



ASSISTANT SECRETARY OF DEFENSE

WASHINGTON, D.C. 20301

JAN 10 1985

HEALTH AFFAIRS

BEFORE THE OFFICE, ASSISTANT  
SECRETARY OF DEFENSE (HEALTH AFFAIRS)  
UNITED STATES DEPARTMENT OF DEFENSE

Appeal of )  
Sponsor: ) OASD(HA) File 84-40  
SSN: ) FINAL DECISION

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) Case File 84-40 pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R, chapter X. The appealing party is the beneficiary, the 21-year-old son of a retired officer in the United States Marine Corps. The beneficiary and his father both attended the hearing and the father spoke and testified in behalf of the beneficiary.

The appeal involves the denial of CHAMPUS cost-sharing of an eye examination on January 12, 1981, and a subsequent radial keratotomy procedure, with related services and supplies, on March 12, 1981. A CHAMPUS claim for these services was filed with the CHAMPUS Fiscal Intermediary, Mutual of Omaha, in the amount of \$1,250.00, and \$644.02 was initially paid by the fiscal intermediary as the CHAMPUS cost-share. Following a request for review of the reduced payment, the fiscal intermediary determined that the claim had been paid in error because the eye examination, radial keratotomy, and related services and supplies were not authorized procedures under CHAMPUS. The fiscal intermediary initiated action to recover the erroneous payment of \$644.02 and the beneficiary appealed.

The hearing file of record, the recorded hearing transcript, the Hearing Officer's Recommended Decision, and the Analysis and Recommendation of the Director, OCHAMPUS, have been reviewed. It is the Hearing Officer's recommendation that the OCHAMPUS First Level Review determination, which denied cost-sharing of the eye examination and radial keratotomy procedure, be upheld on the basis that radial keratotomy is an experimental procedure excluded from CHAMPUS cost-sharing under the CHAMPUS regulation, DoD 6010.8-R, chapter IV, G.15. The Director, OCHAMPUS, concurs and recommends adoption of the Recommended Decision to deny CHAMPUS cost-sharing of the beneficiary's claim as the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs).

The Assistant Secretary of Defense (Health Affairs), after due consideration of the appeal record, accepts the recommendation of the Director, OCHAMPUS, and adopts the Hearing

Officer's Recommended Decision. The FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is, therefore, to deny CHAMPUS cost-sharing of the beneficiary's eye examination on January 12, 1981, the radial keratotomy performed on the right eye on March 12, 1981, and related services and supplies. This decision is based upon a finding that radial keratotomy is an experimental or investigatory procedure and is not within the generally accepted norm for medical practice in the United States. Therefore, the radial keratotomy procedure, and all related services and supplies are excluded from CHAMPUS cost-sharing.

#### FACTUAL BACKGROUND

According to the medical records, the beneficiary received a complete eye examination on January 12, 1981, resulting in the diagnosis of myopia. On March 12, 1981, the beneficiary underwent a radial keratotomy of the right eye as treatment of the diagnosed myopia.

A CHAMPUS claim was submitted to the CHAMPUS Fiscal Intermediary for this care, as well as charges for legend drugs unrelated to the eye examination or radial keratotomy procedure. The prescription drug charges (\$61.48) have been cost-shared by CHAMPUS and are not involved in this appeal. The remainder of the claim involved a \$35.00 charge for an eye examination, a surgeon's fee of \$965.00 for the radial keratotomy procedure, an operating room charge of \$230.00, and a medical supplies charge of \$20.00.

A CHAMPUS Explanation of Benefits issued by the fiscal intermediary on May 8, 1981, indicates the surgeon's fee was reduced to \$633.70 as the reasonable charge allowable under CHAMPUS, the eye examination charge was reduced to \$25.00, and the remaining charges for the operating room and related medical supplies were allowed in full. The CHAMPUS allowable charges on the \$1,250.00 charges, then, were \$908.70. After deducting the patient's \$50.00 annual deductible and his 25 percent cost-share, the fiscal intermediary issued a \$644.02 CHAMPUS cost-share payment to the patient.

