴⁵ But, when the consideration is feasibility in a mass screening program, applanation tonometry has little to offer. It requires much more expensive equipment;⁴⁶ each test takes longer to perform than with the Schiøtz tonometer;⁴⁷ and it requires more expertly trained personnel. Indeed, it appears that a large scale screening program would not be feasible if the more accurate applanation tonometry were the required method.

It is therefore difficult to imagine that any court would find it negligent to screen with Schiøtz tonometers instead of applanation tonometers—especially since Schiøtz tonometers are far more common even in private offices than are applanation tonometers. A supporting analogy is found in the important *Battistella* case.⁴⁸ There, an employer gave prospective employees a pre-hiring physical examination that included a

the program was undertaken. 2 Harper & James, Torts § 16.9, at 929 (1956). That the particular balancing conclusion is "merely a fiat" and not susceptible to articulation of reasons, see L. Hand J., in *Sinram v. Pennsylvania R.R. Co.*, 61 F.2d 767, 771 (2d Cir. 1932). Facts may change and alter the present balance as to the future. See text at note 55, *infra*.

⁴⁵ Applanation is considered accurate to within one millimeter of mercury. Since normal blood pressure will cause fluctuations in eye tension of about one millimeter, this is the limit of clinical accuracy. On the other hand, Schiøtz tonometry is accurate to within two or three millimeters of mercury for 95.5% of the population and is less accurate for the remaining 4.5%. Sugar, *The Glaucomas* 84-85 (2d ed. 1957); Levene, *Interpretation of Tonometry Readings* 3 (mimeo 1961—on file at the National Society for the Prevention of Blindness). The difference in accuracy between these two measurements is significant because normality and abnormality are so close numerically. One authority states that a reading of 24 millimeters is suspicious, while 25 is usually pathologic. Presumably, 22 or 23 would be normal. See Sugar, *supra*, at 177.

⁴⁶ The applanation instrument itself costs about \$300. But it must be used with a slit lamp that costs about \$1500. The slit lamp is useful for many other procedures in a private practitioner's office but would have no other uses in a screening program. Schiøtz instruments cost about \$60 each and require no other equipment.

⁴⁷ It takes at least five minutes for applanation tonometry against less than two minutes for Schiøtz tonometry. See statement of Dr. Kaplan in "Symposium, Community Projects for the Early Detection of Glaucoma," 30 *Sight Saving Rev.* 4, 20 (1960).

⁴⁸ *Battistella v. Society of the N.Y. Hosp.*, 9 App. Div. 2d 75, 191 N.Y.S.2d 626 (1st Dep't 1959).

chest x-ray. The 3-1/2" × 4-1/2" picture was the standard size used in mass chest surveys. The two readers of the film did not spot a tubercular indication, and the plaintiff was put to work on a job that aggravated his condition. He sued his employer for negligence in failing to tell him that he had tuberculosis and in assigning him to the aggravating job. It was admitted that the spot might well have been detected had a larger picture been made, such as the common 14" × 17" private office size. Economic considerations apparently rule out use of the large size for mass testing. Although the court did not discuss the use of small-sized x-ray pictures, the opinion shows an awareness of the practical problems of mass screening and indicates that the court would not require the same protections for the plaintiff that it would require for a private patient in the traditional physician-patient relationship.⁴⁹ Yet, it is very likely that a private physician who relief for diagnosis on his reading of one small-sized x-ray picture would be deemed negligent for not using larger-sized film or not taking more pictures from different angles.⁵⁰ It is even clearer that Schiotz tonometry, which is apparently the private patient standard, would be proper in mass screening.

Another problem of some forms of screening is the establishment of the quantitative standard for determining which screenees should be referred to ophthalmologists for further study. In tuberculosis x-rays a quantitative standard is not used because referrals are determined by visual inspection of individual x-rays—usually by two readers.⁵¹ If anything looks suspicious, no matter how small, referral is made. But with tonometry, numbers tell the story. The danger level has been determined empirically and is subject to change as new data alter earlier ideas of presumptive normality.⁵² If the referral figure is set

⁴⁹ This position is not based on the fact that the screening in the case was given by an employer for his own benefit. See note 4 supra. The court suggests that even in a public screening that is conducted for the benefit of the persons being examined, "it is doubtful that the same grade of skilled technician would be required as in the case of the private consultation at patient's request." *Battistella v. Society of the N.Y. Hosp.*, supra note 48, at 78, 191 N.Y.S.2d at 630.

