



ASSISTANT SECRETARY OF DEFENSE  
WASHINGTON, D. C. 20301

HEALTH AFFAIRS

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

27 NOV 1984

Appeal of )  
 )  
Sponsor: ) OASD(HA) File 84-29  
 ) FINAL DECISION  
SSN: )

This is the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) in the CHAMPUS Appeal OASD(HA) Case File 84-29 pursuant to 10 U.S.C. 1071-1092 and DoD 6010.8-R, chapter X. The appealing party is the spouse of a retired officer of the United States Air Force and represented herself. The appeal involves the denial of CHAMPUS cost-sharing for injections of Demerol/Sparine and Demerol/Phenergan for treatment of recurrent migraine headaches from April 22, 1981, to August 26, 1982. The amount in dispute is \$2,586.00. The CHAMPUS Fiscal Intermediary initially paid \$1,283.62 of the total \$2,586.00 in claims submitted, but has initiated action to recover the payment as erroneous.

The hearing file of record, the tape of oral testimony and the argument presented at the hearing, 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 charges for the Demerol/Sparine and Demerol/Phenergan injections for the period from April 22, 1981, to August 26, 1982, be denied CHAMPUS cost-sharing. The Hearing Officer found that the use of these substances for treatment of the diagnosed condition of migraine headaches was not medically necessary nor appropriate medical care in that the use of these drugs for migraine headaches is not in keeping with the generally accepted norm for medical practice in the United States. The Hearing Officer, however, found that \$139.00 of the billed charges were for office visits, injections, and laboratory procedures not related to the treatment of the migraine headaches and recommended these claims be cost-shared by CHAMPUS.

The Director, OCHAMPUS, concurs in the Recommended Decision and recommends adoption of the Recommended Decision as the FINAL DECISION. The Assistant Secretary of Defense (Health Affairs), after due consideration of the appeal record, concurs in the recommendation of the Hearing Officer and hereby adopts the recommendation of the Hearing Officer as the FINAL DECISION.

The FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is, therefore, to deny CHAMPUS cost-sharing of the appealing party's claims for injections of Demerol/Sparine and Demerol/Phenergan for the treatment of migraine headaches. This determination is based on findings that: (1) the injections of Demerol/Sparine and Demerol/Phenergan were not medically necessary, and (2) the injections of Demerol/Sparine and Demerol/Phenergan for the treatment of migraine headaches were not appropriate care in that the use of these drugs for a diagnosis of migraine headaches is not in keeping with the generally accepted norm for medical practice in the United States.

#### FACTUAL BACKGROUND

The beneficiary, the spouse of a retired United States Air Force Lieutenant Colonel, had been experiencing migraine headaches since 1968 when the beneficiary suffered a subarachnoid hemorrhage. In the early 1970s the beneficiary began a treatment plan using Valium and/or Demerol, and began using Demerol/Sparine and Demerol/Phenergan in 1979. From April 22, 1981, to August 26, 1982, the beneficiary received 163 injections, which equate to receiving an injection on an average of every 4.5 days.

In my review, I find that the Hearing Officer's Recommended Decision described in detail the beneficiary's medical condition, the events leading to the treatment plans prescribing the use of Demerol/Sparine and Demerol/Phenergan, and the subsequent care received by the beneficiary after August 26, 1982. The Hearing Officer also has provided a detailed summary of the factual background, including the appeals that were made and the previous denials, as well as the medical opinions resulting from medical reviews conducted by the fiscal intermediary and reviewing physicians under the auspices of the Colorado Foundation for Medical Care. Because the Hearing Officer adequately discussed the factual record it would be unduly repetitive to summarize the record, and it is adopted and incorporated in full in this FINAL DECISION.

The hearing was held on March 13, 1984, at Dayton, Ohio, before OCHAMPUS Hearing Officer, Joseph L. Walker. Present at the hearing were the beneficiary and a representative from CHAMPUS. The Hearing Officer has issued his Recommended Decision and issuance of FINAL DECISION is proper.