After a request from the beneficiary to review the reduction in the surgeon's fee, the fiscal intermediary determined that the claim had been paid in error. Consequently, the fiscal intermediary initiated a recoupment procedure and advised the beneficiary of the erroneous payment. The basis for the fiscal intermediary's denial of the claim and initiation of the recoupment action was a finding that the diagnosis of myopia is considered a refractive error and, therefore, not a condition cost-shared under CHAMPUS. It was also based upon a finding that the radial keratotomy surgical procedure was classified as an experimental procedure and excluded as a CHAMPUS benefit by regulation.

The fiscal intermediary's actions were ultimately appealed by the beneficiary to OCHAMPUS. In his appeal, the beneficiary asserted that the radial keratotomy procedure is not experimental. He also stated that the request for a refund of the erroneous CHAMPUS payment would create a hardship for him and was considered to be unfair. The OCHAMPUS First Level Appeal determination was issued in February 28, 1983. It upheld the previous denials of the radial keratotomy as an experimental procedure and the denial of the eye examination because it was not rendered in connection with the medical or surgical treatment of a covered illness or injury. The beneficiary requested a hearing and the hearing was held before an independent Hearing Officer on August 23, 1983. The Recommended Decision of the Hearing Officer, Mr. Harold H. Leeper, has been received and issuance of a FINAL DECISION is proper.

#### ISSUES AND FINDINGS OF FACT

The primary issue in this appeal is whether the eye examination and subsequent radial keratotomy procedure performed on the beneficiary on March 12, 1981, were properly excluded from cost-sharing under CHAMPUS.

The Department of Defense Appropriation Act of 1976, Public Law 94-212, prohibits the use of CHAMPUS funds to pay, among other matters,

" . . . any other service or supply which is not medically necessary to diagnose and treat a mental or physical illness, injury, or bodily malfunction . . ."

All subsequent Department of Defense Appropriation Acts have contained similar restrictions. The CHAMPUS regulation, DoD 6010.8-R, implements these statutory restrictions by excluding from CHAMPUS coverage "services and supplies which are not medically necessary for the diagnosis and/or treatment of a covered illness or injury." (Paragraph G.1., Chapter IV, DoD 6010.8-R.) The CHAMPUS regulation defines "medically necessary" as "the level of services and supplies (that is, frequency, extent, and kinds) adequate for the diagnosis and treatment of illness or injury . . . Medical necessity includes the concept of appropriate medical care." (Paragraph B.104., Chapter II, DoD 6010.8-R.)

"Appropriate medical care" is defined by DoD 6010.8-R, chapter II, B.14, as:

"a. That medical care where the medical services performed in the treatment of disease or injury, . . . are in keeping with the generally acceptable norm for medical practice in the United States.

"b. The authorized individual professional provider rendering the medical care is qualified to perform such medical services by reason of his or her training or education and is licensed and/or certified by the state where the service is rendered or appropriate national organization or otherwise meets CHAMPUS standards; and

"c. The medical environment in which the medical services are performed is at the level adequate to provide the required medical care."

The CHAMPUS Regulation DoD 6010.8-R, chapter IV, paragraph G.15., also includes the following exclusion:

"Services and supplies not provided in accordance with accepted professional medical standards; or related to essentially experimental procedures or treatment regimens."

The Regulation in DoD 6010.8-R, chapter II, paragraph B.68., provides:

"'Experimental' means medical care that is essentially investigatory or an unproven procedure or treatment regimen (usually performed under controlled medicolegal conditions) which does not meet the generally accepted standards of usual professional medical practice in the general medical community."

On April 6, 1981, OCHAMPUS issued an instruction, OCI 6010.34, classifying radial keratotomy as experimental. The instruction stated radial keratotomy is defined as "a surgical procedure used in the treatment of myopia (nearsightedness) in which sixteen (16) radial incisions are made into the corneal tissue." The OCHAMPUS instruction specifically noted that, "any denial decision is appealable since a Program determination of what constitutes experimental (investigational) surgery is judgmental, and thus an appealable issue." The OCHAMPUS instruction in its background discussion noted that:

"Studies were conducted by the National Advisory Eye Counsel (NAEC), the principal advisory body to the Eye Institute, concerning the efficacy and safety of radial Keratotomy. As a result of these studies, a resolution was passed May 29, 1980, by the NAEC classifying radial keratotomy as an experimental procedure . . . . The widespread presence of nearsightedness in the



CHAMPUS beneficiary population, however, makes this particular situation somewhat unique. It therefore became important to issue a statement of policy on this issue, which appeared in the Federal Register on April 1, 1981."