⁵⁰ There is a strong admonition against reliance on small-sized pictures in Diagnostic Standards 32 (Nat'l Tuberculosis Ass'n 1950).

⁵¹ See Diagnostic Standards 28 (Nat'l Tuberculosis Ass'n 1950), in which it is suggested that tuberculosis screening programs use two readers for each x-ray or that the same reader look at each picture twice with an interval of time between. Another source suggests there is as much as 30% variation among different readers interpreting the same film, and also recommends two readers. Shultz, "Screening Methods for Pulmonary Tuberculosis," in Hilleboe & Larimore, *Preventive Medicine* 521, 528 (1959).

⁵² In 1957, Sugar suggested 24 millimeters as suspicious. See note 45, supra. A recent study suggests 21 millimeters as the upper limit of normality. Levene, *Interpretation of Tonometry Readings* 6 (mimeo 1961—on file at the National Society for the Prevention of Blindness).

Relative referral standards are utilized along with the absolute standards. Thus, if the screenee's tensions in the two eyes are more than four millimeters apart, he should be referred no matter how low both readings are in absolute terms. See Sugar, *The Glaucomas* 177 (2d ed. 1957).

too high, the result will be more false negatives; if set too low the result will be more false positives. Although referral standards are a serious practical problem, they cannot be discussed meaningfully without an extended statistical presentation that would be inappropriate in this general survey of problems.

EXECUTION OF SCREENING PROCEDURE

The second source of problems is the actual execution of the procedure. In the original choice of the procedure safety and effectiveness were major considerations. If chest x-rays were unreasonably dangerous because of excessive radiation, there might be negligence in the choice of that screening method. Similarly, if the safest anesthetic used in tonometry injured an inordinately large number of people, this might make the choice of tonometry negligent when viewed against the benefits it offered. However, even a decision that the method chosen is reasonably safe does not preclude liability in its application. Every procedure, no matter how safe, has its possible danger spots. The blood sampling in diabetes testing may lead to infection; the tonometer may scratch the eye. But these possibilities of physical injury present few questions that are unique to screening and not present in the physician-patient relationship as it is traditionally conceived.⁵³

A problem that is unique to screening is the increased possibility of starting an epidemic in the community. When the tonometer touches the eye of a screenee it may pick up a virus or other germ and pass it on to future screenees unless precautions are taken. This raises the question of whether the tonometers must be sterilized before each use or whether cleansing is sufficient. Cleansing will remove some foreign matter but will not kill viruses or other highly resistant micro-organisms.

Sterilization is obviously the most desirable possible procedure, but it has its drawbacks. First, it takes a long time, which means that each screening program will need many additional tonometers. Secondly, the sterilization process generally involves intense heat, and there is the danger that a hot tonometer may be put on an eye, causing greater injury than would the virus that might be conveyed. Further, in the time required to cool the heated tonometer sufficiently to be placed on the eye, some new foreign bodies may infect the instrument. Sterilization

⁵³ The physical injuries that may be suffered at the test by screenees are essentially the same as those that might be suffered by patients in a private physician's office; anesthetic reaction and corneal abrasion. However, the fact that a person of lower skill may perform the actual tests at a screening program may increase the likelihood of injury and raise new liability questions. See text following note 67 *infra*.

methods other than heat are quite expensive in terms of equipment and take even longer to operate.

But doing nothing more than cleansing is not so serious as it might appear. First, the eye has its own defense mechanisms, including tears, that fight infection. Second, if contagious eye disease is present in the community no testing is done. Third, even though there is the theoretical risk of spreading a virus disease through tonometry, the experience of recent mass screening programs suggests that the risk is greatly over-rated.⁵⁴

It may well be that balancing the likelihood of harm and the severity of harm, if it occurs (discomfort but no permanent damage likely), against the utility of relying on cleansing, a court might find no negligence in the failure to sterilize—at least until the first reported epidemic. After the first epidemic, if one should occur, the balance may very well shift since the frequency of injury and, perhaps, potential severity may then appear higher than at present.⁵⁵