#### ISSUES AND FINDINGS OF FACT

The primary issue in this appeal is whether the office visits and injections of Demerol/Phenergan and Demerol/Sparine administered by the attending physicians from April 22, 1981, to August 26, 1982, were medically necessary and appropriate medical care for the treatment of migraine headaches as defined by the CHAMPUS regulation, DoD 6010.8-R.

The Hearing Officer, in his Recommended Decision, correctly stated the issues and correctly referenced the applicable law, regulations, and a prior precedential FINAL DECISION in this area (OASD(HA) Case File 22-79) which was issued by this office on June 2, 1980.

The Hearing Officer found that the use of Demerol/Sparine and Demerol/Phenergan injections for the treatment of migraine headaches was not medically necessary and was not appropriate care in that the use of these medications for a diagnosis of migraine headache is not in keeping with the generally accepted norm for medical practice in the United States.

The Hearing Officer recommended that CHAMPUS deny cost-sharing of the Demerol/Sparine and Demerol/Phenergan injections on the grounds that the services were not medically necessary and that these drugs were not provided in accordance with the generally accepted norm for medical practice in the United States. The Hearing Officer, however, recommended that CHAMPUS cost-share \$139.00 of CHAMPUS claims for office visits, injections, and laboratory procedures which were not related to the treatment of migraine headaches, and which represented services otherwise authorized for CHAMPUS cost-sharing. I concur in the Hearing Officer's findings and recommendations. I hereby adopt in full the Hearing Officer's Recommended Decision, including the findings and recommendations, as the FINAL DECISION in this appeal.

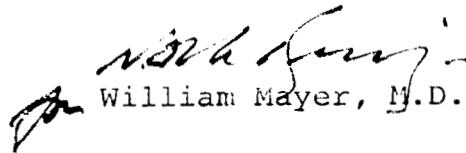
#### Precedential Decisions

In addition to the precedential decision, cited by the Hearing Officer in his Recommended Decision, this office has recently issued a FINAL DECISION (OASD(HA) Case File 84-05) wherein CHAMPUS' cost-sharing of the use of the prescription drugs Nubain and Phenergan was denied for treatment for a diagnosis of migraine headaches on the basis that such treatment was not medically necessary and was inappropriate care in that the use of those drugs for the treatment of migraine headaches was not in keeping with the generally accepted norm for medical practice in the United States. These FINAL DECISIONS have established a precedent and are controlling in the present appeal. No new evidence has been presented by the appealing party which contradicts the previous decisions on this issue.

#### SUMMARY

In summary, the FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) is to deny CHAMPUS cost-sharing of the beneficiary's Demerol/Sparine and Demerol/Phenergan injections and related office visits from April 22, 1981, to August 26, 1982. This decision is based on findings that the use of these medications for the treatment of migraine headaches was not medically necessary and was not appropriate care in that the use of these drugs for the treatment of migraine headaches was not in keeping with the generally accepted norm for medical practice in

the United States. Further, it is FINAL DECISION of the Assistant Secretary of Defense (Health Affairs) to allow CHAMPUS cost-sharing of those office visits, injections, and laboratory procedures not related to the treatment of migraine headaches which the Hearing Officer has determined to be subject to CHAMPUS cost-sharing. Because the record indicates that CHAMPUS has erroneously paid funds for the Demerol/Sparine and Demerol/Phenergan injections and related office visits, the Director, OCHAMPUS, is directed to review this case for appropriate final recoupment action in accordance with the Federal Claims Collection Act. Issuance of this FINAL DECISION completes the administrative appeals process under DoD 6010.8-R, chapter X, and no further administrative appeal is available.

  
William Mayer, M.D.

RECOMMENDED DECISION  
CLAIM FOR CHAMPUS BENEFITS  
CIVILIAN HEALTH AND MEDICAL PROGRAM  
OF THE UNIFORMED SERVICES  
(CHAMPUS)

In The Appeal of:

Beneficiary :

Sponsor : Lt.Col.

Sponsor SSN :

Hearing Date: March 13, 1984

This is the Recommended Decision of CHAMPUS Hearing Officer Joseph L. Walker in the CHAMPUS appeal case file and is authorized pursuant to 10 U.S.C. 1071-1089 and DoD 6010.8-R Chapter X. The appealing party is the beneficiary, the wife of a retired U.S. Army Lieutenant Colonel. The appeal involves the denial of CHAMPUS cost-sharing for office visits and injections rendered in the treatment of recurrent migraine headaches from April 22, 1981, to August 26, 1982.