The statement of policy published in the Federal Register contains the following:

"This policy statement identifies radial keratotomy, a surgical procedure to correct nearsightedness (myopia), as an experimental procedure. Public Notice of this benefit policy decision is necessary because of the widespread interest generated by this procedure. This statement informs CHAMPUS beneficiaries and providers of the exclusion of benefits for radial keratotomy as an experimental procedure.

"[T]he CHAMPUS Regulation . . . specifically excludes services and supplies not provided in accordance with accepted professional medical standards, or related to essentially experimental procedures or treatment regimens, from the CHAMPUS Basic Program.

"For example, the National Advisory Eye Council (NAEC), the principal advisory body to the National Eye Institute, approved a resolution on May 29, 1980, expressing concern about the widespread adoption of the operation intended to correct nearsightedness called radial keratotomy. The NAEC considers radial keratotomy to be an experimental procedure because of its lack of adequate scientific evaluation in animals and humans. In addition, available research materials reviewed by the Department of Defense, as well as professional experts consulted, supported this conclusion.

"Based on its experimental classification and the widespread interest that could be generated among the CHAMPUS beneficiary population because of the high incidence of nearsightedness, this statement of policy identifies radial keratotomy as an experimental procedure and, therefore, is excluded as a benefit in accordance with the provisions of the Basic Program."

At the hearing OCHAMPUS introduced a statement published in The Medical Letter on November 14, 1980, concerning the status of radial keratotomy. It provides in part as follows:

"Many millions of people are myopic due to a refractive error that focuses light rays in front of the retina. For most of them, eyeglasses or contact lenses provide a safe and effective remedy. Several different types of operations have been tried from time to time in the hope that they might offer myopic people permanent correction of their vision; all of these have attempted to make the cornea flatter (less convex) in order to reduce its refractive power and focus light rays closer to the retina. Radial keratotomy is the newest procedure for this purpose.

\*  
\*  
\*

"In the latest attempt to cure myopia by surgical flattening of the cornea, radial, equally spaced, deep incisions are made in the anterior surface of the cornea; intraocular pressure then pushes the weakened peripheral cornea slightly forward, flattening the central uncut area and reducing myopia. The procedure can be done in an outpatient operating room under local anesthesia.

"One report from the Soviet Union describes the results of radial keratotomy in 676 patients with myopia ranging from -0.75 to -6.00 diopters; 84 percent of the patients achieved unaided visual acuity of 20/50 or better, permitting them to perform everyday activities without eyeglasses (SN Fyodrov and VV Durnex, Ann Ophthalmol, 11:1885, 1979). Several other studies are being planned or are in progress, including a five-year Prospective Evaluation of radial Keratotomy (PERK) to be conducted by the National Eye Institute in 400 patients at several university centers across the USA.

"Complications reported with this procedure include transient unstable vision, which may require multiple pairs of glasses, glare from permanent corneal scars that may interfere with night driving, and astigmatism. By decreasing myopia, the operation may cause the presbyopia that usually begins in early

middle age to be noticed a few years earlier. So far there have been no reports of severe visual loss.

"Radial keratotomy, the latest attempt at reshaping the cornea to correct myopia, should be considered an investigational procedure. Previous operations for this purpose have caused serious deterioration of vision after a period of years. Myopic patients would be well advised to continue use of eyeglasses or contact lenses until the safety and long-term effectiveness of radial keratotomy can be determined.

The Hearing Officer summarized the testimony and evidence presented by the beneficiary and the sponsor at the hearing as follows:

"At the hearing, the beneficiary and his sponsor testified credibly that the young man, a senior engineering student at the University of Texas, had a right eye evaluated at 20/200 before the operation, and had an FAA pilot license with a third class physical, which required him to wear glasses for myopia, during the times he was operating an aircraft. After the operation, his vision was evaluated at 20/30, went down to 20/60 and then stabilized at 20/50. He now has a second class airman certificate, which does not require him to wear glasses when he is flying an airplane. Moreover, he has had no adverse effects whatsoever from the surgery, which was performed two years before the hearing. He had made application for a Navy commission as an engineering officer, and the Houston District has recommended that he be granted a waiver on his eyesight because of his having had a radial keratotomy. This application was pending at the time of the hearing.

