MINUTES OF THE HUMAN SERVICES COMMITTEE
Friday March 20, 1981

The Human Services Committee convened at 12:30 p.m. on Friday March 20, 1981 in Room 103 of the Capitol with CHAIRMAN BUDD GOULD presiding. All members were present except Representatives SEIFERT and BARDANOUVE.

SB 480
SENATOR Healy opened the hearing on SB480, which was to reestablish the Board of Hearing.

Chairman Gould said that, for purposes of this hearing, the Proponents testifying are to be the hearing aid dispensers (people) and the opponents are to be those who would like to have the bill amended.

SENATOR HEALY stated that he would suggest amending the "exemption" stipulation in the title, and other amendments on page 1, line 13, on page 8, lines 3 through 11, and striking Section 5 entirely.

PROPONENTS:
JOHN SWEENEY, a hearing aid dispenser of Butte, presented written testimony for the committee (EXHIBIT I). He also presented copies of the February 15, 1977 DHEW Federal Register, regarding hearing aid devices. (EXHIBIT II)

ROBERT YUROVICH, a Billings hearing aid dealer, said he had sold hearing aids for 15 years. He said that licensing has been required for the last 12 years. Before, that he told the committee, there were many unscrupulous dealers. The licensing requirement reduced the number of hearing aid dealers from 60 to 30. It has also effected higher quality business practices. He felt the requirement for maintaining an office insured service to the consumer, and felt also that all dealers must be trained. He agreed with the provision that provided for handling complaints.

JIM GOING, a hearing aid dealer in Great Falls, told the committee that he received a degree in audiology in 1967, and that he had worked for the state as an audiologist in the past. He supported the bill but felt that line 12 should be stricken, because he felt that anyone who dispenses hearing aids should have as much training

as possible. He felt that audiologists should not be exempt from licensing as hearing aid dispensers as most universities do not have extensive training in the fitting of hearing aids. He quoted from a periodical of the hearing aid society in which an audiologist said his training was not adequate to fit hearing aids, and that he learned a great deal by trial and error. He also felt the requirement of having an office was to the consumer's advantage. (EXHIBIT III).

ERVIN KING, Billings, presented written testimony (EXHIBIT IV). CECELIA SWEENEY, a hearing aid dispenser in Butte for 26 years distributed written material (EXHIBITS V AND VI to the committee.

MRS. SWEENEY commented that knowledge alone was not enough in fitting hearing aids, but that experience was invaluable. A hearing aid dispenser from Great Falls, BARBARA GOING distributed copies of a booklet entitled DO CLASSROOM CREDIT HOURS ADD UP TO HEARING AID EXPERTISE FOR CLINICAL AUDIOLOGISTS? EXHIBIT VII).

GARY LANGLEY, representing the National Federation of Independent Business, concurs with the bill in its present form.

CHUCK ROLAND, a hearing aid dispenser from Billings, told a joke about strawberries to explain his views of the bill at hand.

CHRIS GROVER, a Helena audiologist who is also a hearing aid dealer, felt that having offices was an advantage to a consumer. He also felt the experience gained taught the dealer a great deal about the fitting of aids. For the reasons stated, he felt that audiologists should be included in the bill.

OPPONENTS:
An audiologist who works for the state DHES, MERLE DE VOE, the Maternal and Child Development Bureau, appeared not as a representative of the department but representing himself. He explained the training an audiologist receives, and told the committee that he worked for a School for the Deaf (children) in Oregon at which most of the 284 children in attendance wore hearing aids.

MR. DEVOE supported the bill, but also supported the proposed amendment exempting audiologists from being licensed. He felt that the idea was for a medical examination to come first, the audiologist to test the hearing and recommend an amplifying device, secondly, and finally, the hearing aid dealer to fit the patient with an aid and give him follow-up care. He disagreed with the requirement for an office. A sound-proof testing room ties an audiologist to a location, since it is not easily moved, so the requirement is not necessary. He also disagreed with the requirement for an audiologist to serve a traineeship under a hearing aid dispenser, saying the audiologist had much more training.

CHRISTIE DECK, President of the Montana Speech, Language Hearing Association, supports the bill with amendments which excludes audiologists who are licensed by the Board of Speech Pathology and Audiology. (EXHIBIT X)

SHIRLEY DE VOE, Chairman of the board of Speech Pathologists and Audiologists, presented written testimony favoring SB480, as amended by the Senate. (EXHIBIT XI)

DARYL MICKEN, audiologist and director of the Montana Easter Seal Society, reviewed legal rights of audiologists in the past. He stated that audiologists have made ear molds for years and are capable of doing so. Training in this area for audiologists is relatively new, but is being done. He referred to page 8, line 20 regarding "fitting". He also called attention to a quorum on the board, and to the traineeship requirement. He felt that dispensers would not want to provide the traineeship to their future competitors.

QUESTIONS FROM THE COMMITTEE:

REP. WINSLOW asked why there was a decrease in the number of dealers if present statute was supposedly "fostering" business. MR. SWEENEY said that the original board "grandfathered" in a lot of dispensers. Some aids were even being sold in drug stores. Unscrupulous dealers were going from town to town selling aids and giving no follow-up service. Consequently, many licenses were revoked, he said.

REP. WINSLOW asked if Healy compared audiologists to traveling hearing aid dealers. HEALY said "that depends". When he started in the business, there were no audiologists. He felt the hearing aid companies and dealers had greatly improved in guality of equipment and care, and that their cost had risen minimally in comparison to other health care costs.

REP. WINSLOW asked Mr. De Voe what his training was as an audiologist. He said there was a 4 year undergraduate course in speech and hearing sciences including anatomy, physiology, rehabilitation, evaluation of hearing and related classes. The fittings of aids was learned partly by experience in working

with the more than 200 children wearing aids at the school in Salem, he said.

REP. WINSLOW asked ROLAND where he learned to fit hearing aids. ROLAND said he was trained in an office and by going to work-shops.

SENATOR HEALY closed the hearing on the bill.

EXECUTIVE SESSION

SB 212.

REP. NILSON moved that SB212 BE CONCURRED IN.

REP. METCALF moved the following amendment (suggested by DHES):

Page 10, lines 19 through 22
Strike: subsection (b) in its entirety
Renumber: subsequent subsection

The amendment was accepted by the committee UNANIMOUSLY.

RUSS JOSEPHSON read 2 suggested amendments to the Statement of Intent.

They were as follows:
1. Statement of Intent, Page 1, line 9.
Following: "Act ("
Strike: "Sects: 75-10-201, et seq. MCA"
Insert: "Title 75, ch. 10, part 2"
2. Statement of Intent, page 2, line 18.
Following: "penalties"
Strike: "for hazardous wastes"

REP. NILSON MOVED THAT SB212, AS AMENDED, BE CONCURRED IN. The motion was seconded and PASSED UNANIMOUSLY.

REP. METCALF was asked to carry the bill.

REP. GOULD announced that the committee members were to be the guests of the Dental Association for lunch on Monday, March 30 at 12 Noon.

The meeting adjourned at 2 p.m.

CHAIRMAN BUDD GOULD

RJ

VISITORS' REGISTER

HOUSE Human Services COMMITTEE

BILL SB 480 Date 3-20-81

SPONSOR Haley

NAME	RESIDENCE	REPRESENTING	SUPPORT	OPPOSE
Shirley DeVoe	Helena	Bd So. Path + Aud	✓	
Christel Deck	Great Falls	Mt Speech Lang Hearing Assoc	✓	
Mark Kelly	418 Butler	Self		✓
Lavina King	Billings	Self.	✓	
Robert Jurovich	Billings	Hearing Aid Dealer	✓	
[illegible]	Butte	Hearing Aid [illegible]	✓	
[illegible]	Butte	[illegible]	✓	
Jim & Barbara Haug	Great Falls.	Hearing Aid Office	✓	
[illegible]	Helena	Hearing Aid Office	✓	

IF YOU CARE TO WRITE COMMENTS, ASK SECRETARY FOR LONGER FORM.

PLEASE LEAVE PREPARED STATEMENT WITH SECRETARY.

WITNESS STATEMENT

NAME _____ BILL No. 455

ADDRESS 8662 Elk Butte MT DATE 2-20-91

WHOM DO YOU REPRESENT _____

SUPPORT V with Am OPPOSE _____ AMEND Emphasis

PLEASE LEAVE PREPARED STATEMENT WITH SECRETARY.

Comments: from Stevens of Helena

FORM CS-34
1-81

By John Sweeney

Mr. Chairman, I first want to thank you for your courtesy in arranging this date for the hearing so we as business people could attend.

Mr. Chairman, ladies and gentlemen:

As Mr. Healy explained to you we are disturbed by the addition to the bill which was made in the Senate on 3rd reading, and we feel the amendment now being introduced is very critical to this bill to allow Montana to be in compliance with the Federal Rules and Regulations of the Food and Drug Administration.

To show you what we mean, I would like to quote several passages from "Hearing Aid Devices, Professional and Patient labeling and conditions for Sale", printed in the Federal Register Tuesday, Feb. 15, 1977, part IV. I will include a marked copy of this with my copy of the testimony.

Page 9287--1st column

"The Commissioner notes also that the hearings before the Senate Permanent Subcommittee on Investigations of the Hearing Aid Industry (REF 15) produced testimony that the competency and training of hearing health professionals, whether physicians, audiologists, or hearing aid dispensers was of utmost importance to the delivery of quality hearing aid health care services. The Commissioner notes, however, that the Federal Food, Drug, and Cosmetic Act regulates the safety, effectiveness, and labeling of the hearing aid itself. State and local licensing laws, as administered by State and local agencies are the appropriate legal mechanisms for establishing minimum competency standards for the practice of a health profession or related activity. A major purpose of such licensing laws is to establish standards for the various activities within their purview and to exclude from activities those persons who will not, or cannot, conform to these standards. Such licensing statutes thereby protect the public against unfit and inept practitioners in the health professions and other occupations affecting the public health and safety."

Page 9287--bottom of middle column, top of 3rd column

"The Commissioner rejects the contention that hearing aid dispensers should not be included in a characterization of the hearing health care team. The various services provided by hearing aid dispensers, such as testing hearing for selecting and fitting hearing aids, motivating prospective users to try amplification making impressions for ear molds, selecting and fitting hearing aids, counseling hearing-impaired persons on adapting to a hearing aid, and repairing damaged hearing aids are regarded by many of the hearing impaired as indispensable to their welfare. Many hearing aid users wrote to FDA supporting this position. Many hearing aid users emphasized that hearing aid dispensers were readily accessible for essential services such as repair work. Great importance was attached to the fact that the hearing aid dispenser operated from a place of business that was near to the hearing aid user and also that hearing aid dispensers typically did not require an appointment for services."

Page 9288--3rd column

Comments on the proposed regulation expressed a wide diversity of opinion as to the reliability of audiological tesing in predicting to a certainty whether or not a patient may benefit from a hearing aid. The American Council of Otolaryngology (ACO) stated that it was unable to find evidence to support the contention that audiological testing procedures will predict a patients acceptance of a hearing aid device. It was pointed out by ACO that the terms "acceptance, benefit and satisfaction" when applied to hearing aids often involved a subjective response by the patient."

Page 9288--bottom of 3rd column , page 9289 top of first column
"After reviewing all the conflicting information in the public record regarding the predictive value of audiological testing in determining whether or not a patient will benefit from a hearing aid, the Commissioner has concluded that a requirement that a patient obtain certain mandatory audiological tests from an audiologist is not appropriate at this time. The Commissioner has concluded that the record does not justify requiring mandatory audiological evaluation to determine hearing aid candidacy or patient benefit from the use of amplification. Mandatory audiological evaluation would create an additional barrier to the receipt of a hearing aid device in those areas of the country where audiological services are scarce. Such a requirement also would increase the cost of obtaining a hearing aid without providing any conclusive assurance that the patient would benefit from amplification."

Page 9289, bottom of second column, top of third column
"Ten comments suggested that the definition of "seller" should be changed to indicate clearly that it applies to anyone who dispenses a hearing aid to a member of the consuming public. These comments pointed out that in addition to the hearing aid dealer, many physicians and audiologists dispense hearing aids.

The Commissioner agrees with these comments. The regulations are necessary to protect the consumer regardless of who dispenses the hearing aid device. The term "seller" is therefore changed to "dispenser" wherever appropriate in the regulation."

Page 9294, 3rd column
"(3) "Dispenser" means any person, partnership, corporation, or association engaged in the sale, lease, or rental of hearing aids to any member of the consuming public or any employee, agent, sales person, and/or representative of such a person, partnership, corporation, or association."