The Hearing file of record has been reviewed. It is the OCHAMPUS Position that the Formal Review determination, issued August 26, 1983, denying CHAMPUS cost-sharing of the services in question, be upheld on the basis that the services were not provided in accordance with accepted professional medical standards as defined by CHAMPUS Regulation DoD 6010.8-R and are specifically excluded under the Regulation and further that the services have not been shown to have been medically necessary.

The Hearing Officer, after due consideration of the appeal record, concurs in the recommendation of OCHAMPUS to deny CHAMPUS cost-sharing.

## FACTUAL BACKGROUND

During the period April 22, 1981, to August 26, 1982, the beneficiary was under the care and attention of Doctors Berly and Hyde of Yellow Springs, Ohio, for the treatment of recurrent migraine headaches. Treatment consisted of office visits and injections of either Demerol and Sparine, or Demerol and Phenergan. Three claims were submitted to the CHAMPUS fiscal intermediary, Mutual of Omaha Insurance Company, totalling \$2,576.00. In processing the claims, the fiscal intermediary rejected many of the charges but did pay a total of \$1,283.62 to the beneficiary. (Exhibits 1, 2)

On March 3, 1983, Mutual of Omaha reviewed the beneficiary's claims and found that its payments had been improper. A full refund of the \$1,283.62 was requested on the grounds that the office visits "were related to your injections." (Exhibit 8) The beneficiary subsequently requested a review of the intermediary's decision (Exhibit 10), advising that since her cerebral hemorrhage in 1968 she has "fought a continuous battle with severe vascular or migraine headaches" and that "an exhaustive list of medical protocols has been tried without sustained success..." She added that the injections provide "last resort" relief.

Upon review, the fiscal intermediary upheld its earlier decision. (Exhibit 11) On April 14, 1983, the reconsideration decision was released, which again affirmed the decision to deny benefits on the grounds that "...the treatment of a diagnosis of migraine headaches by the continued use of narcotic or addicting substances cannot be justified." (Exhibit 14)

On May 31, 1983, the beneficiary requested review of the matter by OCHAMPUS (Exhibit 18), and subsequently a letter from the attending physician was sent to the agency in support of the appeal. In his letter, the physician stated that the beneficiary "has had a pattern of repeated intense unilateral headaches associated with disabling nausea and generalized malaise." (Exhibit 19) In its investigation of the case, OCHAMPUS obtained a peer review opinion from the Colorado Foundation of Medical Care. It was the reviewing physicians'

opinion that "giving Demerol injections on average every 4.5 days is not appropriate treatment for headaches" and that the treatment plan is not in keeping with the generally acceptable norm for medical practice in the United States." (Exhibit 22) The Formal Review Decision was issued on August 26, 1983, and it was the conclusion of OCHAMPUS that the services were not "appropriate treatment" and were "not medically necessary." (Exhibit 23)

Thereafter, the beneficiary requested a hearing on the matter. Additional evidence was presented in the form of (1) an examination report from the beneficiary's September 27, 1983, visit to the Neurology Clinic, Wright Patterson Air Force Base (Ohio) Medical Center, and (2) a similar report from the beneficiary's October 18, 1983, visit to the Diamond Headache Clinic, Chicago, Illinois.

The hearing was held on March 13, 1984, in Dayton, Ohio, before CHAMPUS Hearing Officer Joseph L. Walker. The beneficiary, \_\_\_\_\_, attended the hearing, as well as Barbara Udelhofen, Attorney/Advisor for OCHAMPUS.

#### ISSUES AND FINDINGS OF FACT

The primary issue in dispute is whether the office visits and injections administered by the attending physicians from April 22, 1981, to August 26, 1982, were medically necessary and represented appropriate medical care, as defined by CHAMPUS Regulation DoD 6010.8-R.

#### Medical Necessity/Appropriate Medical Care

The statutory authority for the payment of certain medical charges can be found in Chapter 55, Title 10, United States Code. Regulation DoD 6010.8-R, promulgated under the authority of and in accordance with the statute, established policy for the worldwide operation of the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS).