His sponsor said that the IBM Corporation's health insurance pays for radial keratotomy operations, and considers it a routine procedure. He was unaware of any other insurance companies' decisions of a similar nature. He said he learned of the OCHAMPUS Policy refusing to pay for experimental procedures when the matter was appealed to OCHAMPUS in a First Level Appeal. On cross examination, neither the beneficiary nor the sponsor knew of any patients who had undergone such a procedure five or ten years

ago and could still see well. Young Mr. had read in the AOPA magazine, issued by the Aircraft Owner and Pilot's Association, an article stating that although there was some concern over the procedure, a lot of pilots were having it done, and no adverse effects had resulted. The Federal Air surgeon has not ruled on the merits of the procedure.

"They pointed out that Dr. Leslie had been doing the radial keratotomy procedure for several years, having been trained by a physician in New York who learned the procedure in Russia in 1974. Upon a suggestion of the Hearing Officer, both gentlemen agreed to contact Dr. Leslie and request him to furnish any information he had, including professional journal articles, or evaluations of any nature, concerning the procedure. Both of them agreed to do so, and to furnish them to the Hearing Officer, with a copy to Ms. Gray as soon as possible.

"On December 5, the beneficiary forwarded the Hearing Officer the following information: (1) Exhibits 23 and 24, copies of statistical data prepared by Dr. Leslie. Exhibit 23 reflected statistics for 1710 cases at 6 months post-operative follow-up, and Exhibit 24 lists a one-year follow-up of 959 eyes. The statistics quoted are very impressive, indicating that persons with small to medium degrees of myopia up to 8.00 D have benefitted tremendously by the operation, and from 67% to 97% of them could see 20/40 or better a year after the operation. Also furnished as Exhibit 25 is a booklet entitled "Myopia Surgery" prepared by the Austin Eye Associates and Dr. Leslie. The booklet describes the procedure, the level of myopia it is intended to improve, and gives the number of testimonials of patients who have been benefitted by the surgery. On page 13, the paragraph entitled 'The Final Analysis' is quoted:

"Be advised that my generally favorable opinion of radial keratotomy may not necessarily be shared by the majority of ophthalmologists across the state. The operation is, however, fairly well accepted in the Austin ophthalmological and medical community. I believe that in the future, it will be a common and well accepted procedure,



and that for many near-sighted people, it is a better alternative than either spectacles or contacts.

"In the final analysis, you would have to decide these issues for yourself, and weigh whether the benefits are worth the risks. Check all the facts, and it might be helpful for you to talk with someone who has had the surgery. Our office would be happy to arrange it for you."

Based upon an evaluation of the evidence of record, the Hearing Officer found that the evidence presented by OCHAMPUS "strongly" supports its position that the radial keratotomy surgery is "experimental" and is not "appropriate medical care" because it is not in keeping with the generally accepted norm for medical practice in the United States. He also found that the evidence presented by the beneficiary did "not meet his burden of producing substantial evidence to support his opposition to the CHAMPUS determination, and to establish that the radial keratotomy procedure was not experimental and was appropriate medical care in keeping with the generally accepted norms for medical practice in the United States." Based upon this evaluation of the evidence, the Hearing Officer concluded that the CHAMPUS position was established by convincing medical evidence, from sources that are regarded as authoritative. Therefore, the Hearing Officer found that the radial keratotomy procedure provided to the beneficiary on March 12, 1981, and any ancillary charges connected therewith are not eligible for CHAMPUS cost-sharing. Based upon this finding the Hearing Officer recommended that the First Level Appeal Decision of OCHAMPUS dated February 28, 1983, be upheld on the basis that it correctly denied the claims of the appealing party because the radial keratotomy for myopia is not covered as a part of the CHAMPUS basic program as defined by DoD Regulation 6010.8-R.

Based upon my evaluation and review of the evidence of record I concur with the Hearing Officer's recommendation. The situation involved here is essentially similar to that encountered in the previous FINAL DECISION issued by this office, OASD(HA) Case File 83-06. That case dealt with a radial keratotomy performed on both eyes of the beneficiary in March 1980. In that case the CHAMPUS Fiscal Intermediary also erroneously cost-shared a portion of the charges for the surgery involved. The fiscal intermediary subsequently determined that the payments had been erroneously made and initiated recoupment action to recover the claims payment. The case was appealed through the CHAMPUS appeals system and a FINAL DECISION issued on May 31, 1983. That FINAL DECISION found that the inpatient care and radial keratotomy surgery performed on both eyes of the beneficiary in March 1980 involved experimental procedures and, therefore, were specifically excluded from CHAMPUS coverage.