Therefore, Mr. Chairman, ladies and gentlemen, we feel that any person who comes under the above definition of Dispenser in the FDA rules must be included under this bill with no exceptions.

Thank you for your kind attention.

federal register

TUESDAY, FEBRUARY 15, 1977

PART IV

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

HEARING AID DEVICES

Professional and Patient Labeling and Conditions For Sale

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER H—MEDICAL DEVICES

[Docket No. 76N-0019]

PART 801—HEARING AID DEVICES

Professional and Patent Labeling and Conditions for Sale

The Food and Drug Administration (FDA) is establishing uniform professional and patient labeling requirements and conditions for sale of hearing aid devices. The regulations prescribe the types of information that must be included in the labeling to provide hearing health professionals and patients with adequate directions for the safe and effective use of a hearing aid; specify the technical performance data that must be included in the labeling to ensure that hearing health professionals have adequate information to select, fit, and repair a hearing aid for a patient; and restrict the sale of a hearing aid to those patients who have undergone medical evaluation within the past 6 months, but with a provision that fully informed adult patients (18 years of age or older) may waive the medical evaluation because of personal or religious beliefs. These regulations shall become effective August 15, 1977.

In the FEDERAL REGISTER of April 21, 1976 (41 FR 16756), the Commissioner of Food and Drugs proposed to amend Chapter I of Title 21 of the Code of Federal Regulations by adding new §§ 801.420 and 801.421 to establish professional and patient labeling and conditions for sale for hearing aid devices, referred to hereinafter as hearing aids. Interested persons were given until June 21, 1976 to submit written comments, suggestions or objections. Approximately 500 comments were received from consumers, consumer groups, hearing aid dispensers, trade associations, manufacturers, audiologists, physicians, and government agencies.

The following text contains pertinent background information and a summary of the comments received on the proposal, as well as the Commissioner's evaluation of and response to the comments:

The preamble to the proposed regulation contained a section entitled "Background," which summarized the activities of consumer groups, Congress, and the Department of Health, Education, and Welfare (HEW) that have identified problems in the present hearing aid health delivery system. The "Background" section in the proposal failed, however, to reference the efforts of two Congressional committees that held open hearings on the hearing aid health care delivery system. In May of 1975, the Subcommittee on Government Regulations of the Select Committee on Small Business, United States Senate, chaired by Senator Thomas J. McIntyre, held hearings on economic problems in the hearing aid industry (Ref. 14). The subcommittee investigated matters such as competition, prices, advertising and marketing practices, research and development, government purchasing and reimbursement, the role of small business, and in general, how the hearing aid industry has responded to the needs of the hearing impaired. In April of 1976 the Senate Permanent Subcommittee on Investigations, chaired by Senator Charles H. Percy, also held hearings on the hearing aid industry. These hearings reconfirmed that many hearing-impaired consumers do not obtain a medical evaluation of their hearing impairment before purchasing a hearing aid. Senator Percy, in closing the hearings, stated that "Twenty million hearing-impaired Americans are being denied top-fight treatment by a delivery system that simply is not working" (Ref. 15). As a result of testimony presented at these hearings, Senator Percy recommended that FDA promulgate regulations that would restrict the sale of hearing aids to those patients who have undergone a medical evaluation.

FEDERAL TRADE COMMISSION ACTIVITIES AFFECTING THE HEARING AID INDUSTRY

The Federal Trade Commission (FTC) also has been studying the hearing aid health care delivery system to determine what steps should be taken to protect consumers from unfair or deceptive acts or practices in the sale of hearing aids. In the FEDERAL REGISTER of June 24, 1975 (40 FR 26646), the FTC published an "initial notice" of a proposed trade regulation rule for the hearing aid industry. The rule making record was closed on October 22, 1976. The reports of the presiding officer and the FTC staff concerning the proposed rule are now being prepared.

The essential provisions of the FTC proposed rule are: (1) A requirement that every hearing aid buyer (with certain exceptions) be given the right to cancel the purchase for any reason any time within 30 calendar days of delivery and receive a refund of most of the purchase price (in effect, a mandatory trial rental period); (2) a requirement that sellers of hearing aids obtain prior express written consent to a sales visit in the buyer's home or office; (3) a prohibition of certain other selling techniques; (4) a prohibition of certain representations concerning hearing aid sellers; (5) a prohibition of certain representations concerning hearing aids; and (6) requirements that certain advertising representations be qualified.

Subsequent to the publication of the FTC proposed rule, the Medical Device Amendments of 1976 (Pub. L. 94-295) became law on May 28, 1976. The Amendments added new paragraph (r) to section 502 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 352(r)), which provides that a restricted device will be deemed to be misbranded unless all advertisements and other descriptive matter with respect to it (1) bear the device's established name, (2) include a brief statement of the intended uses of the device, relevant warnings, precautions, side effects, and contraindications, and (3) in instances in which it is necessary to protect the public health, include a description of the components of the device or its formula. Section 502(r) further provides that an advertisement for a restricted device shall not, with respect to matters covered by section 502(r) or covered by regulations issued under that section, be subject to the provisions of sections 12 through 15 of the Federal Trade Commission Act (15 U.S.C. 52 through 55), as that act relates to the dissemination of false advertisements for devices. (Section 502(r) of the act closely parallels section 502(n) of the act (21 U.S.C. 352(n)), relating to prescription drugs.)

Section 502(r) gives FDA jurisdiction for regulating certain specified advertising of restricted devices, and the section concurrently removes FTC authority to apply the sanctions of court injunction or criminal penalties under sections 12 through 15 of the Federal Trade Commission Act to prevent these acts. It is the Commissioner's opinion, however, that section 502(r) limits FTC authority only to the extent specifically stated in the section, i.e., section 502(r) applies only to restricted devices and only to possible FTC use of court injunctions or criminal penalties to prevent false advertising relating to the items of information specified in section 502(r). Moreover, section 502(r) does not extend to, or in any way limit, any other authority of FTC related to the regulation of the sale of devices, such as the authority provided to FTC under section 5 of the Federal Trade Commission Act (5 U.S.C. 45) to prevent unfair or deceptive acts or practices.

In sum, it is the Commissioner's opinion that the net effect of section 502(r), as of the comparable provision under section 502(n) relating to prescription drugs, is to enable each agency to approach the regulation of restricted devices from the perspective of its particular statutory mandate. It is also the Commissioner's belief that both agencies will continue, as they have in the past, to work together in pursuit of their separate but closely related mandates. The Food and Drug Administration has long been aware of the FTC activities in the regulation of hearing aids that led to the FTC proposed rule, and the Commissioner believes these activities complement, rather than conflict with, this FDA regulation relating to labeling and conditions of sale of hearing aids. The Commissioner generally supports the FTC proposed rule and believes that the matters addressed therein are particularly within the FTC statutory mandate and expertise.

GENERAL COMMENTS ON THE PROPOSED REGULATIONS

Many comments on the proposed regulations asserted that the proposal did not adequately deal with several major concerns about the present hearing aid health care delivery system. The inadequacy or absence of State licensing laws in requiring minimum competency standards for persons who dispense hearing aids was often mentioned in the comments.

The Commissioner recognizes that the professional and patient labeling regulations and restrictions on the sale of hearing aids are only a partial solution to the problems in the hearing aid health care delivery system, and that these regulations do not address the adequacy of existing State licensing laws that control the dispensing of hearing aids. The Commissioner notes also that the hearings before the Senate Permanent Subcommittee on Investigations of the Hearing Aid Industry (Ref. 15) produced testimony that the competency and training of hearing health professionals, whether physicians, audiologists, or hearing aid dispensers, was of utmost importance to the delivery of quality hearing aid health care services. The Commissioner notes, however, that the Federal Food, Drug, and Cosmetic Act regulates the safety, effectiveness, and labeling of the hearing aid itself. State and local licensing laws, as administered by State and local agencies, are the appropriate legal mechanisms for establishing minimum competency standards for the practice of a health profession or related activity. A major purpose of such licensing laws is to establish standards for the various activities within their purview and to exclude from activities those persons who will not, or cannot, conform to these standards. Such licensing statutes thereby protect the public against unfit and inept practitioners in the health professions and other occupations affecting the public health and safety.

The Commissioner is aware of the efforts of the American Speech and Hearing Association, the National Hearing Aid Society, and other professional organizations to develop minimum competency standards for testing hearing loss for the purpose of selecting and fitting hearing aids. These programs often lead to certificates of competency from the sponsoring organization and often require participation in a continuing education program to maintain the certificates of competency. A shortcoming of such an approach is that these certification programs apply only to the members of the organization. Where State licensing laws are weak or nonexistent, a person dispensing hearing aids can ignore the certification program by not participating in the professional association.

The Comissioner therefore believes that strong State and local licensing laws are needed to establish and maintain minimum competency requirements for those persons who test for hearing loss and select and fit hearing aids. The Commissioner notes, however, that the establishment of such licensing laws is primarily the responsibility of State and local officials.

There were many comments that the proposed regulations provided no relief from the high cost of hearing aids. Moreover, many comments expressed concern that the regulations would add to the cost of hearing aids. The Commissioner notes also that both the Senate hearings and the HEW Intradepartmental Task Force produced testimony that suggested that many elderly Americans do not have hearing aids because of their high cost.

Although FDA does not have any direct control over the price of hearing aids, the Commissioner recognizes that ill-conceived and unnecessary regulations could cause the price of hearing aids to rise, thus creating an additional barrier to the receipt of quality hearing aid health care services. For this reason, FDA has judiciously exercised its rulemaking authority to provide for minimal Federal intervention consistent with essential protection of the public health in the delivery of hearing aid health care services. This approach recognizes the limitations of FDA statutory authority in dealing with such factors as the cost of a hearing aid and the inadequacy or absence of State licensing laws.

The Commissioner also recognizes that personal motivation often plays a major role in determining whether a person who has a hearing impairment will seek assistance. Information collected by the HEW Intradepartmental Task Force on Hearing Aids indicates that an estimated 10 million hearing-impaired persons have not received medical attention to assess their hearing loss and to determine what steps, if any, can be taken to improve their hearing (Ref. 4). The Commissioner believes that it is of paramount importance that any FDA regulations intended to protect the health and safety of the hearing impaired be positive in orientation and not create unnecessary economic or psychological barriers to the receipt of quality hearing aid health care. For these reasons, the FDA regulations have been developed in full awareness of the FTC proposed trade regulation rule for the hearing aid industry, and duplication of effort has been avoided.

A section in the preamble to the FDA proposed regulations entitled "Hearing Health Care Team" drew many comments from audiologists. In general, the audiologists objected to wording in this section, which identified hearing aid specialists or dealers (hearing aid dispensers) as hearing health professionals and legitimate members of the hearing health care team. Many audiologists stated that it was inaccurate to recognize hearing aid dispensing as a profession because many hearing aid dispensers have little academic training.

The Commissioner rejects the contention that hearing aid dispensers should not be included in a characterization of the hearing health care team. The various services provided by hearing aid dispensers, such as testing hearing for selecting and fitting hearing aids, motivating prospective users to try amplification, making impressions for ear molds, selecting and fitting hearing aids, counseling hearing-impaired persons on adapting to a hearing aid, and repairing damaged hearing aids are regarded by many of the hearing impaired as indispensable to their welfare. Many hearing aid users wrote to FDA supporting this position. Many hearing aid users emphasized that hearing aid dispensers were readily accessible for essential services such as repair work. Great importance was attached to the fact that the hearing aid dispenser operated from a place of business that was near to the hearing aid user and also that hearing aid dispensers typically did not require an appointment for services.

The Commissioner recognizes that the accessibility of hearing aid services is of great importance to the quality of hearing aid health care services. The hearing aid dispenser is the most accessible member of the hearing aid health care team, and the hearing aid dispenser sees the hearing-impaired person with greater frequency than either the physician or the audiologist. For these reasons the Commissioner regards the hearing aid dispenser as an important member of the hearing health care team, strategically positioned within the delivery system to provide the hearing aid user with essential services.

The Commissioner has concluded, however, that necessary improvements in the quality of hearing aid health care services depend largely on hearing aid dispensers recognizing their obligation to achieve greater competency in testing hearing in order properly to select and fit a hearing aid. Although many hearing aid dispensers already have obtained specialized training in hearing aid evaluation from hearing aid manufacturers and have completed formal academic programs in the selection and fitting of hearing aids, other hearing aid dispensers need additional training.