A general definition of CHAMPUS, from Chapter IV of the Regulation, is cited in pertinent part herein:

## BASIC PROGRAM BENEFITS

- A. General. The CHAMPUS Basic Program is essentially a Supplemental Program to the Uniformed Services direct medical care system. In many of its aspects, the Basic Program is similar to private medical insurance programs, and is designed to provide financial assistance to CHAMPUS beneficiaries for certain prescribed medical care obtained from civilian sources.
1. Scope of Benefits. Subject to any and all applicable definitions, conditions, limitations, and/or exclusions specified or enumerated in this Regulation, the CHAMPUS Basic Program will pay for medically necessary services and supplies required in the diagnosis and treatment of illness or injury, including maternity care. Benefits include specified medical services and supplies provided to eligible beneficiaries from authorized civilian sources such as hospitals, other authorized institutional providers, physician and other authorized individual professional providers as well as professional ambulance service, prescription drugs, authorized medical supplies and rental of durable equipment.

The Regulation defines the terms "medically necessary" and "appropriate medical care" in Chapter II (Definitions), as follows:

- B.104. Medically Necessary. "Medically Necessary" means the level of services and supplies (that is, frequency, extent, and kinds) adequate for the diagnosis and treatment of illness or injury (including maternity care). Medically necessary includes concept of appropriate medical care.
- B. 14. Appropriate Medical Care. "Appropriate Medical Care" means:
- a. That medical care where the services performed in the treatment of a disease or injury, or in connection with an obstetrical case, 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 and 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.



Additional excerpts from Chapter IV of the Regulation, which are pertinent to the issue, are as follows:

D. Other Benefits.

3. Other Covered Services and Supplies.

f. Prescription Drugs and Medicines. Prescription drugs and medicines which by law of the United States require a physician's or dentist's prescription and which are ordered or prescribed for by a physician or dentist (except that insulin is covered for a known diabetic, even though a prescription may not be required for its purchase) in connection with an otherwise covered condition or treatment, including Rhogam.

(1) Drugs administered by a physician or other authorized individual professional provider as an integral part of a procedure covered under Sections B or C of this CHAPTER IV (such as chemotherapy) are not covered under this Sub-paragraph inasmuch as the benefit for the institutional services or the professional services in connection with the procedure itself also includes the drug used.

(2) CHAMPUS benefits may not be extended for drugs not approved by the Food and Drug Administration for general use by humans (even though approved for testing with humans).

E. Special Benefit Information.

11. Drug Abuse. Under the CHAMPUS Basic Program, benefits may be extended for medically necessary prescription drugs required in the treatment of an illness or injury or in connection with maternity care (refer to Section D of this CHAPTER IV). However, CHAMPUS benefits cannot be authorized to support and/or maintain an existing or potential drug abuse situation, whether or not the drugs (under other circumstances) are eligible for benefit consideration and whether or not obtained by legal means.

a. Limitations on Who Can Prescribe Drugs. CHAMPUS benefits are not available for any drugs prescribed by a member of the beneficiary/patient's family or by a non-family member residing in the same household with the beneficiary/patient (or sponsor). CHAMPUS Contractors are not authorized to make any exception to this restriction.

b. Drug Maintenance Programs Excluded. Drug maintenance programs where one addictive drug is substituted for another on a maintenance basis (such as methadone substituted for heroin) are not covered. Further, this exclusion applies even in areas outside the United States where addictive drugs are legally dispensed by physicians on a maintenance dosage level.

- c. Kinds or Prescription Drugs Which Are Carefully Monitored by CHAMPUS for Possible Abuse Situations.
- (1) Narcotics. Examples are morphine and demerol.
  - (2) Non-Narcotic Analgesics. Examples are Talwin and Darvon.
  - (3) Tranquilizers. Examples are Valium, Librium, and Meproamate.
  - (4) Barbituates. Examples are Seconal and Nembutal.
  - (5) Non-barbiturate Hypnotics. Examples are Doriden and Chloral Hydrate.
  - (6) Stimulants. Examples are Amphetamines and Methedrine.

As stated, it is the position of OCHAMPUS that the services provided the beneficiary during the April 22, 1981 - August 26, 1982, period do not satisfy the criteria specified by the Regulation for medical necessity or appropriateness. Counsel for OCHAMPUS reiterated that position at the hearing, noting that CHAMPUS benefits are limited by the Regulation and that the required conditions for payment have not been met. Further, OCHAMPUS contends that not only was the treatment not appropriate for the diagnosis, but that such prolonged use of Demerol tends to promote or encourage a possible addictive situation.

The beneficiary testified at the hearing that her problems began with a spontaneous subarachnoid hemorrhage for which she was hospitalized for six weeks. Although she had experienced some headaches in the past, (once every three or four months), they became "excruciating" following the incident. Since that time, the beneficiary has attempted multiple drug trials, TENS (transcutaneous electrical nerve stimulation), biofeedback, and treatment at the Diamond Clinic in Chicago. Further, the beneficiary testified that she was the victim of an auto accident in May, 1981, and the headaches worsened. She has also been hospitalized twice for GI bleeding.

Regarding the office visits and injections during the period in question, the beneficiary stated that if her headaches lasted more than three or four hours and if oral medications were ineffective, she would then contact her physician for treatment. She said that the effect of the injection was not immediate - she would go home and stay in a dark room while using an ice pack. In response to questions

posed by the OCHAMPUS attorney, the beneficiary testified that she began treatment via Valium and/or Demoral in the early 1970's, and began the treatment regimen at issue in 1979 upon relocating to Yellow Springs, Ohio. Current treatment at the Diamond Clinic consists of the use of DHE-45 (a self-injected vasodilator) and Dolofine, Verapomil and Doxocaine. The beneficiary stated that she has had only one Demerol injection since November, 1983.

In his post-hearing analysis of this case, the hearing officer noted the existence of a previous Final Decision on the issue of Demerol injections in the treatment of migraine headaches. That decision, rendered by the Principal Deputy Assistant Secretary of Defense (Health Affairs) was issued on June 2, 1980, under the identification OASD(HA) Case File 22-79. It is noted that the primary issue involved "whether the 107 hospital emergency room visits for the purpose of receiving injections of Demerol for relief of migraine headache constituted care which was appropriate, essential and medically necessary and in keeping with generally acceptable norms for medical practice in the United States." In that case, the beneficiary had a long history of migraine headaches which had consistently been treated by injections of Demerol. The beneficiary claimed that other therapies had been unsuccessful. In addition to finding that "the use of Demerol was essentially a palliative measure which did not treat the condition but offered only temporary pain relief" the Final Decision found that "...any long term use of such a potentially addictive drug for a chronic, non-terminal condition must be considered generally inappropriate." Denial of CHAMPUS benefits was upheld on the grounds that the case was inappropriate (not provided in accordance with accepted standards) and that there was indication of a strong potential for drug abuse.

In the present case, the beneficiary has testified that the treatment in question was medically necessary - that it was a "last resort" in obtaining relief from the migraine headaches. The beneficiary has offered no evidence, however, to contradict the principal basis for the denial of CHAMPUS benefits - that the treatment was not appropriate medical care and was not provided in accordance "with the generally acceptable norm for medical practice in the United States."

Regulation DoD 6010.8-R makes clear that the burden of proof in perfecting a claim for CHAMPUS benefits rests with the appealing party (Chapter X, F.16.i.). In light of the expert medical opinion presented in this case by the Colorado Foundation for Medical Care and the Final Decision noted previously, the weight of the evidence supports a conclusion that the charges for Demerol injections for the treatment of migraine headaches were properly rejected on the grounds that the services were not medically necessary or appropriate as defined by the Regulation.

Although the central issue in this appeal has been the Demerol injections, it is noted that the attending physicians' treatments also included Sparine and Phenergan injections, with one or the other injected at the time of each Demerol injection. Although the record reflects little specific discussion about either drug, the hearing officer notes that Sparine (promazine hydrochloride) is used as a major tranquilizer and is generally classified as an antipsychotic drug. As noted earlier, the Regulation instructs CHAMPUS to carefully monitor for possible abuse certain kinds of drugs, one of which is Tranquilizers. The hearing officer is unable to ascertain from the record exactly why Sparine was utilized in the treatment of migraine headaches and what benefit was obtained or expected. Denial of the cost of the Sparine injections is correct in view of the peer review opinion and lack of evidence to support the use of the drug in this case.

Phenergan (promethazine hydrochloride) is classified as an antihistamine and according to the 37th Edition of the Physician's Desk Reference is indicated for the following conditions:

- "1. Amelioration of allergic reactions to blood or plasma.
2. In anaphylaxis as an adjunct to epinephrine and other standard measures after the acute symptoms have been controlled.
3. For other uncomplicated allergic conditions of the immediate type when oral therapy is impossible or contraindicated.
4. Active treatment of motion sickness.
5. Preoperative, postoperative, and obstetric (during labor) sedation.
6. Prevention and control of nausea and vomiting associated with certain types of anesthesia and surgery.
7. As an adjunct to analgesics for the control of postoperative pain.

8. For sedation and relief of apprehension and to produce light sleep from which the patient can be easily aroused.
9. Intravenously in special surgical situations such as repeated bronchoscopy, ophthalmic surgery, and poor-risk patients, with reduced amounts of meperidine or other narcotic analgesic as an adjunct to anesthesia and analgesia."

Again, the hearing officer cannot determine why Pheregan was injected for migraine headaches and cannot establish appropriateness. In point of fact, the Physician's Desk Reference warns that Phenergan "may increase, prolong, or intensify the sedative action of central-nervous-system depressants..." Accordingly, the hearing officer agrees with the peer review opinion that treatment was not appropriate and in keeping with the generally acceptable norm for medical practice.

With respect to the physicians' charges for office visits, it is the OCHAMPUS position that the visits were for the purpose of administering the injections and are therefore excluded under CHAMPUS. For most service dates, the hearing officer would agree. No medical evidence has been brought forth to establish that the beneficiary received any medical services on those occasions other than the injections. A careful review of the record, however, (Exhibit 3) will show that there were seven occasions during the period at issue where the beneficiary had medical problems either instead of or in addition to the migraine headaches that would certainly warrant an office visit to a physician. Those occasions were :

<u>Date</u>	<u>Charge</u>	<u>Diagnosis</u>
May 5, 1981	\$17.00	Abdominal pain and GI hemorrhage
October 8, 1981	\$18.00	URI with headache
November 18, 1981	\$18.00	URI, vomiting, diarrhea
January 3, 1982	\$18.00	Swelling in legs
March 21, 1982	\$18.00	URI with sinusitis
April 11, 1982	\$18.00	Herpes simplex on lips
July 25, 1982	\$18.00	GI cramps

In addition, exhibit 3 shows that in connection with the above-indicated problems, the physicians rendered other services as well:

<u>Date</u>	<u>Charge</u>	<u>Service</u>
May 5, 1981	\$ 6.00	Hemoglobin
May 5, 1981	\$ 5.00	Hematocrit
June 3, 1981	\$ 6.00	Hemoglobin
October 8 & 9, 1981	\$12.00	Penicillin injection X 2
January 11, 1982	\$12.00	Depo-medrol injection
July 25, 1982	\$10.00	Hemocult

It is the hearing officer's opinion that these office services were both medically necessary and appropriate and represent covered CHAMPUS services for the diagnoses stated.

#### SUMMARY

It is the Recommended Decision of the undersigned Hearing Officer that the denial under CHAMPUS of the charges for Demerol, Sparine and Phenergan injections and related office visits (\$2,437.00) in the treatment of migraine headaches from April 22, 1981, to August 26, 1982, was correct on the grounds that the treatment was not medically necessary and was not appropriate medical care as defined by DoD 6010.8-R, II.B.104 and II.B.14. Further, the previously noted office visits, injections, and laboratory procedures not related to treatment of the migraine headaches (\$139.00) represent covered CHAMPUS services and are subject to cost-sharing.

  
Joseph L. Walker  
CHAMPUS Hearing Officer

April 30, 1984

Columbus, Ohio