This case has produced no new medical evidence establishing the scientifically validated safety and effectiveness of the radial keratotomy procedure in the treatment of myopia. Nor has there been any additional evidence produced that this procedure now meets the generally accepted standards for practice in the general medical community. For these reasons, I find that radial keratotomy does not qualify for CHAMPUS benefits because it is essentially an unproven treatment regimen, the safety, efficacy, medical necessity, and appropriateness of which have not to date been demonstrated.

While the Department of Defense recognizes that there may be individual improvement in vision as the result of the radial keratotomy procedure, I am constrained by regulatory authorities here, as in OASD(HA) Case File 83-06, to authorize benefits only for services which are generally accepted in the medical community and are documented by authoritative medical literature and recognized professional opinion. The evidence herein does not establish the documented long term safety or effectiveness of radial keratotomy. Instead, the file clearly indicates its unproven nature.

The CHAMPUS regulation, DoD 6010.8-R, chapter IV, G.66., excluded from CHAMPUS coverage:

"All services and supplies (including inpatient institutional costs) related to a noncovered condition or treatment; . . ."

Having determined that the radial keratotomy procedure was excluded from CHAMPUS coverage, all services and supplies related to the noncovered treatment are also excluded from coverage. In this case, the operating room charge and the related medical supplies are determined to be excluded from CHAMPUS coverage.

Similarly, eye examinations are generally excluded from CHAMPUS coverage by law (10 U.S.C. §1079(a)(3).) As implemented by DoD 6010.8-R, chapter IV, G.50., the general exclusion of eye examinations applies, ". . . except when rendered in connection with medical or surgical treatment of a covered illness or injury." Having determined that the surgical treatment of myopia through radial keratotomy is excluded from CHAMPUS coverage, it follows that the patient's eye examination was not rendered in connection with a covered condition and is excluded from CHAMPUS coverage.

The hearing file of record establishes that the fiscal intermediary erroneously paid the beneficiary's claim for the radial keratotomy procedure and related eye examinations and services. Therefore, the Director, OCHAMPUS, shall review this case based upon this FINAL DECISION and take appropriate action under the Federal Claims Collection Act in regards to this erroneous payment.

SUMMARY

In summary, it is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) that the eye examination on January 12, 1981, and radial keratotomy procedure and related services provided to the beneficiary on March 12, 1981, were not benefits under CHAMPUS. This determination is based upon a finding that radial keratotomy is an unproven treatment modality, the safety, medical necessity, and appropriateness of which have not been established. These findings are based on the lack of medical documentation, authoritative medical literature, and recognized professional opinions sufficient to establish the general acceptance and safety of the procedure at the time that the care was received. The appeal and the CHAMPUS claim of the beneficiary, therefore, are denied. The Director, OCHAMPUS, shall review the claims file and take appropriate action under the Federal Claims Collection Act in regards to the payments of the CHAMPUS claims for the episode of care in question. Issuance of this FINAL DECISION completes the administrative appeal process as provided under DoD 6010.8-R, chapter X, and no further administrative appeal is available.



Vernon McKenzie

Acting Principal Deputy Assistant Secretary

RECOMMENDED DECISION

Claim for CHAMPUS Benefits

Civilian Health and Medical Program of the Uniformed Services

- Beneficiary

USMC-Ret - Sponsor

SSN

This case is before the undersigned Hearing Officer pursuant to the Appealing Party's undated request for hearing concerning the denial by OCHAMPUS in its First Level Appeal Decision dated February 28, 1983 of his claim totaling approximately \$1250 for services rendered by Dr. Doyle Leslie of Austin, Texas, in performing a radial keratotomy on the right eye. The Fiscal Intermediary had found, and OCHAMPUS concurred in that finding, that the services furnished were experimental and did not meet the generally accepted professional norms for medical practice in the United States, and thus were not a covered benefit under the CHAMPUS program.