The Commissioner sees no value in characterizing hearing aid dispensers solely as "sales persons," or in minimizing the importance of "selling" as it relates to motivating persons to try amplification. Often a person with a hearing impairment lacks the motivation to try a hearing aid or believes a social stigma is attached to wearing a hearing aid (Ref. 4). Although there are a number of documented cases of excessive and abusive sales practices, this is not to say that some selling practices and techniques such as a trial-rental or purchase-option plan, which strengthen motivation to try a hearing aid, are inherently bad. When the number of hearing-impaired persons who currently wear hearing aids is contrasted with the number of people in the United States with a hearing impairment who could be helped by a hearing aid, it is clear that many people are reluctant to acknowledge their hearing impairment or to seek assistance. Ethical selling practices that provide the potential hearing aid user with incentives to try a hearing aid are therefore to be encouraged.

A majority of the comments addressed the medical evaluation provision of the proposed regulation, which required as a condition of sale that a person with hearing impairment obtain a medical evaluation from a physician, preferably an ear specialist, before buying a hearing aid.

The Commissioner has concluded, after consideration of these comments, that good hearing health care practice requires that persons with hearing loss have a medical evaluation by a licensed physician (preferably a physician who spe-

cializes in diseases of the ear) prior to the purchase of a hearing aid. The medical evaluation by the physician is necessary in determining the cause of, and the pathology associated with, the patient's hearing loss. Such a medical evaluation often includes an interpretation of a medical history, a physical examination, laboratory studies, X-ray studies, and, in some instances, a hearing test.

The Commissioner agrees with the American Council of Otolaryngology and other physicians who commented that the recognition of an organic cause for hearing impairment is of extreme importance to the health and safety of the hearing-impaired patient. The American Council of Otolaryngology pointed out that some of the causes for sensorineural hearing loss include conditions such as brain tumor, syphilis, endocrine disorder, collagen diseases, and endolymphatic hydrops. Accordingly, the final regulation continues to require as a condition for sale, that a person, as a general rule, have obtained a medical evaluation from a licensed physician within the preceding 6 months before he is sold a hearing aid. The Commissioner has determined that the medical evaluation is necessary to protect the health and safety of hearing-impaired patients because patients, audiologists, and hearing aid dispensers are unable to differentiate, diagnose, evaluate, and treat the medical cause or causes of a hearing impairment.

The Commissioner emphasizes, however, that the primary health concern underlying the medical evaluation requirement is not immediately related to any direct risk to a user from the hearing aid itself; rather, the medical evaluation requirement is based upon the recognition that an unnecessary or partially effective hearing aid device may be substituted for primary medical or surgical treatment, thus depriving the hearing-impaired patient of benefit of appropriate medical diagnosis and care and resulting in a detriment to health. In addition to delaying proper medical diagnosis and possibly reducing the efficacy of the correct treatment, purchase of a hearing aid device that may not achieve its intended effect involves a high and unnecessary cost to the patient.

A number of comments indicated that there is some confusion about the purpose of the medical evaluation requirement in the proposed regulation. Simply stated, the purpose of the medical evaluation by a licensed physician is to assure that all medically treatable conditions that may affect hearing are accurately identified and properly treated before a hearing aid is bought. It should be emphasized that the medical evaluation requirement does not require the physician to prescribe, recommend, or certify that a patient may be helped by a hearing aid. The provision simply requires that the physician provide the patient with a written statement indicating that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid.

The Commissioner notes that a hearing aid device is not an inherently dangerous device and that the number of persons who will in fact require a medical or surgical treatment is relatively small in comparison to the number of individuals who may benefit from amplification. For this reason, FDA has attempted to design the medical evaluation requirement to reflect the practical and logistical problems of medical evaluation, the availability of licensed physicians, the mobility of the hearing impaired, and the personal and religious beliefs of those persons who refuse to consult with physicians.

Several consumers wrote that since the hearing impaired patient is paying for the hearing aid and subsequent services, any medical evaluation requirement is ultimately an infringement of individual rights. These persons emphasized that currently it is a personal decision whether or not to see a physician. Other consumers objected to a medical evaluation on the basis of philosophical and political grounds, expressing the preference for freedom of choice. Other consumers indicated that a mandatory medical evaluation requirement would impose serious hardships in obtaining the services of a physician, particularly an ear specialist. The National Hearing Aid Society and a number of consumers felt that the medical evaluation requirement should be mandatory only before the fitting of the first hearing aid. They contended that this approach would assure adequate attention to the medical needs of the hearing-impaired person while promoting convenience, economy, and efficiency in the hearing aid health care delivery system.

In view of these comments, the Commissioner has concluded that the final regulation should contain provisions that would enable a fully informed adult to waive the medical evaluation. But, because the Commissioner believes that the exercise of such a waiver of medical evaluation is not in the best health interest of the patient, the opportunity for waiver is limited to fully informed adult patients. The final regulation prohibits any hearing aid dispenser from actively encouraging a prospective user to waive a medical evaluation.

Under proposed § 801.421(a)(3) a waiver of the medical evaluation would not have been permitted where it was evident to the dispenser after inquiry, actual observation, and review of any available information concerning the prospective user, that the prospective hearing aid user had any of seven designated otologic conditions at the time of sale. Because these otologic conditions may indicate that the hearing loss is symptomatic of a more serious medical dysfunction, and that other treatment is needed, the proposed regulation would have prohibited a dispenser from selling a hearing aid to a prospective user if any of these otologic conditions were evident.

The Commissioner is concerned that a hearing aid user would interpret the absence of these seven designated otologic conditions as a justifiable reason for ignoring the required medical evaluation. The Commissioner is also concerned that undue importance has been attached to the seven designated otologic conditions by incorporating these conditions into the waiver provision. In the proposed regulation, the seven designated otologic conditions were to serve as screening criteria for the hearing aid dispenser to use in determining whether the prospective hearing aid user could exercise the waiver to the medical evaluation requirement. The Commissioner has concluded that the health interest of the prospective user would be best served by obtaining a medical evaluation from a licensed physician before purchasing a hearing aid. A prospective user should not be misled into thinking that the absence of any of the seven otologic conditions indicates that there is no need to obtain a medical evaluation.

The Commissioner believes, however, that the designated otologic conditions continue to serve as useful warning signals or "red flags." Accordingly, reference to the presence of any of the designated otologic conditions has been moved to a new section of the User Instructional Brochure, entitled "Warning to Hearing Aid Dispenser." This new provision requires a hearing aid dispenser to advise a prospective hearing aid user to consult promptly with a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid if the hearing aid dispenser determines through inquiry, actual observation, or review of any other available information, that the prospective user has any of the designated otologic conditions. The complete text of the "Warning to Hearing Aid Dispenser" is also required to appear in the User Instructional Brochure to inform prospective users, as well as the dispenser, of the necessity to consult a physician if any of the designated otologic conditions are evident.

The American Speech and Hearing Association and many audiologists commented that a mandatory audiological evaluation by an audiologist should be required by Federal regulation as a condition for sale of a hearing aid. Comments on the proposed regulation expressed a wide diversity of opinion as to the reliability of audiological testing in predicting to a certainty whether or not a patient may benefit from a hearing aid. The American Council of Otolaryngology (ACO) stated that it was unable to find evidence to support the contention that audiological testing procedures will predict a patient's acceptance of a hearing aid device. It was pointed out by ACO that the terms "acceptance, benefit and satisfaction" when applied to hearing aids often involved a subjective response by the patient.

After reviewing all the conflicting information in the public record regarding the predictive value of audiological testing in determining whether or not a patient will benefit from a hearing aid, the Commissioner has concluded that a requirement that a patient obtain certain

mandatory audiological tests from an audiologist is not appropriate at this time. The Commissioner has concluded that the record does not justify requiring mandatory audiological evaluation to determine hearing aid candidacy or patient benefit from the use of amplification. Mandatory audiological evaluation would create an additional barrier to the receipt of a hearing aid device in those areas of the country where audiological services are scarce. Such a requirement also would increase the cost of obtaining a hearing aid without providing any conclusive assurance that the patient would benefit from amplification.

Because of the difficulty of determining in advance whether an individual will benefit from a hearing aid, FDA supports the requirement of a trial-rental or purchase option plan embodied in the FTC proposed rule, which will afford every prospective hearing aid user the opportunity to wear the selected hearing aid in a variety of uses during which the hearing-impaired user can make an informed judgment on whether a benefit is obtained from the use of amplification. The Commissioner believes that in the final analysis the hearing aid user is the person best qualified to determine whether or not a hearing aid is useful and efficacious for its intended purpose. A trial-rental option is better than mandatory audiological tests in determining patient benefit from amplification.

The Commissioner is aware that the FTC proposed rule requiring a mandatory trial-rental period will not be promulgated for some time. But the National Hearing Aid Society and several hearing aid manufacturers have adopted voluntary trial-rental or purchase-option programs for prospective hearing aid users. The Commissioner believes that these voluntary actions are important enough to the welfare of the hearing impaired to require that the User Instructional Brochure contain information advising prospective hearing aid users to inquire about the availability of a trial-rental or purchase-option program. In addition to helping to assure that the selected aid or aids will be beneficial, such a requirement will encourage hearing aid use among those prospective hearing aid users who lack the motivation to try a hearing aid because of the fear that they will spend a great deal of money with no guarantee of benefit.

Although the final regulation does not require a mandatory audiological evaluation as a condition for sale of a hearing aid, the Commissioner recognizes that the audiologist is an important member of the hearing health care team, qualified by academic and clinical training to assist in the prevention, identification, evaluation, and rehabilitation of persons with auditory disorders that impede or prevent the reception and perception of speech and other acoustic signals. In addition to basic audiometric evaluation, audiologists may provide hearing aid orientation, auditory training, speech reading, speech conservation, language development, and counseling and guidance services. The audiologist often provides health related services to children and adults with such identifiable disorders as receptive and/or expressive language impairment, stuttering, chronic voice disorders, and serious articulation problems affecting social, emotional and vocational achievement, and speech and language disorders accompanying conditions of hearing loss, cleft palate, cerebral palsy, mental retardation, emotional disturbance, multiple handicapping conditions, and other sensory and health impairments.

Because hearing loss may impede or prevent the reception and perception of speech and other acoustic signals, the Commissioner is requiring that the User Instructional Brochure contain advice that a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation. The Commissioner expects that the physician, in conducting the medical evaluation of a patient, will determine whether the patient's hearing loss or speech impairment will require the consultation of an audiologist. Notwithstanding this fact, the Commissioner has concluded that the User Instructional Brochure should contain special reference to the need for audiological consultation when the person experiencing the hearing impairment is a child.

RESPONSES TO SPECIFIC COMMENTS

1. Three comments suggested that in the definition of "hearing aid" the word "designated" should be changed to "designed" so as to conform to the definition in the regulations proposed by FTC.

The Commissioner agrees with these comments and the change is made. The Commissioner notes that the definition for "hearing aid" as used in the regulation, includes over-the-ear, in-the-ear, eyeglass, and on-the-body type air-conduction hearing aids.

One comment noted that group auditory trainers, defined as a group amplification system purchased by a qualified school or institution for the purpose of communicating with or educating individuals with hearing impairments, would fall under the definition of "hearing aid" as used in the proposal. The comment further noted that it would be inappropriate to apply the proposed conditions for sale for hearing aid devices to group auditory trainers.

The Commissioner agrees with this comment and a change is made in the regulation so that the normal conditions for sale requirements do not apply to this special type of hearing aid.

2. Ten comments suggested that the definition of "seller" should be changed to indicate clearly that it applies to anyone who dispenses a hearing aid to a member of the consuming public. These comments pointed out that in addition to the hearing aid dealer, many physicians and audiologists dispense hearing aids.

The Commissioner agrees with these comments. The regulations are necessary to protect the consumer regardless of who dispenses the hearing aid device. The term "seller" is therefore changed to "dispenser" wherever appropriate in the regulation.

3. Two comments said that "sale" or "purchase" should not be applied to the lease or rental of a hearing aid because such transactions are substantially different from a sale or purchase in that the title to the hearing aid device remains with the lessor.

Although "sale" or "purchase" and "lease" or "rental" may be substantially different terms in business and legal effect, the Commissioner has determined that they should be treated in the same manner for the purposes of this regulation. Medical evaluation, the User Instructional Brochure, and the required notices to the prospective purchaser are all equally necessary to protect the consumer whether the transaction is in the form of a sale or lease or rental. Accordingly, these comments are rejected.

4. Seven comments suggested that "otolaryngologist" (ear specialist) and "audiologist" should be definited to clarify their roles in the hearing aid delivery system.

The Commissioner agrees with these comments and definitions of "audiologist" and "ear specialist" have been included in the regulation.

5. One comment suggested that the term "used hearing aid" should be defined, since the hearing aid dispenser must designate a "used hearing aid" as such. This comment pointed out that it may not be clear at what point a hearing aid becomes a "used hearing aid."

The Commissioner agrees with this comment and defines "used hearing aid" in the final regulation. The FTC proposed rule also requires that a "used hearing aid" be designated as such. The Commissioner believes that there should be conformity in this area and is adopting the definition included in the FTC proposed rule.

6. Various comments addressed the proposed labeling required to be placed on the hearing aid device, which included the name of the manufacturer or distributor, the model name, the serial number, and the month and year of manufacture. Five comments suggested that the information required would not fit on some of the smaller hearing aid units. Eight comments noted that the year of manufacture is irrelevant in that hearing aid models are not changed every year and therefore the fact that a hearing aid was manufactured in a previous year does not indicate that it is not the latest model. One of these comments further noted that the month of manufacture is certainly irrelevant. Four comments suggested that including the month and year of manufacture on hearing aids would cause inventory problems for manufacturers and dispensers because dispensers would be unwilling to order in advance, fearing that the hearing aids would remain on their shelves for some time and that customers would consider them outdated.

The preamble to the proposed regulation stated that this information was required to be placed on hearing aids for several reasons: To assure that the hear-

ing aid is adequately identified for quality control and repair, to identify the hearing aid in the event that a product defect warrants recall of the device, and to protect prospective users from false and misleading claims concerning the newness of the device. The Commissioner believes that these reasons are still persuasive, but he does believe that some adjustments can be made to mitigate some of the problems noted by the comments. The requirement that the model name be marked on the hearing aid is changed to "model name or number." This may ease the problem of including all this information on the smaller hearing aid units. The final regulation is also being changed to require that only the year, and not the month, of manufacture be marked on the hearing aid. Requiring that the month as well as the year of manufacture be marked on the hearing aid adds little to the solution of the problems necessitating this requirement, and omitting the requirement will reduce the amount of information to be included on the smaller hearing aids.

7. About the requirement that hearing aids be marked with a "+" symbol to indicate the positive connection for battery insertion, one comment suggested that FDA should require that all hearing aids be manufactured so that it is physically impossible to insert the battery in the reversed position.

Such a requirement would be of little value to the hearing aid user and would require a major redesign of many hearing aids, thus increasing the cost of hearing aids. The comment is therefore ejected.

8. Five comments said that the requirement that the User Instructional Brochure contain an illustration of the hearing aid adjustments should be modified to require that only user adjustments be illustrated. These comments pointed out that users would otherwise make adjustments which only qualified individuals should make and this would cause unnecessary problems in the use of the aid.

The Commissioner agrees with these comments and the change is made accordingly.

9. Three comments said that it would be very difficult to compile a complete list of suitable replacement batteries for inclusion in the User Instructional Brochure, as required by the proposed regulation, and that it would be better to require only a generic designation of replacement batteries.

The Commissioner agrees with these comments and the change is made.

10. Four comments said it would be impossible to list all repair facilities, as required by the proposed regulation.

The Commissioner agrees that it would be difficult to list all repair facilities and feels that a more general statement is desirable. As a result, the final regulation requires that the User Instructional Brochure contain information regarding how and where to obtain repair service, including a specific address, or addresses, where the user can go or send the hearing aid to have the repair done.

11. Three comments said the requirement that the User Instructional Brochure contain a description of environmental conditions that the hearing aid user may reasonably encounter that could adversely affect the hearing aid is vague.

The Commissioner agrees with these comments and the requirement is rewritten to provide examples of such conditions. The User Instructional Brochure is now required to include only commonly occurring avoidable conditions that could adversely affect or damage the hearing aid.

12. Twenty-nine comments said that the proposal did not include several side effects from hearing aid use that may warrant consulting with a physician, and that should be included in the User Instructional Brochure. These include tinnitus, headaches, dizziness, pain in the ear, acoustic trauma, feeling of blockage, loss of balance, fatigue, additional hearing loss, active drainage, and sudden hearing loss.

The Commissioner believes that such conditions would not be actual side effects from the use of the hearing aid but would be the result of misevaluation of the hearing problem or the result of a medical problem unrelated to the hearing aid itself.

But two comments mentioned that the ear may secrete additional cerumen (ear wax) to protect against the foreign object, i.e., the earmold, and that this would necessitate more frequent cleaning of the cerumen from the ear.

The Commissioner agrees with these comments and is amending the final regulation to include reference to the accelerated accumulation of cerumen as a possible side effect from the use of a hearing aid.

13. Five comments objected to the requirement that the User Instructional Brochure include the statement that infrequent use of a hearing aid usually does not permit the user to attain full benefit from its use. These comments pointed out that, in certain cases, the user should wear the hearing aid only at certain times. For example, a hearing aid user who works in high intensity noise conditions should not use the hearing aid at work. One of these comments said that the required statement would be confusing to such people.

The Commissioner believes that this statement is appropriate in the vast majority of cases and is therefore necessary because many users, to their own detriment, use their hearing aid only part-time. The Commissioner has, however, modified the statement to clarify the fact that it does not apply in all situations. The Commissioner believes that it is the responsibility of hearing aid dispensers to obtain sufficient information from the user regarding his type of employment or other activities to be able to inform him as to whether or not the hearing aid should be worn at all times.

14. Three comments objected to the requirement that the User Instructional Brochure include a statement that the use of a hearing aid is only part of hearing habilitation and that auditory training and instruction in lipreading may also be necessary. These comments noted that the dispenser would inform the user of any need for counseling during the adjustment period.

A hearing aid will not restore normal hearing, nor will a hearing aid always increase the ability of the user to distinguish different sounds. As a result, some hearing aid users become discouraged in the process of adapting to the use of a hearing aid, put the hearing aid aside, and discontinue its use in auditory habilitation.

The HEW Task Force pointed out that the problems resulting from a hearing loss are multidimensional, affecting both the total health and social well-being of the hearing-impaired person, and that there is a need to pursue a comprehensive and vigorous attack on hearing problems. Many people with hearing problems are not aware of the necessity and availability of auditory training and instruction in lipreading. The Commissioner has, therefore, determined that this statement should be retained in the User Instructional Brochure.

15. Five comments suggested that the manufacturer should not be required to include technical data relating to the hearing aid in the User Instructional Brochure because such information would not be understood by the average person and would be of little use to the consumer.

The Commissioner emphasizes that the User Instructional Brochure is intended not only for the hearing aid user but also for the physician, audiologist, and dispenser—it is useful to these person when fitting the hearing-impaired person with a hearing aid, when evaluating the appropriateness of an aid with which the user has been fitted, and when repairing the hearing aid. The Commissioner therefore rejects these comments.

16. The proposed regulation provided that the medical evaluation could not be waived if the prospective purchaser exhibited any one of seven listed conditions:

i. Visible congenital or traumatic deformity of the ear.

ii. History of active drainage from the ear within the previous 90 days.

iii. History of sudden or rapidly progressive hearing loss within the previous 90 days.

iv. Acute or chronic dizziness.

v. Unilateral hearing loss of sudden or recent onset within the previous 90 days.

vi. Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.

vii. Visible evidence of cerumen accumulation or a foreign body in the ear canal.

Many comments questioned whether dispensers could determine the existence of these conditions. Others questioned the completeness of the list.

The final regulation requires that all prospective hearing aid users obtain a medical evaluation to determine the cause of their hearing loss before pur-

chase of a hearing aid, unless the medical evaluation is specifically waived. The regulation also requires that each prospective user be provided with a User Instructional Brochure, which emphasizes the importance of medical evaluation. Although a waiver of the medical evaluation requirement is allowed, the hearing aid dispenser is prohibited from actively encouraging the use of this waiver.

The Commissioner wishes to avoid creating the impression that a medical evaluation is needed only if the enumerated symptoms are exhibited. As a result, the Commissioner is removing these seven conditions from the waiver provision. The final regulation requires that the hearing aid dispenser advise the prospective user to consult promptly with a licensed physician (preferably a physician who specializes in diseases of the ear) if the dispenser observes any of the listed conditions in the prospective user.

The original list of seven conditions was developed by the American Council of Otolaryngology (ACO) for use as a screening procedure by hearing aid dispensers. Although hearing aid dispensers cannot diagnose the cause of hearing loss, the Commissioner agrees with the ACO that hearing aid dispensers can recognize the existence of these symptoms. The Commissioner expects that hearing aid dispensers will be conscientious in impressing the importance of a medical examination upon prospective users exhibiting any of these symptoms.

One condition, pain or discomfort of the ear, has been added to the seven listed, because such pain or discomfort would indicate a medical problem that should be diagnosed and treated.

17. Nine comments objected to the caution statement required for hearing aids with a maximum sound pressure capability greater than 132 decibels (dB). Six of these comments stated that hearing aids with lower maximum output levels can cause auditory damage. The other three comments objecting to this statement, however, said that there is not sufficient evidence to support the assumption that hearing aids with maximum sound pressure capabilities greater than 132 dB can cause auditory damage.

As stated in the preamble to the proposed regulation this statement was based on a recommendation from the Academy of Rehabilitative Audiology (ARA). It was stated by ARA that its recommendation was based on information available on the hazardous effects of high-level industrial and environmental noise and on certain scientific articles that advise caution in fitting high-output hearing aids. The academy noted that 132 dB might eventually be determined to be too high and some lower level should be substituted but that, in the absence of such data, the statement should be included in the regulation as proposed.

To avoid unnecessarily alarming persons who have reservations about hearing aids, the Commissioner feels that this statement should be required only for hearing aids whose maximum sound pressure capability exceeds 132 dB. The Commissioner expects that hearing health professionals will take the possible side effects from a high-output aid into consideration in selecting and fitting a hearing aid. Under the final regulation, this statement is required to be included in the warning statement entitled "Warning to Hearing Aid Dispensers."

18. Seven comments objected to the requirement that the entire text of proposed § 801.421, Hearing aid devices; conditions for sale be included in the User Instructional Brochure. These comments said that this section is long and cumbersome, would be difficult for the average consumer to understand, and certain passages of it, such as those about recordkeeping, are of little interest to the consumer.

The Commissioner is revising the final regulation so that the User Instructional Brochure include a summary of the requirements of § 801.421. This summary is now contained in the notice entitled "Important Notice for Prospective Hearing Aid Users." The Commissioner agrees that it is not necessary to require that the entire text of the regulation be included because the required summary will be more easily understood by hearing-impaired consumers.

19. Four comments suggested that the word "caution" be deleted from the "caution statements" required to be included in the User Instructional Brochure, because the word "caution" implied a danger that did not exist and would be unnecessarily alarming to some consumers. Eight comments objected to the required caution statement with reference to the sale of hearing aids being restricted by Federal regulation, because this tended to place hearing aids in the category of prescription devices, which they said is inappropriate. Two comments objected to the inclusion of the caution statement with respect to a hearing aid not restoring normal hearing and not preventing or improving the cause of the hearing loss. These comments said that this might be interpreted as implying that hearing aids will not improve hearing.

The final regulation is revised to require that the substance of three of the four caution statements in the proposed regulation be included in one section of the User Instructional Brochure under the heading, "Important Notice for Prospective Hearing Aid Users." The other caution statement concerning hearing aids with a maximum sound pressure capability greater than 132 dB is included in the User Instructional Brochure in the section entitled "Warning to Hearing Aid Dispensers."

The word "caution" is deleted from the "Important Notice for Prospective Hearing Aid Users" because the Commissioner believes that the use of such a word is not essential to the communication of necessary hearing aid health information and might unnecessarily frighten those consumers who have a negative attitude toward the use of a hearing aid.

The "Important Notice for Prospective Hearing Aid Users" does point out that Federal law restricts the sale of hearing aids. Upon the effective date of the regulation, hearing aids will become restricted devices under section 520(e) of the Federal Food, Drug, and Cosmetic Act. The Commissioner believes that it is necessary to alert hearing aid consumers and dispensers to this fact so that they are aware of the restrictions that apply to the sale of a hearing aid.

The Commissioner believes that the statement in the proposal that hearing aids do not restore normal hearing and do not prevent or improve hearing loss is necessary to protect prospective hearing aid users from misleading claims about the benefits to be expected from a hearing aid and, accordingly, is retaining the requirement that this statement appear in the User Instructional Brochure. Some promotional material for hearing aids, in the past, has been worded to imply that the hearing aid would restore normal hearing or would prevent or improve the organic conditions causing hearing loss.

Several comments suggested that a child with a hearing loss should be directed to an audiologist because of the importance of hearing habilitation to speech and language development, and the educational and social growth of the child.

The Commissioner agrees with these comments and is including such a statement in the "Important Notice for Prospective Hearing Aid Users".

20. Three comments objected to the fact that technical data, required to be provided in the User Instructional Brochure, would have to be measured in accordance with the test procedures of the Acoustical Society of America, Standard for Specification of Hearing Aid Characteristics, ASA STD 7–1976 (previously ANSI S 3.22–1976). These comments generally pointed out that it was inappropriate for the Commissioner to establish such a test-reference requirement. One of these comments also argued that it would be necessary for the Commissioner to follow the procedures of section 514 of the Medical Device Amendments of 1976 to establish performance standards.

It should be emphasized that the proposed regulation did not establish, nor did it contain, performance standards for hearing aids. The regulation would merely describe the test reference methods to be used to determine the technical data values that must be included in hearing aid labeling and would not prescribe any minimum or maximum performance levels or product design requirements. The purpose of the test reference method requirement is to simplify comparing the performance of various hearing aids and measuring the performance of a particular hearing aid to determine if it is performing within labeled specifications and thus to ensure that the labeling is accurate and not false or misleading. The Commissioner believes that the technical data requirement is needed and is authorized by section 701(a) of

Federal Food, Drug, and Cosmetic Act for the effective enforcement of section 502 of the act, and that the labeling requirement is meaningless without a standardized test procedure to develop the required information.

21. Seven comments suggested that the term "useful gain" has no scientific meaning, was not used by the Acoustical Society of America, and should not be used in the regulation. These comments suggested that the term "Reference test gain" alone be used.

The Commissioner agrees with these comments and the change is made accordingly.

22. Four comments suggested that for clarity, the regulation should indicate that induction coil sensitivity is required only for aids with telephone coils. Further, five comments suggested that "input-output curve" and "attack and release times" are required only for hearing aids with automatic gain control.

The Commissioner agrees with all these comments and these changes are made accordingly.

23. One comment objected to the prohibition against including in the User Instructional Brochure any statement prohibited by FTC regulations. It asserted that the requirement is inappropriate as a matter of law because FDA regulations are enforceable by criminal penalties while FTC regulations are enforceable only by civil penalties, and if Congress had intended FTC regulations to be enforceable by criminal penalties, it would have so stated in the legislation governing that agency.

This statement (the prohibition) is not intended to incorporate by reference FTC regulations. The statement is intended to indicate that the requirement does not prevent FTC from enforcing its regulations. If a statement in the User Instructional Brochure violates FTC regulations but does not violate FDA regulations or otherwise constitute misbranding under section 502 of the act, the case will be referred to FTC for enforcement. It should be noted that certain statements that are prohibited by FTC regulations may also constitute misbranding under section 502 of the act and may thus be subject to action by either agency.

24. Two hundred and twenty-three comments supported the general requirement that a hearing aid shall not be sold unless the prospective user has been examined by a physician who has determined that the patient may be considered a candidate for a hearing aid. One hundred comments opposed this requirement.

Those comments supporting the general requirement generally stated that it is necessary that a physician examine a patient to determine the cause of the hearing loss and whether conditions causing the hearing loss are medically correctable. They also pointed out that a physician alone is trained to make such a diagnosis and that, if a hearing aid is purchased and a medically correctable condition goes undiagnosed and untreated, it could cause serious health problems for the hearing aid user.

Those opposing the general medical evaluation requirement generally argued that consumers should not be forced to see a physician if they do not want to, that the requirement would add an unnecessary cost to the already high cost of a hearing aid, and that physicians are not generally aware of the capabilities of hearing aids, even when such use is appropriate.

The Commissioner has determined that it is very important that all medically treatable conditions that may affect hearing be identified and treated before the hearing aid is purchased. The physician is the only person who is qualified to make a medical diagnosis and prescribe treatment. Some persons with remediable ear disease do not receive medical attention and rely solely on a hearing aid until the disease is no longer remediable. One purpose of the medical evaluation requirement is to prevent treatable conditions from going undiagnosed and untreated.

The general medical evaluation requirement is not expected to add considerably to the cost of a hearing aid. The Commissioner is aware of dispensing practices where the fee paid to the physician will be saved in the form of a lower fee paid to the hearing aid dispenser for the hearing aid. Further, many consumers will be saved the expense of an unnecessary purchase of a hearing aid.

The argument of people who feel that they should not be forced to undergo a medical evaluation is discussed below in the section dealing with the waiver of the medical evaluation requirement.

For these reasons, the Commissioner has determined that medical evaluation should generally be required before the purchase of a hearing aid.

25. Twenty-seven comments suggested that a medical evaluation should only be required for the first purchase of a hearing aid, because once the medical evaluation has been made, no conditions could arise that would make medical evaluation necessary in the future.

The Commissioner rejects these comments. The period between purchases could be 3 years or more. Many conditions causing further hearing loss could arise during such a period, and such conditions would warrant medical evaluation.

26. Forty-eight comments addressed the requirement that the medical evaluation occur 6 months before the purchase of the hearing aid. Twenty-one of these comments stated that the period should be less than 6 months. Most of these comments suggested a period of 3 months or less. The comments were generally based on the argument that too many changes could occur in a 6-month period and that these changes would negate a previous medical clearance. Ten comments said that 6 months was an appropriate period. Seventeen comments said that the period should be more than 6 months. Most of these comments suggested a period of 12 to 24 months. These comments generally argued that many people were slow to purchase a hearing aid and that the medical evaluation, once made, would be sufficient.

The Commissioner has determined that medical evaluation should be made no more than 6 months before the purchase of the hearing aid. This period is sufficiently long to give the purchaser time to shop around for a proper hearing aid, and it is sufficiently short to decrease the likelihood of substantial changes in the prospective user's medical condition.

27. Eight comments said that the parent or guardian of a prospective hearing aid user under the age of 18 should be permitted to waive the medical evaluation requirement for the child because parents should be free to determine what is in the best interest of their children.

Seventeen opposing comments specifically said that under no circumstance should a prospective hearing aid user under the age of 18 or the parent or guardian of such a person be permitted to obtain a hearing aid without a medical evaluation of the hearing loss because proper hearing is vital to the educational and social development of people in that age group.

The Commissioner has determined that, for those under the age of 18, there is a special concern that medical conditions that led to hearing impairment be identified, diagnosed, and treated by a physician. In addition to the risk to a child's health because of undiagnosed and untreated conditions, there is concern that a child's untreated, or inadequately treated, hearing impairment may interfere with the development of speech and language, learning, and normal adaptation to society. Accordingly, the final regulation does not allow a waiver of the medical evaluation requirement for anyone under the age of 18.

28. Three comments suggested that a physician may be unwilling to sign the required statement saying that he has found "no medical reasons why the individual should not be fitted with a hearing aid."

The Commissioner agrees that many physicians may be unwilling to sign such a statement. Such a statement is not necessary for the purposes of this regulation. The wording is therefore changed to reflect that the patient has been examined and that the physician has determined that the patient is a candidate for a hearing aid. This language was suggested in the comment of the American Council of Otolaryngology.

29. Thirty comments specifically said that a waiver of the medical evaluation requirement should be allowed. Sixty-one comments specifically said that such a waiver should not be allowed.

Comments supporting the waiver generally said that such a provision was necessary to protect the freedom of those who had strong feelings against being examined by a physician, especially those who had religious beliefs that forbade them from being treated by a physician. Many also pointed out that elderly peo-

ple in rural areas would be heavily burdened by the medical evaluation requirement, if a waiver were not allowed. Those who opposed the waiver, on the other hand, generally argued that medical evaluation is an absolute necessity because serious health problems could arise if a medical evaluation is waived and a correctable condition causing the hearing loss goes untreated.

Although the Commissioner strongly recommends that all prospective hearing aid users obtain a medical evaluation of a hearing loss before purchasing a hearing aid, he recognizes that a waiver should be allowed for those who have religious or personal beliefs against a medical evaluation and for the rare circumstance where an individual would have great difficulty in obtaining a medical evaluation due to the lack of a physician in the area. Accordingly, the final regulation permits a prospective hearing aid user over the age of 18 to waive the medical evaluation requirements.

30. Four comments objected to the statement in proposed § 801.421(a)(4) that State and local governments may impose more stringent conditions for sale than are imposed by the FDA regulation. These comments pointed out that section 521 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k), which was added by the Medical Device Amendments of 1976, provides that State and local laws that are inconsistent with or in addition to the regulation are preempted.

Specifically section 521(a) of the act provides that no State or local government may establish or continue in effect any requirement with respect to the safety and effectiveness of a device or to any other requirement applicable to the device under the act, if such requirement is different from, or in addition to, requirements which are applicable to the specific device under the act. Section 521(b) provides that the Commissioner may upon application of a State or local government exempt a requirement from the preemption of section 521(a) if the State or local requirement for the device is more stringent than requirements for the device imposed by FDA under the act, or if the requirement is necessitated by compelling local conditions and compliance with the State or local requirement would not cause the device to be in violation of a requirement under the act.

Section 521 of the act applies to specific State and local requirements with respect to the safety and effectiveness of hearing aids. The section does not, however, preempt State and local laws with respect to the licensing of hearing aid dispensers, audiologists, or physicians. In the Commissioner's view, such laws do not constitute "requirements with respect to a device" within the meaning of section 521 of the act. Moreover, another provision of the Medical Device Amendments, section 520(e) (21 U.S.C. 360j(e)), explicitly recognizes the continued viability of State licensing laws to prescribe the practitioners qualified to administer or use devices.

Therefore, because State and local governments will be required to petition for exemptions from section 521(a) of the act for differing requirements concerning hearing aid labeling or conditions on the sale of hearing aids, the Commissioner has determined that the statement in the proposed regulation is inappropriate, and it is deleted from the final regulation. A proposed regulation governing the procedures pursuant to which State and local governments may petition for exemption from section 521(a) of the act will be published in the FEDERAL REGISTER in the near future.

The Commissioner has also determined that the preemption provision of section 521(a) of the act does not apply to rules or requirements established by Federal, State, or local agencies to control the expenditure of public funds for purchasing hearing aids and hearing health care services for the hearing impaired, i.e., third-party payment programs. Such requirements often establish standards for the screening and diagnosis of individuals who will receive hearing aids through publicly funded programs. These standards are to assure the proper use of public funds. It is the Commissioner's view that such rules and requirements for the expenditure of public funds for hearing aids are payment criteria established by the payer or purchaser and do not represent "requirements with respect to a device" within the meaning of section 521(a) of the act.

31. Four comments objected to the requirement that the dispenser read and explain to the prospective user the four caution statements imposed by § 801.420(c)(2). These comments said this requirement is impractical and unnecessary and is an unwarranted interference in the hearing aid dispenser's business.

The Commissioner believes that this requirement is necessary to assure that the prospective user is informed of matters essential for the safe and effective use of a hearing aid. The burden placed on the hearing aid dispenser by this requirement is minimal. Therefore, the comments are rejected. The cautionary statements have been condensed into new sections entitled "Important Notice for Prospective Hearing Aid Users" and "Warning to Hearing Aid Dispensers". This notice for prospective hearing aid users describes, in lay language, the restrictions on the sale of hearing aids and the steps a prospective hearing aid user should follow to obtain quality hearing health care. The dispenser will be required to review this information with the prospective user before dispensing a hearing aid.

32. Four comments objected to the requirement that manufacturers and distributors provide, upon request, sufficient copies of the User Instructional Brochure for distribution to users or prospective users of hearing aids. These comments generally pointed out that this requirement was too broad, that too many people would request copies, and that it should be limited to those who have already decided to purchase a particular hearing aid.

The Commissioner believes that the User Instructional Brochure should be readily available to those who are shopping for a hearing aid and that such persons should be aware of the information contained in the User Instructional Brochure. The Commissioner also believes that any problems of persons requesting brochures for no reason will be minimal and will not significantly increase the cost of producing the brochure. Accordingly, this requirement is not changed in the final regulation.

33. Four comments objected to the requirement that the hearing aid dispenser retain for 3 years a copy of the physician's statement or the patient's waiver. Two of these comments said the period should be 5 years—the average life of a hearing aid. The other two comments said 1 year was sufficient because any problems would show up within 1 year.

The Commissioner is retaining the 3-year period for maintaining such records. Any problems resulting from the failure of the hearing aid dispenser to inform the user of the necessity of a medical evaluation would likely occur during the 3-year period after the sale.

34. Two comments suggested that it be clarified that mail order sales are not prohibited by the regulation.

The Commissioner is not aware of any abuses in mail order sales of hearing aids, and several users have indicated their satisfaction with hearing aids bought through the mail. The Commissioner has determined not to prohibit mail order sales provided that all the requirements of the regulation have been met. No statement in the regulation to this effect is necessary.