The fact that the anesthetic takes fifteen to twenty minutes to lose its effect raises another problem of execution that is more serious in a screening context than in a private patient relationship. The danger here is that after the screenee leaves the screening center a foreign body may enter his eye and cause some damage without his being aware of it. In a private consultation the ophthalmologist can usually adjust for this by doing other procedures after using the anesthetic so that it will have time to wear off while the patient is still in the office. In a screening program that combines tests for several diseases at the same time, the glaucoma test could be done first so that the screenees would be inside the building until the anesthetic wore off. In the case of a screening program limited to tonometry, however, the problem of what to do with the screenees before the anesthetic wears off is a serious one. Presumably, the screening group would fulfill its obligation of due care and be acting in the most practical manner by warning screenees of the risk of foreign bodies entering their eyes and then by providing a place for them to wait for the anesthetic to wear off if they so desire.

At this point we might consider some recent cases that have found liability against physicians for mishaps that were not shown to be

⁵⁴ Seven mass screening programs involving over 52,000 people did not cause any epidemics although no tonometers were sterilized. See *Screening for Glaucoma* (U.S. Pub. Health Serv., Publication No. 666, 1959). Similarly, Ryan did tonometry on 4,100 factory workers without sterilization and did not report any trouble. Ryan, "Glaucoma—A New Challenge to Occupational Medicine," 1 *Archives of Environmental Health*, 278, 281 (1960). No such epidemic is known to have occurred anywhere.

⁵⁵ See the text following note 31, *supra*, for a discussion of the balancing process in another context.

due in any way to the physician's negligence in choosing or applying the procedure.⁵⁶ Liability was based on the fact that the physician had not enabled the patient to make a decision about proposed treatment with full knowledge of the procedure's inherent risks as well as its benefits. There was a significant possibility in each case that had such warnings been given, the patient would not have consented to the treatment and would not have suffered the alleged injury.⁵⁷ This does not mean that that every conceivable risk must be disclosed in advance of every medical procedure. The proper approach is suggested by one court as follows:

[T]he 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 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 unduly 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 risks by reason of the physiological results of the apprehension itself. The other is to recognize 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 the full disclosure of facts necessary to an informed consent.⁵⁸

This advice may provide meaningful guidance to private physicians because of its stress on the individual nature of the problem. But this individual consideration is impossible in screening; either all patients will be told something or none will.⁵⁹

A review of the cases requiring disclosure provides a basis for determining whether such notice is necessary in a mass screening program. In each case either the risk of injury was high or the possible injury would be serious, or both. In one case involving electroshock and insulin treatments, evidence disclosed a nineteen to twenty-five per-

⁵⁶ *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 317 P.2d 170 (1957); *Natanson v. Kline*, 186 Kan. 393, 350 P.2d 1093, on rehearing, 187 Kan. 186, 354 P.2d 670 (1960); *Mitchell v. Robinson*, 334 S.W.2d 11 (Mo. 1960). But cf. *Hunt v. Bradshaw*, 242 N.C. 517, 88 S.E.2d 762 (1955). For discussion of these cases, see also note, 60 Colum. L. Rev. 1193 (1960).

⁵⁷ This is the element of actual causation which is necessary for every tort action. 2 Harper & James, *Torts* § 20.2 (1956); Prosser, *Torts* § 44 (2d ed. 1955). Were the plaintiff to recover even though he admitted he would have submitted to the procedure in any event, it could not be said that the failure to inform played any part in the infliction of the injury.

⁵⁸ *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, supra note 56, at 560, 317 P.2d at 181.

⁵⁹ This, of course, applies only to the general literature and directions. During the actual testing, the tester may say different things to different people and will attempt to approximate as closely as possible a private office atmosphere.

cent risk that the patient would suffer broken bones.⁶⁰ In another, there was a serious risk of burns from radiation treatments that were advised after cancer surgery.⁶¹ In both cases it was not unlikely that with a complete understanding of the prospective benefits of the procedure and its risks, the patient would have preferred the status quo. Moreover, neither knowledge of the risks nor any consequent fear would have reduced the likelihood of successful treatment in either case, so that there was no medical justification for withholding the information.⁶²

Against this background there seems good reason not to require full disclosure of all possible risks to every patient in a screening. First, the risks of no current screening program come close to those of the cases considered above in either frequency of injury or potential severity. Second, there is no opportunity to talk with each screenee about the risks and benefits of the procedure. A large sign or printed literature would be the only ways of conveying such information to prospective screenees. The personal reassurance possible during a private conversation with a physician would not be available. Any mass communication might cause many persons to be wary and to refuse to be tested, even though any objective appraisal of the risk compared with the benefit in any of these screening programs suggests that refusal to take the test because of fear of injury is illusory.