The hearing was held pursuant to Regulation DoD 6010.8-R, Civilian Health and Medical Program of the Uniformed Services, Chapter X, Section F, Paragraph 4, in Austin, Texas on August 23, 1983. was present and was accompanied by his father, who testified in his son's behalf. OCHAMPUS was represented by Linda M. Bray, Esq.

ISSUES

The general issue before the Hearing Officer is whether the services furnished to by Dr. Leslie between January and March 1981 may be cost-shared by the CHAMPUS Program.

The specific issues to be decided are: (1) Whether the radial keratotomy was experimental; and whether that procedure was in keeping with the generally accepted norm for medical practice in the United States, and thus constituted "appropriate medical care" as defined in the CHAMPUS Regulation. (2) Whether the services related to the radial keratotomy are services related to a non-covered condition or treatment.

LAW AND REGULATIONS

Regulation DOD 6010. 8-R is promulgated under the authority of, and in accordance with, Chapter 55, Title 10, United States Code.

The following citations from Regulation DOD 6010.8-R contain the relevant provisions of the CHAMPUS Regulation which must be considered in resolving the issues in this appeal:

- Chapter II.B.14a - Appropriate Medical Care
- Chapter II.B. 104- Medically Necessary
- Chapter II.B.68 - Experimental Treatment
- Chapter IV.G.1 - CHAMPUS Exclusion; Not Medically Necessary
- Chapter IV.A.1 - Scope of Benefits
- Chapter IV.G.16 - CHAMPUS Exclusion: Not Provided in Accordance with Accepted Standards; Experimental

#### EVIDENCE CONSIDERED

The Hearing Officer has considered all of the documents described in the List of Exhibits attached to this Recommended Decision and the testimony of the witnesses at the hearing.

#### DISCUSSION OF PERTINENT REGULATIONS

There is no dispute between the parties as to the nature of the services rendered, nor the amount of the charges that were presented. The only question is whether the testing and treatment provided to the Beneficiary by Dr. Leslie met the requirements of the Department of Defense Regulation cited above.

At the outset, it should be recognized that the CHAMPUS Program is an extension of the medical benefits program for members of the Uniformed Services; it is not an insurance program involving a contract guaranteeing the payment of specified claims in return for premiums paid. Further, the CHAMPUS program is not subject to regulation by administrative bodies or courts which control the private insurance sector in the States. This appeal must be adjudicated solely on the basis of the policies contained in the Department of Defense Regulation, which itself is not subject to review in this appeal; such a challenge may be raised only in a proceeding in a United States District Court.

A fundamental concept in the Regulation is that CHAMPUS may cost-share only those medically necessary services and supplies which are covered by and are not excluded by the applicable DoD Regulations.

"Medically necessary" treatment is that level of services and supplies which is adequate for the diagnosis and treatment of illness or injury. This includes the concept of appropriate medical care.

"Appropriate medical care" is defined as "that medical care where the medical services performed in the treatment of a disease or injury...are in keeping with the generally accepted norm for medical practice in the United States."

Thus, the principal question herein is whether the treatment received by from Dr. Leslie constituted "appropriate medical care in keeping with the generally accepted norm for medical practice in the United States," or was "experimental."



Under the CHAMPUS Regulation, the question of what constitutes the general standard for medical practice in the United States is a question of fact, and this is one of the reasons the CHAMPUS hearing is held, so that the Appealing Party may have an opportunity to meet his burden of documenting his claim for benefits by substantial evidence. The Regulation places on the Beneficiary the burden of producing evidence to prove that the treatments he received during the relevant period were in keeping with the generally accepted norm for medical practice in the United States for treatment of his diagnosed condition. Thus, the instance appeal must be decided solely on the basis of the evidence in the record concerning the nature of the treatment, plus the arguments of the parties as to whether that treatment was "experimental" and "appropriate medical care" for right eye.

#### EVIDENCE PRESENTED BY OCHAMPUS

The National Advisory Eye Council (NAEC), in a Resolution passed on May 29, 1980, classified radial keratotomy as an experimental procedure. The NAEC is a professional organization whose evaluations of treatment regimes and procedures is given great weight by the OCHAMPUS officials in determining whether a particular procedure is eligible for CHAMPUS cost-sharing.