REVIEW OF LABELING

In the preamble to the proposed regulation, the Commissioner stated that the final regulation would be accompanied by a notice published in the same issue of the FEDERAL REGISTER and that the notice would require submission of copies of the proposed User Instructional Brochure and all other labeling for hearing aids no later than 60 days before the effective date of the final regulation.

At the time of the proposal, the legal authority for requiring such information was section 704 of the act (21 U.S.C. 374) relating to factory inspection. Section 704 authorizes FDA to enter at reasonable times and in a reasonable manner, establishments where devices are manufactured or held for sale and to inspect such establishments and related equipment and materials and specifically to inspect device labeling. It is the Commissioner's opinion that section 704 of the act, in authorizing on-site inspections of device labeling, also authorizes the Commissioner to require the submission of such labeling to FDA.

With the enactment of the Medical Device Amendments, additional authority was provided to FDA to require the submission of device labeling. Newly enacted section 519 of the act (21 U.S.C.

360i), Records and Reports on Devices, specifically authorizes FDA, within certain limits, to prescribe regulations to require device manufacturers to submit device labeling to FDA.

Accordingly, based on the authority provided to FDA by sections 519 and 704 of the act, the Commissioner has decided to require manufacturers of hearing aids that were in commercial distribution of the effective date of the regulation—August 15, 1977—to submit to FDA copies of the User Instructional Brochure and all other labeling for hearing aids. The Commissioner has also decided that this requirement should be included in the body of the final hearing aid labeling regulation, rather than as a separate notice as indicated in the proposal, to satisfy the requirements of section 519 of the act that a "regulation" be issued to require such submissions.

The Commissioner has determined that the submission of such labeling is necessary to ensure conformance with the requirements of § 801.420 and to determine whether such devices are adulterated or misbranded, or otherwise in violation of the act. The Commissioner has also determined that this requirement is not "unduly burdensome" within the meaning of section 519 of the act since such labeling is generally prepared by the manufacturer or distributor in the normal course of business.

The Commissioner also notes that the labeling for devices newly marketed subsequent to August 15, 1977 will be reviewed by FDA in accordance with the procedures of section 510(k) of the act (21 U.S.C. 360(k)) (premarket review); section 513(f)(2) of the act (21 U.S.C. 360c(f)(2)) (reclassification); or section 515 of the act (21 U.S.C. 360e) (premarket approval) of the act, as applicable.

Two comments on this portion of the proposal suggested that it would be difficult to comply with the labeling submissions requirement within the 120-day period allowed by the preamble to the proposed regulation. Accordingly, to allow more time to comply, § 801.420(d) requires that the manufacturer of a hearing aid submit to FDA a copy of the User Instructional Brochure and all other labels and labeling for the hearing aid on or before the effective date of the regulation—August 15, 1977—for those hearing aids in commercial distribution at that time.

Background data and information on which the Commissioner relies in promulgating this regulation have been placed on file for public review in the office of the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857. The following is a list of these documents:

1. "Paying Through the Ear: A Report on Hearing Health Care Problems," Public Citizen's Retired Professional Action Group, 1973.

2. "Hearing Aids and the Older American," Hearings before the Subcommittee on Consumer Interests of the Elderly of the Special Committee on Aging, United States Senate, 93d Cong. 1st sess., Parts 1 and 2, Washington, DC, September 10, 1973.

3. Memorandum on the HEW Intradepartmental Task Force on Hearing Aids, including minutes of the HEW Intradepartmental Task Force Meetings and agency comments on the Task Force reports.

4. "Final Report to the Secretary on Hearing Aid Health Care," prepared by the Department of Health, Education, and Welfare Intradepartmental Task Force on Hearing Aids, July 1975. The report contains the following appendices:

Appendix A—Preliminary Report on Hearing Aid Health Care, September 1974.

Appendix B—Supplementary Report on Hearing Aid Health Care, October 1974.

Appendix C—Synopsis of written comments on the Preliminary and Supplementary Task Force Reports.

Appendix D—Transcript of public hearings on the Preliminary and Supplementary Task Force Reports.

Appendix E—Hearing Aid Specialists Act.

5. "1971 Health Survey Report," National Center for Health Statistics, Health Resources Administration, Public Health Service, Department of Health, Education, and Welfare.

6. "A Partnership in Better Hearing," a paper submitted by the Hearing Aid Industry Conference to the HEW Intradepartmental Task Force on Hearing Aids, August 13, 1974.

7. Minneapolis Study—Congressional Record—Senate, July 18, 1974, S12850. New York City Study—Congressional Record—Senate, July 11, 1974, S10300 through S10304. Baltimore Study—RPAG Report, "Paying Through the Ear—A Report on Hearing Health Care Problems," Private Citizens, Inc., 1973, Chapter I, p. 5. Detroit Study—Congressional Record—Senate, July 18, 1974, S12851 through S12854.

8. "The Hearing Aid Industry, A Survey of the Hard of Hearing," a report to the National Hearing Aid Society and the Hearing Aid Industry Conference, prepared by Market Facts, Inc., April 1971.

9. "1974 FDA Report on Hearing Aid Label Review."

10. S 3.22, 1976 American National Standard for Specification of Hearing Aid Characteristics.

11. S 3.3, 1960 (R. 1971) American National Standard Methods for Measurement of Electroacoustical Characteristic of Hearing Aids.

12. S 3.8, 1967 (R. 1971) American National Standard Method of Expressing Hearing Aid Performance.

13. "Staff Study of the State Licensing Laws and Training Requirements for Hearing Aid Dealers," Permanent Subcommittee on Investigations of the Senate Committee on Government Operations, 94th Cong., 1st Sess., October 1975.

14. "Problems of the Hearing Aid Industry," Hearings before the Subcommittee on Government Regulation of the Select Committee on Small Business, United States Senate, 94th Cong., 1st Sess., on Economic Problems in the Hearing Aid Industry, Washington, DC, May 20, 21, and 22, 1975.

15. Hearings before the Senate Permanent Subcommittee on Investigations, United States Senate, 95th Cong., 1st Sess., Hearings on the Hearing Aid Industry, Washington, DC, April 1 and 2, 1976.

16. Acoustical Society of America Standard, Specification of Hearing Aid Characteristics, ASA STD 7-1976 (ANSI S 3.22-1976), published by the American Institute of Physics for the Acoustical Society of America, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201 (h), (k), (m), (n), 502, 519, 520(e), 701(a), 704, 52 Stat. 1040-1041, as amended 1050-1051 as amended, 1055, 67 Stat. 477 as amended, 90 Stat. 564-565, 567 (21 U.S.C. 321(h), (k), (m), (n), 352, 360i, 360j(e), 371(a), 374)) and under authrity delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262)), Part 801 is amended as Subpart H by adding new §§ 801.420 and 801.421, to read as follows:

§ 801.420 Hearing aid devices; professional and patient labeling.

(a) *Definitions for the purposes of this section and § 801.421.* (1) "Hearing aid" means any wearable instrument or device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.

(2) "Ear specialist" means any licensed physician who specializes in diseases of the ear and is medically trained to identify the symptoms of deafness in the context of the total health of the patient, and is qualified by special training to diagnose and treat hearing loss. Such physicians are also known as otolaryngologists, otologists, and otorhinolaryngologists.

(3) "Dispenser" means any person, partnership, corporation, or association engaged in the sale, lease, or rental of hearing aids to any member of the consuming public or any employee, agent, sales person, and/or representative of such a person, partnership, corporation, or association.

(4) "Audiologist" means any person qualified by training and experience to specialize in the evaluation and rehabilitation of individuals whose communication disorders center in whole or in part in the hearing function. In some states audiologists must satisfy specific requirements for licensure.

(5) "Sale" or "purchase" includes any lease or rental of a hearing aid to a member of the consuming public who is a user or prospective user of a hearing aid.

(6) "Used hearing aid" means any hearing aid that has been worn for any period of time by a user. However, a hearing aid shall not be considered "used" merely because it has been worn by a prospective user as a part of a bona fide hearing aid evaluation conducted to determine whether to select that particular hearing aid for that prospective user, if such evaluation has been conducted in the presence of the dispenser or a hearing aid health professional selected by the dispenser to assist the buyer in making such a determination.

(b) *Label requirements or hearing aids.* Hearing aids shall be clearly and permanently marked with:

(1) The name of the manuacturer or distributor, the model name or number, the serial number, and the year of manufacture.

(2) A "+" symbol to indicate the positive connection for battery insertion, unless it is physically impossible to insert the battery in the reversed position.

(c) *Labeling requirements for hearing aids*—(1) *General.* All labeling information required by this paragraph shall be included in a User Instructional Brochure that shall be developed by the manufacturer or distributor, shall ac-

company the hearing aid, and shall be provided to the prospective user by the dispenser of the hearing aid in accordance with § 801.421(c). The User Instructional Brochure accompanying each hearing aid shall contain the following information and instructions for use, to the extent applicable to the particular requirements and characteristics of the hearing aid:

(i) An illustration(s) of the hearing aid, indicating operating controls, user adjustments, and battery compartment.

(ii) Information on the function of all controls intended for user adjustment.

(iii) A description of any accessory that may accompany the hearing aid, e.g., accessories for use with a television or telephone.

(iv) Specific instructions for:

(*a*) Use of the hearing aid.

(*b*) Maintenance and care of the hearing aid, including the procedure to follow in washing the earmold, when replacing tubing on those hearing aids that use tubing, and in storing the hearing aid when it will not be used for an extended period of time.

(*c*) Replacing or recharging the batteries, including a generic designation of replacement batteries.

(v) Information on how and where to obtain repair service, including at least one specific address where the user can go, or send the hearing aid to, to obtain such repair service.

(vi) A description of commonly occurring avoidable conditions that could adversely affect or damage the hearing aid, such as dropping, immersing, or exposing the hearing aid to excessive heat.

(vii) Identification of any known side effects associated with the use of a hearing aid that may warrant consultation with a physician, e.g., skin irritation and accelerated accumulation of cerumen (ear wax).

(viii) A statement that a hearing aid will not restore normal hearing and will not prevent or improve a hearing impairment resulting from organic conditions.

(ix) A statement that in most cases infrequent use of a hearing aid does not permit a user to attain full benefit from it.

(x) A statement that the use of a hearing aid is only part of hearing habilitation and may need to be supplemented by auditory training and instruction in lipreading.

(xi) The warning statement required by paragraph (c) (2) of this section.

(xii) The notice for prospective hearing aid users required by paragraph (c) (3) of this section.

(xiii) The technical data required by paragraph (c) (4) of this section, unless such data is provided in separate labeling accompanying the device.

(2) *Warning statement.* The User Instructional Brochure shall contain the following warning statement:

WARNING TO HEARING AID DISPENSERS

A hearing aid dispenser should advise a prospective hearing aid user to consult promptly with a licensed physician (preferably an ear specialist) before dispensing a hearing aid if the hearing aid dispenser determines through inquiry, actual observation, or review of any other available information concerning the prospective user, that the prospective user has any of the following conditions:

(i) Visible congenital or traumatic deformity of the ear.

(ii) History of active drainage from the ear within the previous 90 days.

(iii) History of sudden or rapidly progressive hearing loss within the previous 90 days.

(iv) Acute or chronic dizziness.

(v) Unilateral hearing loss of sudden or recent onset with the previous 90 days.

(vi) Audiometric air-bone gap equal to or greater than 15 decibels at 500 hertz (Hz), 1,000 Hz, and 2,000 Hz.

(vii) Visible evidence of significant cerumen accumulation or a foreign body in the ear canal.

(viii) Pain or discomfort in the ear.

Special care should be exercised in selecting and fitting a hearing aid whose maximum sound pressure level exceeds 132 decibels because there may be risk of impairing the remaining hearing of the hearing aid user. (This provision is required only for those hearing aids with a maximum sound pressure capability greater than 132 decibels (dB).)

(3) *Notice for prospective hearing aid users.* The User Instructional Brochure shall contain the following notice:

IMPORTANT NOTICE FOR PROSPECTIVE HEARING AID USERS

Good health practice requires that a person with a hearing loss have a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. Licensed physicians who specialize in diseases of the ear are often referred to as otolaryngologists, otologists or otorhinolaryngologists. The purpose of medical evaluation is to assure that all medically treatable conditions that may affect hearing are identified and treated before the hearing aid is purchased.

Following the medical evaluation, the physician will give you a written statement that states that your hearing loss has been medically evaluated and that you may be considered a candidate for a hearing aid. The physician will refer you to an audiologist or a hearing aid dispenser, as appropriate, for a hearing aid evaluation.

The audiologist or hearing aid dispenser will conduct a hearing aid evaluation to assess your ability to hear with and without a hearing aid. The hearing aid evaluation will enable the audiologist or dispenser to select and fit a hearing aid to your individual needs.

If you have reservations about your ability to adapt to amplification, you should inquire about the availability of a trial-rental or purchase-option program. Many hearing aid dispensers now offer programs that permit you to wear a hearing aid for a period of time for a nominal fee after which you may decide if you want to purchase the hearing aid.

Federal law restricts the sale of hearing aids to those individuals who have obtained a medical evaluation from a licensed physician. Federal law permits a fully informed adult to sign a waiver statement declining the medical evaluation for religious or personal beliefs that preclude consultation with a physician. The exercise of such a waiver is not in your best health interest and its use is strongly discouraged.

CHILDREN WITH HEARING LOSS

In addition to seeing a physician for a medical evaluation, a child with a hearing loss should be directed to an audiologist for evaluation and rehabilitation since hearing loss may cause problems in language development and the educational and social growth of a child. An audiologist is qualified by training and experience to assist in the evaluation and rehabilitation of a child with a hearing loss.

(4) *Technical data.* Technical data useful in selecting, fitting, and checking the performance of a hearing aid shall be provided in the User Instructional Brochure or in separate labeling that accompanies the device. The determination of technical data values for the hearing aid labeling shall be conducted in accordance with the test procedures of the Acoustical Society of America Standard for Specification of Hearing Aid Characteristics, ASA STD 7–1976.[1] As a minimum, the User Instructional Brochure or such other labeling shall include the appropriate values or information for the following technical data elements as these elements are defined or used in such standard:

(i) Saturation output curve (SSPL 90 curve).

(ii) Frequency response curve.

(iii) Average saturation output (HF-Average SSPL 90).

(iv) Average full-on gain (HF-Average full-on gain).

(v) Reference test gain.

(vi) Frequency range.

(vii) Total harmonic distortion.

(viii) Equivalent input noise.

(ix) Battery current drain.

(x) Induction coil sensitivity (telephone coil aids only).

(xi) Input-output curve (ACG aids only).

(xii) Attack and release times (ACG aids only).

(5) *Statement if hearing aid is used or rebuilt.* If a hearing aid has been used or rebuilt, this fact shall be declared on the container in which the hearing aid is packaged and on a tag that is physically attached to such hearing aid. Such fact may also be stated in the User Instructional Brochure.

(6) *Statements in User Instructional Brochure other than those required.* A User Instructional Brochure may contain statements or illustrations in addition to those required by paragraph (c) of this section if the additional statements:

(i) Are not false or misleading in any particular, e.g., diminishing the impact of the required statements; and

(ii) Are not prohibited by this chapter or by regulations of the Federal Trade Commission.

(d) *Submission of all labeling for each type of hearing aid.* Any manufacturer of a hearing aid described in paragraph (a) of this section shall submit to the Food and Drug Administration, Bureau of Medical Devices and Diagnostic Products, Division of Compliance, HFK–116, 8757 Georgia Ave., Silver Spring, MD 20910, a copy of the User Instructional Brochure described in paragraph (c) of this section and all other labeling for each type of hearing aid on or before August 15, 1977.

[1] Copies available from the Acoustical Society of America, 335 E. 45th St., New York, N.Y. 10017.

§ 801.421 Hearing aid devices; conditions for sale.

(a) *Medical evaluation requirements*—(1) *General.* Except as provided in paragraph (a) (2) of this section, a hearing aid dispenser shall not sell a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician that states that the patient's hearing loss has been medically evaluated and the patient may be considered a candidate for a hearing aid. The medical evaluation must have taken place within the preceding 6 months.

(2) *Waiver to the medical evaluation requirements.* If the prospective hearing aid user is 18 years of age or older, the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation requirement of paragraph (a) (1) of this section provided that the hearing aid dispenser:

(i) Informs the prospective user that the exercise of the waiver is not in the user's best health interest;

(ii) Does not in any way actively encourage the prospective user to waive such a medical evaluation; and

(iii) Affords the prospective user the opportunity to sign the following statement:

I have been advised by

(Hearing aid dispenser's name)

that the Food and Drug Administration has determined that my best health interest would be served if I had a medical evaluation by a licensed physician (preferably a physician who specializes in diseases of the ear) before purchasing a hearing aid. I do not wish a medical evaluation before purchasing a hearing aid.

(b) *Opportunity to review User Instructional Brochure.* Before signing any statement under paragraph (a) (2) (iii) of this section and before the sale of a hearing aid to a prospective user, the hearing aid dispenser shall:

(1) Provide the prospective user a copy of the User Instructional Brochure for a hearing aid that has been, or may be selected for the prospective user;

(2) Review the content of the User Instructional Brochure with the prospective user orally, or in the predominate method of communication used during the sale;

(3) Afford the prospective user an opportunity to read the User Instructional Brochure.

(c) *Availability of User Instructional Brochure.* (1) Upon request by an individual who is considering purchase of a hearing aid, a dispenser shall, with respect to any hearing aid that he dispenses, provide a copy of the User Instructional Brochure for the hearing aid or the name and address of the manufacturer or distributor from whom a User Instructional Brochure for the hearing aid may be obtained.

(2) In addition to assuring that a User Instructional Brochure accompanies each hearing aid, a manufacturer or distributor shall with respect to any hearing aid that he manufactures or distributes:

(i) Provide sufficient copies of the User Instructional Brochure to sellers for distribution to users and prospective users;

(ii) Provide a copy of the User Instructional Brochure to any hearing aid professional, user, or prospective user who requests a copy in writing.

(d) *Recordkeeping.* The dispenser shall retain for 3 years after the dispensing of a hearing aid a copy of any written statement from a physician required under paragraph (a) (1) of this section or any written statement waiving medical evaluation required under paragraph (a) (2) (iii) of this section.

(e) *Exemption for group auditory trainers.* Group auditory trainers, defined as a group amplification system purchased by a qualified school or institution for the purpose of communicating with and educating individuals with hearing impairments, are exempt from the requirements of this section.

Effective date. This regulation shall become effective August 15, 1977.

(Secs. 201(h), (k), (m), (n), 502, 519, 520(e), 701(a), 704, 52 Stat. 1040–1041 as amended, 1050–1051 as amended, 1055, 67 Stat. 477 as amended, 90 Stat. 564–565, 567 (21 U.S.C. 321 (h), (k), (m), (n), 352, 360i, 360j(e), 371(a), 374).)

Dated: February 10, 1977.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

NOTE.—Incorporation by reference approved by the Director of the Office of the Federal Register on January 13, 1977, and it is on file in the FEDERAL REGISTER library.

[FR Doc.77-4654 Filed 2-14-77;8:45 am]

James Going III

WITNESS STATEMENT

NAME JAMES L. GOING BILL No. SB 480

ADDRESS BOX 1174 GREAT FALLS DATE 3-20-81

WHOM DO YOU REPRESENT MONTANA HEARING AID DEALERS SOCIETY + MYOWN OFFICE

SUPPORT SB 480 OPPOSE _____ AMEND WITH AMENDMENT

PLEASE LEAVE PREPARED STATEMENT WITH SECRETARY.

Comments: My background: Masters degree in audiology 1964. Employed as audiologist for ear specialist 1964-6., as audiologist for state dept. of Health in Montana 1966-1972; industrial audiologist 1972. Owner of private business for hearing testing, hearing aid sales & service. 1973 to present. I was removed from the American Speech & Hearing Assoc. in 1973 because I broke the Code of Ethics by owning a business in which hearing aids were sold. Since then ASHA has had 180° change of mind & allows audiologists to now sell aids

My main concern is consumer protection and anyone fitting hearing aids should receive as much training as possible. Thus I am against exempting audiologists from licensing as a hearing aid dispenser. Graduate training in audiology is not adequate at present to allow audiologists to fit hearing aids without licensing.

Most of the audiologists now work for the state or Easter Seal - who also service public schools in the state. They are in the office a very little amount of time. This does not allow the hearing aid user frequent access or daily access to the office of the audiologist who fit him.

If a person is committed in this field he will respond to the hearing aid wearer when he needs emergency service whether it is during office hours or after hours.

FORM CS-34
1-81

Mr McVoy's statement:

Audiologists have not been fitting aids for years as he says. They have tested + referred to hearing aid dispensers — who always provided the ongoing service as he provided through his own office.

The national audiologists' exam does not have a comprehensive portion dealing with knowledge of hearing aid fitting.

Barbara [illegible]

WITNESS STATEMENT

NAME [illegible] BILL NO. [illegible]

ADDRESS [illegible] DATE [illegible]

WHOM DO YOU REPRESENT [illegible] H.A. Service ([illegible] H.A.A.)

SUPPORT [illegible] OPPOSE AMEND

PLEASE LEAVE PREPARED STATEMENT WITH SECRETARY.

Comments:

Reason for asking that the audiologists be exempt from the Board of Hearing Aid Licensing is that in the past the hearing aid dealers did not have [illegible] [illegible] in Rehabilitation. Too many audiologists are [illegible]. The Board members are educated in the [illegible] of speech & hearing. Both have B.S. degrees and [illegible] [illegible] with their audiology degree.

Feeling also that the line and section exemption [illegible] audiologist [illegible]. Anyone wanting to go into a [illegible] needs to pass a certain criteria. [illegible] would be a training or tuition. [illegible] that would be practical experience. Rehabilitation [illegible] need to be trained in the area of fitting or at least under the [illegible].

FORM CS-34
1-81

SCIENTIFIC FITTING AND SERVICING OF HEARING AIDS

Beltone HEARING AID CENTER

AUTHORIZED BELTONE DEALER

2808 3RD AVENUE NORTH
P.O. BOX 2112
BILLINGS, MONTANA 59103
TELEPHONE 259-7983

ERVIN E. KING
CERTIFIED HEARING AID AUDIOLOGIST

March 19, 1981

HOUSE OF REPRESENTATIVES RE: Senate Bill 480

Dear Committee Member:

As a member of the Montana Board of Hearing Aid Dispensers and a hearing aid dealer for the past twenty-three years here in Montana, I strongly urge the reinstatement of Senate Bill #480 with no exemptions.

It is my observation that since licensing has been in effect during the past twelve years, the vast majority of abuse to the hard-of-hearing public caused by out-of-state vendors has virtually been eliminated. Without licensing there is no consumer protection against vendors who may be operating "out of the trunk of their car", with only a post office box, or from another state where service might be several hundred miles away.

Allowing exemptions to audiologists will not provide this protection either. A degree in audiology should not be a licensure to allow a person to sell hearing aids in any manner he sees fit.

All persons dispensing hearing aids should have to live by the same rules. Every dispensor should have to maintain an office in the State open to the public, and be available for service in accordance with the rules adopted by the Board. Speech pathologist and audiologist licensure does not cover these requirements.

Very truly yours,

Ervin King

Mr. Chairman, members of the committee:

Since the publication of the rules in 1977, a number of states applied for ~~preemption~~ EXEMPTION from some of the FDA rules. The Food and Drug Administration has ruled as follows:

issues and facts '81

FDA Issues Rule on Exemption from Preemption

THE LONG-AWAITED Food and Drug Administration (FDA) Rule on the applications of 20 states and the District of Columbia for exemption from preemption under the FDA Hearing Aid Regulation appeared in the Federal Register October 10, 1980.

In brief, the rule adheres closely to the proposed decisions which were published in the Federal Register on July 28, 1978. The final regulation denied exemption for most of the state requirements they had previously proposed to deny, and even reversed a few minor items where they had proposed exemption.

The substantive issues, provision of a waiver for informed adults, and the absence of a mandatory audiological evaluation, were not compromised.

In the preamble to the regulation, FDA states: "After reviewing the conflicting information in the public record regarding the predictive value of audiological testing in determining whether a patient would benefit from a hearing aid, FDA has concluded that audiological evaluation is not necessary to provide reasonable assurance of the safety or effectiveness of hearing aids."

In regard to the Waiver of Medical Evaluation, the FDA has concluded that they will maintain a nationally uniform waiver provision, and will preempt any state or local regulation that differs in this regard. As they state it: "FDA believes that any informed adult who objects to medical evaluation for religious or personal reasons should be permitted to waive the medical evaluation requirement." Also denied exemption were those state laws that do not permit a waiver when one or more of the "red flags" is noted. They do expect hearing aid dispensers to be conscientious in impressing the importance of medical evaluation in all cases, especially when one or more of the eight red flags is noted.

The FDA has decided to exempt from preemption those state and local regulations that require both physician and clinical audiology evaulations prior to the sale of a hearing aid to a minor.

HIA Releases Results of Gallup Survey

GLENN L. KENNEDY, President of the Hearing Industries Association (HIA) has announced that the results of the Gallup Poll conducted last summer are now available. Commissioned by the HIA, the poll's purpose was to identify public attitudes toward the use of hearing aids, and to sample public impressions of the hearing aid industry.

Mr. Chairman and Members of the Committee

I speak from over 26 years of experience in the hearing aid field, and six years on the Dispensers' Board.

I firmly believe every hard of hearing consumer has rights when purchasing a hearing aid.

They have the right to purchase an aid from whatever dispenser they wish.

They have the right to have that dispenser fully qualified to fit the hearing aid, and a further right to a fully trained dispenser's knowledge of service and trouble-shooting on problems of the wearing of the aid as this is of paramount importance to the consumer. This should be available in open offices at all times.

They have the right to have the aid delivered by a licensed dispenser who can fully counsel and adjust the aid at initial delivery.

They have the right to have one single board to handle any complaints on misfitting, problems or lack of service on the aid, with the power of regulation on necessary items.

As you know, the FDA defines a Dispenser, and unless all of these dispensers are included under one license board, without any exceptions, some of the hard of hearing consumers would become second class citizens with no recourse on complaints or problems.

The Hearing Aid Dispenser Board does not cost the State of Montana any funding producing it's own earmarked revenue, which now has a built up amount. In its 11 years it has tried to give the hard of hearing consumer the above rights. The dispensers members of the Board, and some of the other members have often attended Board meetings and hearings at their own expense when appropriated Board funds are low, because they have wanted to give the consumer his rights and protection.

I request the committee to continue the Board of Hearing Aid Dispenser, with no exceptions on licensing, and include all dispensers as defined by the Federal Food and Drug, as stated in the Federal Register on Tuesday, Feb. 15, 1977, part IV --page 9289, Section 2, bottom of middle column.

Thank you.

Cecilia Sweeney

March 20, 1981

House Public Health Committee
Capitol Building
Helena, MT 59620

Committee Members:

I'm writing to express general support for SB 480 but particular support for the amendment which indicates the bill (re-establishing the Board of Hearing Aid Dispensers) shall not apply to licensed audiologists.

Reasons:

1) The audiologists' credentials to be licensed by the Board of Speech Pathologists and Audiologists (Masters Degree plus one year as intern plus National Exam plus Montana License) are already far superior to those required by the dealers board.

2) Legislative Auditor staff plus Senate Public Health Committee were concerned why the audiologist should need both licenses - hence the amendment.

3) The hearing aid dealers have for years handcuffed the audiologist from practicing in areas for which he is trained using the license to dispense as a shield.

4) Demanding a dispensers license of the audiologist is not more protection for the consumer but financial protection for the dealer, i.e. by training and attorney general's ruling, the audiologist can now and always has (A) fit aids, (B) monitor 30 day trial periods, (C) adjust aids, and (D) counsel consumer, etc. however money paid for the aid must go to the "licensed dealer". Only when some audiologists decided to charge for their work and service did the dealers claim "you can't do this and so without a dealers license to sell" —thus a financial handcuffing, not a credentialing regulation for the consumer.

With great resignation some audiologists have gone ahead and also obtained a dispenser's license. This is an added "hassle" value and expense. The audiologist should not need two licenses to practice his profession which includes fitting hearing aids. The hearing aid dispensing law and board should not apply to the licensed audiologist.

Sincerely,

Merle + Shirley

Merle & Shirley DeVoe
418 Butler
Helena
442-7343

Please call us should you have any questions.

VIII

Ruling by the Attorney General

VOLUME NO. 36 OPINION NO. 12

AUDIOLOGISTS - Licensed audiologists employed by charitable or nonprofit organizations, licensing as a hearing aid dispenser;

HEARING AID DISPENSERS - License requirements, audiologists, employees of charitable or nonprofit organizations;

MONTANA CODE ANNOTATED - Sections 37-15-101, et seq., 37-16-101, et seq.

HELD: 1. A licensed audiologist who is an employee of a charitable or nonprofit organization primarily supported by voluntary contributions may make an impression of the ear (which is expressly part of the practice of fitting and dispensing hearing aids) without being licensed as a hearing aid dispenser, based upon the exemption of section 37-16-103, MCA. As explained in 37 OP. ATT'Y GEN. NO. 60, this exemption may be enjoyed only if the hearing aids are not sold, a sale including sales at a profit, at cost, or even at a loss.

2. There is nothing in the law to prohibit a licensed audiologist from acting as an "agent" for a hearing aid dispenser, if he chooses to do so. Since an audiologist who is an employee of a charitable or nonprofit organization primarily supported by voluntary contributions is entitled to fit and dispense hearing aids, either the audiologist or the hearing aid dispenser may complete the final fitting and delivery.

3. No person may select a particular aid for any other person and force the hearing aid dispenser from whom the aid is purchased to abide by that decision. When a licensed hearing aid dispenser sells an aid he is entitled, if not obligated, to use his training and judgment to select the best aid for that client. This is expressly sanctioned by section 37-15-103(7), MCA.

4. A licensed audiologist who is an employee of a charitable or nonprofit organization primarily supported by voluntary contributions may fit an aid, whether permanently or for a trial period, without a dispenser's license. No other person

MONTANA SPEECH, LANGUAGE AND HEARING ASSOCIATION

March 13, 1981

701 Fox Drive
Gt. Falls, MT 59404

Representative Dick Manning
Capitol Station
Helena, MT 59601

Dear Representative Manning,

I am writing on behalf of the Montana Speech-Language and Hearing Association. The intent of this letter is to express the Association's stand on SB 480 which reinstates the Board of Hearing Aid Dispensers. The Association supports the amendment which exempts Audiologists who are licensed by the Board of Speech Pathologists and Audiologists from being licensed by the Board of Hearing Aid Dealers in order to dispense hearing aids.

Because an audiologist who is licensed by the Board of Speech Pathologists and Audiologists has far superior credentials than are required by SB 480, it would be superfluous to require licensed audiologists to obtain yet another license in order to dispense hearing aids.

If the SB 480 does not include the amendment to exempt audiologists, the Association does not support SB 480.

Sincerely,

Christie Deck, President
Montana Speech-Language-
Hearing Association

CD/lf

Deck

EX

WITNESS STATEMENT

NAME Christie Deck BILL No. SB 480

ADDRESS 701 FOX DRIVE GREAT FALLS DATE 3/20/81

WHOM DO YOU REPRESENT Montana Speech Language Hearing Assoc

SUPPORT X with amendments OPPOSE AMEND

which excludes Audiologists who are licensed by Board of Spch Path. & Aud.

PLEASE LEAVE PREPARED STATEMENT WITH SECRETARY.

Comments:

FORM CS-34
1-81

STATE OF MONTANA

DEPARTMENT OF PROFESSIONAL & OCCUPATIONAL LICENSING

BOARD OF SPEECH PATHOLOGISTS AND AUDIOLOGISTS

ED CARNEY, DIRECTOR

LaLONDE BUILDING
HELENA, MT. 59601
(406-449-3737)

March 17, 1981

Public Health Committee
House of Representatives
Capitol Building
Helena, MT 59620

The Board of Speech Pathologists and Audiologists would like to go on record as supporting SB 480 to reinstate the Board of Hearing Aid Dispensers as amended and passed by the Senate.

The amendment to exclude audiologists licensed by the Board of Speech Pathologists and Audiologists was added on the recommendation of the Legislative Audit Committee. The audiologists who dispense aids have had to complete licensing requirements by both boards. Such dual licensing is duplicative, expensive, and superfluous in that the credentials necessary to become a licensed audiologist are already far superior to those required of the hearing aid dispenser.

If we can be of further assistance regarding this proposed legislation, please do not hesitate to contact our Board members.

Thank you.

Sincerely,

Shirley DeVoe, Chairman
BOARD OF SPEECH PATHOLOGISTS AND AUDIOLOGISTS

SD:jm

Greene

WITNESS STATEMENT

NAME _____ BILL No. _____

ADDRESS _____ DATE _____

WHOM DO YOU REPRESENT _____

SUPPORT SB 42 OPPOSE _____ AMEND _____

PLEASE LEAVE PREPARED STATEMENT WITH SECRETARY.

Comments:

FORM CS-34
1-81

March
~~February~~ 5, 1980

Bruce Hillyard, Business Manager
Seattle Hearing & Speech Center
1620 - 18th Ave.
Seattle, WA 98122

Dear Mr. Hillyard:

We have tried several times to contact you for explanation of fees charged by your Clinic. In person, we were merely referred to the bookkeeper; by phone, we were told you "were not available but would return our call." No return call has ever been received; thus this letter.

In February and May 1979 my husband received the following services (and fees) from your Clinic:

Annual evaluation	$ 50.00
Hearing Aid evaluation.	60.00
Shipping and handling	25.00
Fitting fee	50.00
Batteries	3.60
Hearing Aid	175.00
Tax	9.64
Prepaid (for recheck)	25.00

We were presented with this bill of almost $400.00--due in full befor leaving your Center on May 10 (and prior to time recheck was to be performed). We had previously been advised by your Clinic that your fees were the same for all patients, including senior citizens ($50 for evaluation exam and the aid dispensed at "manufacturer's cost"). Since we are retired senior citizens, we had carefully budgeted and were prepared to pay for exam, hearing aid, audiograms and other tests and reasonable costs. But we were certainly NOT prepared to pay $50 for a fitting fee PLUS $25 for shipping and handling PLUS $25 for a recheck prior to the time such recheck was provided. In fact, we'd never heard of a charge for recheck much less prepayment for it. Even $60 for hearing aid evaluation in addition to the initial $50 evaluation seemed a bit excessive. Nevertheless, we paid the entire bill on the spot.

The clincher is that the aid was improperly fitted and as a result was totally unsatisfactory. He was told to return for adjustment if necessary. He did return and the "adjustments" made the aid even more unsatisfactory and uncomfortable. Since we senior citizens live in Kent, traveling to Seattle is not easy either physically or financially. Plus, we had explained to Ms. McDonald that we were going to be away for an extended period and it was vitally important the aid be satisfactory and provide maximum help for my husband's severe hearing loss while we were gone. She emphasized several times that he could go to any dispenser for adjustment without charge while the aid was under warranty.

It seems appropriate to point out that your Clinic is really quite unfair to private dispensers in that your personnel less than subtly encourage patients to seek adjustments of aids provided by your Center from private dispensers -- thus utilizing their time and talents

without compensation while the aid is under warranty to correct improper fitting by your staff. It is further unfair because these private dispensers--and the tax-paying public--are subsidizing your organization with United Way funds.

The bottom line of this unfortunate experience is that no words can describe the misery my husband endured during the past many months. More important is the devastating effect this has had on his attitude towards his disability. It should be obvious to anyone working in the hearing impairment field how difficult it is for the patient to overcome the feeling that "nothing can be done" or "nothing will improve my hearing". For years he has accepted his hearing loss without complaint and, with great effort, has adjusted very well to his severe impairment. The experience with your Clinic has certainly been frustrating, and that frustration has been compounded by the feeling that he's really been ripped off with regard to your charges.

As a result of all this, it's taken these many months for him to face trying again. But he is now finally seeing a private dispenser who has adjusted the aid so he can use it comfortably and satisfactorily. The problem from the beginning seems to have been with the fitting, not the aid. This may well mean additional expense but since we no longer have any confidence in Seattle H&S Center, it's the only alternative and in the long run will surely be less costly and more satisfactory. Plus, we certainly can't afford the luxury of any more "services" from your Center.

Nothing can rectify the misery my husband was subjected to because of improper fitting, but would you PLEASE be good enough to advise us how you justify accepting hand-outs from United Way in view of the fees charged your patients??? We would indeed be interested in learning how you use your United Way funds since your charges would appear to quite adequately cover your services.

Finally, this letter is written in the hope that other senior citizens seeking services from your Center will obtain more satisfactory fitting of their aids. It is especially difficult for older patients to make numerous trips in order to obtain satisfactory fittings. Further, it's difficult enough for most older persons to pay a $400 bill out of pocket much less prepaying for a service in any amount.

Sincerely,

Mrs. Howard T. Davison
26520 Woodland Way South
Kent, WA 98031

cc: United Way (General Admin. Svcs.)
National Hearing Aid Society
Seattle Times Troubleshooter
Sen. Shinpoch

The hearing aid furnished is an Otican.