Even a sign in a glaucoma screening center saying that two in 10,000 suffer minor, temporary injuries, but that one or two people in every 100 tested are found to have glaucoma, might not be advisable. In the electroshock and radiation cases fear of injury would not have decreased the likelihood of successful treatment. However with tonometry, relaxation of the patient is essential to accurate measurement. If the screenee is tense for any reason, the readings will be artificially high and he may become a false positive.⁶³ An excess of false positives caused by fear of physical injury would destroy public confidence in the entire screening program.⁶⁴

Even if no duty exists to warn of the risks involved, there might still

⁶⁰ *Mitchell v. Robinson*, 334 S.W.2d 11 (Mo. 1960).

⁶¹ *Natanson v. Kline*, 186 Kan. 393, 350 P.2d 1093, on rehearing, 187 Kan. 86, 354 P.2d 670 (1960).

⁶² See quotation in text accompanying note 58 *supra*.

⁶³ This may also occur if the patient is not in a completely relaxed position during the testing. Failure to open a collar button and loosen a tie may account for a few millimeters difference.

⁶⁴ See Packer, "Symposium, Community Projects for the Early Detection of Glaucoma," 30 *Sight Saving Rev.* 4, 8-9 (1960), stating that some screenees become angry and consider the screening group responsible when they pay for a diagnosis that shows no glaucoma.

be a duty to advise prospective screenees about what is going to happen to them. For example, in tonometry anesthetic is used at the outset. It has been determined that the incidence of allergic reaction to the anesthetic is probably about one in 10,000.⁶⁵ This is so minimal that there may be no duty to warn expressly of the risk of reaction, but there may still be a duty to advise screenees that first they will receive some anesthetic in each eye. In this way, a person who knows of a previous bad experience with eye anesthetic will have an opportunity—and a duty⁶⁶—to ask questions and take steps to protect himself. Keeping the screenees generally informed about what is going to happen to them may also help to reduce tensions and injuries often caused by ignorance of what is being done.⁶⁷

Once any duty to warn has been satisfied, the actual execution of the procedure presents the problem of who should do the testing itself. In private practice, for example, tonometry is apparently done almost exclusively by ophthalmologists, and only occasionally by general practitioners or by nurses or technicians in private offices. Should this control the staffing of a screening program? Would technicians be practicing medicine illegally if they were trained to do tonometry testing?⁶⁸ This is obviously an important practical question. The expansion of the screening program would be much easier if personnel other than physicians could be used, provided that they could perform as well as physicians.⁶⁹ Concepts of what nurses and technicians may do under the practice statutes are constantly changing, and these

⁶⁵ See note 34 *supra* for the derivation of this figure.

⁶⁶ See *Stokes v. Dailey*, 85 N.W.2d 745 (N. Dak. 1957), second appeal, 97 N.W.2d 676 (1959), in which a patient who knew of previous reactions to a prescription did not tell the physician and was given and used the same prescription again. The court held that the jury could find contributory negligence in the patient's silence and subsequent use of the prescription a second time.

⁶⁷ The patient must be warned not to move his eye while the tonometer is on it—or else he will suffer injury. He must be comfortable and stare straight up—or the reading will be inaccurate. These directions could easily be given with a not-too-clinical explanation of what is happening and would impose some reciprocal obligation on the screenee. See note 66, *supra*.

⁶⁸ Statutes defining the practice of medicine, the practice of nursing, and penalties for illegal practice pose the non-tort problem here. See, e.g., N.Y. Educ. Law §§ 6501, 6513(2)(a), 6901, 6909, 6910(1)(c).

⁶⁹ One report of a glaucoma screening program discloses that plant staff nurses performed over 99.9% of the tonometries done in a survey of 4,100 persons. No injuries were reported. Ryan, "Glaucoma—A New Challenge to Occupational Medicine," 1 *Archives of Environmental Health* 278, 284 (1960). This suggests that non-medical personnel can be trained to do this specific task. This should not be too surprising because the test is a rather mechanical one with virtually no discretion or judgment involved except as to whether the tests should be done at all on persons who manifest contraindications. On the other hand, one author flatly states that eyes "have been lost by technicians anesthetizing them and using a tonometer. . . ." and concludes that technicians should never give these tests. Kuhn, "Glaucoma Detection in Industry," 26 *Indus. Med. & Surgery* 327 (1957).

questions will cause difficulty when the time for decision arrives.⁷⁰ However, in the *Battistella*⁷¹ case a dictum touches on this problem:

Moreover, even where examinations are conducted in such activities as mass tubercular surveys, for the benefit of the person examined, it is doubtful that the same grade of skilled technician would be required as in the case of the private consultation at patient's request.⁷²

Although the dictum does not mention the practice-of-medicine statutes, the language indicates that the personnel standards for screening programs may not be so high as those for private physician-patient relationships.

From a tort standpoint, this problem is confused by the concept of actual causation; if the physician himself had done this examination or supervised it, is there any reason to think that the same injury would not have occurred? If the injury is anesthetic reaction, the answer is probably negative, and there should be no liability even though a statute has been violated.⁷³ However, if the injury is caused by dragging the tonometer across the eye, the operator would be charged with negligence attributable under respondeat superior to the screening group, which delegated the function to the operator.⁷⁴ Of course, if the operator

⁷⁰ The question of whether nurses may give intravenous injections in New York provides a good example of changing attitudes. In 1942, the Attorney General ruled that these injections did not come within the practice of nursing statute so that nurses would be practicing medicine illegally when giving them—except in certain emergency situations. 1942 N.Y. Att'y Gen. 368. In 1961, after considering the question for more than one year, the Attorney General concluded that the medical profession now considers nurses competent to give such injections, and that they may properly do so whenever ordered by a physician. 1961 N.Y. Att'y Gen. — (February 28, 1961).

⁷¹ *Battistella v. Society of the N.Y. Hosp.*, 9 App. Div. 2d 75, 191 N.Y.S.2d 626 (1st Dep't 1959).

⁷² *Id.* at 78, 191 N.Y.S.2d at 629-30.

⁷³ The doctrine of negligence per se will not operate to create liability because some causal relation between the statutory violation and the injury is required. See Prosser, *Torts* § 34, at 157-58 (2d ed. 1955).

⁷⁴ Although physicians are usually thought to be independent contractors, there are situations in which they may be servants. The tonometry that will be done at public screenings would seem to be a perfunctory test which the physician performs more as a highly trained technician than as a physician exercising discretion and judgment. See *Mrachek v. Sunshine Baking Co.*, 308 N.Y. 116, 123 N.E.2d 801 (1954). This suggests that, under general rules of respondeat superior, the screening group might be liable for the negligence of physicians acting as examiners.

But even if the tonometry testing is considered a medical function, the screening group might still be liable if the screenees are not given any indication that the physicians are independent practitioners. The screenees obviously have no duty to inquire into the precise status of the physicians and may reasonably assume that they are employed by the sponsoring group. See *Seneris v. Haas*, 45 Cal. 2d 811, 832, 291 P.2d 915, 927 (1955). Furthermore, since a major purpose of the screening group is the dissemination of information about the disease, it can be argued that the volunteer physicians are directly benefitting the sponsoring group in giving the tests. See *Ferson, Principles of Agency* § 117 (1954).

The screening group may also be liable for the negligence of nurses that the physicians bring with them—as, of course, will the physician. The screening group may be liable under the doctrine of apparent authority because it will appear to the public that the nurse is working for the Foundation and they may rely on this impression. See *Ferson*, *supra*, § 54.

was not competent to do tonometry, then the original delegation might be primary negligence for which the delegator will be liable.⁷⁵

NOTIFICATION OF TEST RESULTS

The third category concerns problems arising from notifying screenees of the test results. In diagnosis the goal is to tell the patient what is wrong with him, and the physician is required to adhere to standard practice in arriving at his conclusions. In screening, however, the result is not intended to be in the least definitive. Indeed, the very nature of screening creates two major problems; the so-called false negatives and the false positives. The results of any screening program will yield initially two, but ultimately four groups. The largest of the four is the true negative group—those who are told accurately that they have shown none of the danger signs being sought and do not have the disease in question. The second group is the true positive—those whose test results warrant further study and who are ultimately determined to have the disease being sought. The third and fourth groups are the false counterparts to the first two; the false negatives are incorrectly classified as not having the disease, and the false positives are notified that their conditions warrant further study though they do not have the disease.⁷⁶

Neither the true negatives nor the true positives offer any medical or legal problem—except that the true negatives must realize the finite

⁷⁵ See 2 Harper & James, *Torts* § 26.1, at 1362-63 (1956).

⁷⁶ The breakdown of major screening programs into these four groups might be along the following general lines:

1. Glaucoma—Schiotz tonometry—per 10,000 screenees over age 40	
true negatives	9,320
false negatives	170
true positives	170
false positives	340
2. Diabetes—urine test—per 10,000 screenees	
true negatives	8,859
false negatives	94
true positives	106
false positives	941
3. Diabetes—blood test—per 10,000 screenees	
true negatives	9,692
false negatives	74
true positives	126
false positives	108

The diabetes figures are reported in Reynolds, "Screening Methods for Diabetes Mellitus," in Hilleboe & Larimore, *Preventive Medicine* 541, 544 (1959). (Although these figures indicate the blood sampling method is more efficient, this must be balanced against the greater likelihood of injury in the blood sampling method from extraction mishaps). The glaucoma estimates are the result of experience discussed and reported throughout this article. See notes 36, 38 *supra*. Tuberculosis figures are difficult to isolate because of the many other chest conditions detected at the same time. However, in New York, chest x-rays of the general population now yield 1.1 true positive cases of tuberculosis for every 1,000 screenees. Shultz, "Screening Methods for Pulmonary Tuberculosis," in Hilleboe & Larimore, *Preventive Medicine* 521, 530 (1959).

nature of this assurance. They should be cautioned that periodic tests are necessary for continued security.⁷⁷ The problems are caused by the false categories.

What causes a negative to be a false negative? In glaucoma screening, there may be several explanations for false negatives. First, the tensions might not have been elevated because the screenee had low-tension glaucoma. Second, the usually high tension might have been low at testing time because of reduced liquid in the body, diurnal fluctuations, scleral rigidity variation, or a spontaneous remission that reduced the tension. The test may have been given carelessly so that the true figures were not achieved or recorded; or, lastly, clerical carelessness may have caused the screenee to receive the wrong notice. The extensive scope of the possibilities demonstrates that only some instances of failure to detect glaucoma are caused by negligence.

From the medical standpoint, false negatives are a problem no matter how caused.⁷⁸ The legal problem is to determine whether a given false negative was caused by negligence of the screening group. The problem of low-tension glaucomas was discussed earlier in considering whether tonometry alone was a permissible choice of screening method.⁷⁹ With no negligence in the choice of the procedure there should be no liability to these false negatives. Similarly, if the cause of falsity was something internal such as the amount of liquid in the body, diurnal fluctuations, a low rigidity, or spontaneous remissions, there would appear to be no negligence. These factors cannot reasonably be considered in a screening program.⁸⁰ On the other hand, if the test is done negligently, if the results are carelessly noted, or if the wrong notification is dispatched to the screenee, these all bespeak negligence.

But how can the plaintiff prove that the falsity of the notification was caused by some act of negligence rather than by some condition beyond the control of the screening group? This is a most difficult proof problem. The possible internal conditions of the plaintiff, including low-tension glaucomas, will be very hard to prove or disprove until much

⁷⁷ See fuller discussion of this aspect of notification in the text at note 88 *infra*.

⁷⁸ The nature of the screening program will dictate to a large extent how widespread the false negative problem will be. Where the test is visual, as with tuberculosis x-rays, and where any questionable case will be referred, the false negative problem should be much less serious than with glaucoma screening where the test is quantitative and only seeks a symptom that is common to most, but not all, chronic glaucoma. Yet, in *Battistella v. Society of the N.Y. Hosp.*, 9 App. Div. 2d 75, 78, 191 N.Y.S.2d 626, 630 (1st Dep't 1959) an expert testified for the defendant that the experience of qualified radiologists disclosed "an error of approximately 27% on survey readings where the finding is negative."

⁷⁹ See note 26 *supra*.

⁸⁰ If this were the diagnosis, however, it might be negligent for a physician not to take steps to determine whether these factors would explain low readings. Reliance on one reading would be questionable practice. See notes 50, 51 *supra*.

more is known about the disease. Even if a plaintiff can prove that he had standard scleral rigidity at test time, that his body held a normal amount of liquid, that the test was not administered near the bottom of his diurnal fluctuation, he still must show that there was no spontaneous remission and that in fact his tension was above the danger line at the time of the test. Each of these items will be very difficult, if not impossible, to prove.⁸¹

But assuming that such proof can be made, or that it can be shown that someone simply mailed the wrong form to the screenee, what liability will exist to false negatives for this negligence? The claim apparently would be that the defendant screening group negligently misrepresented the plaintiff's condition to him and that he was injured by relying on the notice and taking no action.⁸² The validity and sweep of this claim will depend upon the type of notice sent to those thought to be negatives. Presumably the screening group will phrase the notice so as to warn that in two years another test should be taken because the disease may strike at any time. If this is the gist of the notice it seems unlikely that a plaintiff would reasonably be able to rely on his negative notification for more than two years,⁸³ so that even if in a given case there is liability to a false negative, it should not be for more than the damages, if any, attributable to a two-year delay in seeking treatment.⁸⁴

Let us turn now to the problem of the false positive. In glaucoma his false status might be caused by the converses of many of the factors that caused false negatives: a significantly high tension for most people

⁸¹ The very listing of possible causes of injury indicates that, without more, this is not a proper case for the application of traditional *res ipsa loquitur* since it is impossible to say that the error was more likely than not caused by negligence. Prosser, *Torts* § 42 (2d ed. 1955). If the doctrine is invoked in order to force the screening group to come forward to explain the reason for the error, it might be applied to this situation. Cf. *Ybarra v. Spangard*, 25 Cal. 2d 486, 154 P.2d 687 (1944).

Of course, the plaintiff has an easy case if he can pinpoint a negligent cause of the error. In *Union Carbide & Carbon Corp. v. Stapleton*, 237 F.2d 229 (6th Cir. 1956), plaintiff proved that his medical card in defendant's office contained several notations indicating that his chest x-rays appeared to disclose tuberculosis. He convinced the jury that he had never been so informed and the defendant was held liable for negligent failure to inform him of a discovered defect.

⁸² The negligent misrepresentation action requires reasonable reliance by the plaintiff to his detriment. See 1 Harper & James, *Torts* § 7.13 (1956); Prosser, *Torts* § 89 (2d ed. 1955).

⁸³ *Brown v. Dark*, 196 Ark. 724, 119 S.W.2d 529 (1938); *Jenkins v. Charlestown Gen. Hosp.*, 90 W. Va. 230, 110 S.E. 560 (1922).

⁸⁴ In *Jenkins v. Charlestown Gen. Hosp.*, *supra* note 83, the defendant hospital's servant negligently told the plaintiff that x-rays showed that his arm was healing properly. Two weeks later, plaintiff saw a physician who told him that his arm was becoming crooked. The court held the hospital liable for the injury caused by the two-week delay, but said that after the physician's warning the plaintiff could no longer reasonably rely on the hospital's statement.

that does not affect this particular individual;⁸⁵ high scleral rigidity, a high amount of liquid in the body, tension caused by fear or even by failure to loosen the screenee's collar; improper testing procedure; or carelessness in notification. Again, some of these are attributable to negligence while others are not, and the proof problems will be extremely difficult.

If, however, negligence can be shown, what sort of liability might follow? Here the claim appears to be two-fold: First, plaintiff expended money to undergo a full scale diagnosis only to find out that there was nothing wrong with him; and, second, he suffered physical injury from the anxiety caused by the letter of notification. The first claim may vary from \$10 to \$300.⁸⁶ It may even be argued in defense that the expenditure enabled the screenee to have more conclusive peace of mind than would an original negative notification. The real problem is posed by the possible claim of anxiety, especially in the light of the recent New York case of *Ferrara v. Galluchio*.⁸⁷ In that case the defendant physician negligently treated plaintiff's shoulder wound. It failed to heal properly and plaintiff eventually went to a dermatologist who told her not to neglect the wound lest it become cancerous. Plaintiff sought damages from the defendant for both the negligent treatment of the shoulder and also for cancerophobia, which she claimed she had developed after the second physician's warning. There was no claim that plaintiff had or would get cancer, only that she suffered from cancerophobia with possibly permanent anxiety symptoms. The Court of Appeals upheld a jury award of \$10,000 for the original negligence in treatment plus \$15,000 for the cancerophobia.

The implications for screening programs are obvious. If the screenee is negligently told his results are positive and he develops severe anxiety symptoms before the error is discovered, an analogy to *Ferrara* would not be too far-fetched. Of course, there are important differences between the situations. Despite the severe consequences probably neither tuberculosis nor glaucoma is today nearly so dread as cancer in the public mind. Also, only the passage of time could prove or disprove the correctness of the cancer warning in *Ferrara*, while in a screening program any erroneous positive notification will probably be rectified when the screenee goes to a physician for complete diagnosis. This should reduce considerably the duration of possible anxiety.

⁸⁵ This medical situation is the converse of the low tension glaucoma—and again shows the problems arising from reliance on statistical standards for setting referral figures.

⁸⁶ See note 64, *supra*. Apparently, these claims are not pursued past the angry letter stage. The best course in this situation is prevention of such anger by better explanation of the screening goals and limits. See text at note 89, *infra*.

⁸⁷ 5 N.Y.2d 16, 152 N.E.2d 249, 176 N.Y.S.2d 996 (1958).

The importance of the actual wording of notifications to negatives has already been noted, and the phrasing of the notice to the positives is equally important. Both notifications must tread narrow lines. Letters⁸⁸ to negatives should stress the positive aspects of screening—the idea that screening is mainly geared to finding people who have a particular symptom of a particular disease and not in negating the disease in others. The necessity for periodic tests should be emphasized so that no screenee can possibly be misled as to what was done to him and what value it has for the future. Notification to the positives should be sufficiently alarming to get them to see a physician for full diagnosis, but should not frighten the recipients unduly.⁸⁹ This letter might even quote the statistic that two of every three people receiving it do not have glaucoma,⁹⁰ but that the recipient should see his physician just to make sure. Such a letter should serve to allay fears and to prevent or minimize any reaction such as that proven in *Ferrara*.

Apart from its legal implications, accurate and complete information about the nature of screening enables the public to understand the aims of the procedure, how it works, and what its results mean. Such publicity—both before and after the actual testing—will help immeasurably in educating the public⁹¹ to the medical aspects of mass screening programs. It should also help to avoid misunderstandings of the sort now only too common in much current medical-legal controversy.

⁸⁸ It should be obvious that all notifications should be in writing. In *Union Carbide & Carbon Corp. v. Stapleton*, supra note 81, servants of the defendant claimed to have notified plaintiff orally of the tubercular condition that defendant had discovered. Plaintiff denied some conversations entirely and claimed the content of others did not inform him of his condition. The jury believed plaintiff, and defendant was held liable for negligent failure to inform.

⁸⁹ On the other hand, the screening group must be sure to impress on the screenee the potential seriousness of the situation, especially if the disease is relatively unknown. Glaucoma experience has indicated that even with such warnings there are significant numbers who will not, for one reason or another, go to a physician for diagnosis. See report by Garner & Dressler, 31 *Sight Saving Rev.* 41 (1961) on experience in Milwaukee. Of course, if the notice accurately conveys the dangers of failure to see a physician, the screening group will not be liable for injuries suffered by a screenee who did nothing. See *Brown v. Dark*, supra note 83.

⁹⁰ See note 36 supra.

⁹¹ The need for such education is graphically shown by a recent study indicating that 40% of the women in the United States are unaware of the simple smear test for uterine cancer. 1962 *Cancer Facts and Figures* 12 (1961).