The Medical Letter on Drugs and Therapeutics, published by the Medical Letter Inc., on November 14, 1980, reported on the status of the radial keratotomy procedure in the United States. It concluded, "radial keratotomy, the latest attempt at reshaping the cornea to correct myopia, should be considered an investigational procedure. Previous operations for this purpose have caused serious deterioration of vision after a period of years. Myopic patients would be well advised to continue to use eye glasses or contact lenses until the safety and long-term effectiveness of radial keratotomy can be determined." The editorial board of the "Medical Letter" is composed of outstanding physicians and other leaders in the medical profession, and its findings and conclusions are entitled to considerable weight in determining whether a procedure is experimental and whether it is in keeping with the generally accepted norm for medical practice in the United States.

On April 1, 1981 (20 days after the Beneficiary underwent the radial keratotomy of the right eye on March 12) the Assistant Secretary of Defense for Health Affairs issued a Statement of CHAMPUS Policy in the Federal Register, as follows: ". . .the National Advisory Eye Council (NAEC), the principal advisory body to the National Eye Institute, approved a resolution on May 26, 1980, expressing concern about the widespread adoption of the operation intended to correct nearsightedness called radial keratotomy. The NAEC considers radial keratotomy to be an experimental procedure because of its lack of adequate scientific evaluation in animals and humans. In addition, available research materials are reviewed by the Department of Defense, as well as professional experts consulted, supported this conclusion." The DoD policy publication concluded with the statement that radial keratotomy is an experimental procedure and is excluded in the benefit in the CHAMPUS Basic Program.

## EVIDENCE FURNISHED BY THE BENEFICIARY

At the hearing, the Beneficiary and his sponsor testified credibly that the young man, a senior engineering student at The University of Texas, had a right eye evaluated at 20/200 before the operation, and had an FAA pilot license with a third class physical, which required him to wear glasses for myopia, during the times he was operating an aircraft. After the operation, his vision was evaluated at 20/30, went down to 20/60 and then stabilized at 20/50. He now has a second class airman certificate, which does not require him to wear glasses when he is flying an airplane. Moreover, he has had no adverse effects whatsoever from the surgery, which was performed two years before the hearing. He had made application for a Navy commission as an engineering officer, and the Houston District has recommended that he be granted a waiver on his eyesight because of his having had a radial keratotomy. This application was pending at the time of the hearing.

His sponsor said that the IBM Corporation's health insurance pays for radial keratotomy operations, and considers it a routine procedure. He was unaware of any other insurance companies' decisions of a similar nature. He said he learned of the OCHAMPUS Policy refusing to pay for experimental procedures when the matter was appealed to OCHAMPUS in a First Level Appeal. On cross examination, neither the Beneficiary nor the Sponsor knew of any patients who had undergone such a procedure five or ten years ago and could still see well. Young had read in the AOPA magazine, issued by the Aircraft Owner and Pilot's Association, an article stating that although there was some concern over the procedure, a lot of pilots were having it done, and no adverse effects had resulted. The Federal Air surgeon has not ruled on the merits of the procedure.

They pointed out that Dr. Leslie had been doing the radial keratotomy procedure for several years, having been trained by a physician in New York who learned the procedure in Russia in 1974. Upon a suggestion of the Hearing Officer, both gentlemen agreed to contact Dr. Leslie and request him to furnish any information he had, including professional journal articles, or evaluations of any nature, concerning the procedure. Both of them agreed to do so, and to furnish them to the Hearing Officer, with a copy to Ms. Gray as soon as possible.

On December 5, the Beneficiary forwarded the Hearing Officer the following information: (1) Exhibits 23 and 24, copies of statistical data prepared by Dr. Leslie. Exhibit 23 reflected statistics for 1710 cases at 6 months post-operative follow-up, and Exhibit 24 lists a one-year follow-up of 959 eyes. The statistics quoted are very impressive, indicating that persons with small to medium degrees of myopia up to 8.00 D have benefitted tremendously by the operation, and from 67% to 97% of them could see 20/40 or better a year after the operation. Also furnished as Exhibit 25 is a booklet entitled "Myopia Surgery" prepared by the Austin Eye Associates and Dr. Leslie. The booklet describes the procedure, the level of myopia it is intended to improve, and gives a number of testimonials of patients who have been benefitted by the surgery. On page 13, the paragraph entitled "The Final Analysis" is quoted: