

Journal of Contemporary Health Law & Policy (1985-2015)

Volume 11 | Issue 2

Article 11

1995

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Recommended Citation

Steven B. Adams, *Who Will Hear? An Examination of the Regulation of Hearing Aids*, 11 J. Contemp. Health L. & Pol'y 505 (1995).

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WHO WILL HEAR? AN EXAMINATION OF THE REGULATION OF HEARING AIDS

The study of hearing and hearing impairments can be traced back to the Greek scientist Pythagoras and his study relating pitch to the length of strings on musical instruments.¹ Hearing impairment occurs in numerous ways.² The more common causes include diseases, such as rubella of the mother during pregnancy, trauma to the head, stroke, infections of the inner ear, and excessive noise.³ The development of devices to aid those with hearing impairments has advanced rapidly since the early Twentieth Century.⁴ Properly matched to the individual, modern hearing aids can provide a great deal of assistance to the hearing impaired.⁵

Hearing aids are the third most widely used medical assistive device in the United States, following eyeglasses and canes.⁶ An estimated 23.5 million Americans suffer from a hearing loss.⁷ A hearing loss is measured in decibels and may be mild, moderate, severe, or profound.⁸ The majority of individuals suffering from hearing loss do not experience the loss suddenly: rather, the loss is brought about by "an accumulation of many years of trauma to the ear."⁹ A hearing loss can operate not only on the volume of sound perceived, but also on the clarity or ability to distinguish sounds.¹⁰ Often the result is the inability to distinguish a voice from the background noises surrounding it.¹¹

1. WILLIAM A. YOST, *FUNDAMENTALS OF HEARING: AN INTRODUCTION* 4 (3d ed. 1994).

2. PREVENTION OF DEAFNESS & HEARING IMPAIRMENT, REPORT BY THE DIRECTOR-GENERAL, WORLD HEALTH ORGANIZATION, PROVISIONAL AGENDA ITEM 22.2 at 8 (Mar. 27, 1986) (copy on file with the J. CONTEMP. HEALTH L. & POL'Y).

3. *Id.* For a discussion of the causes, detection, and treatment of hearing impairment see the Director-General's report. *See id.*

4. *Id.* The refinement of the microscope in the late Nineteenth Century, coupled with the invention of the oscilloscope in the Twentieth Century, resulted in great advances in the study of hearing. *Id.*

5. DEAFNESS 270-84 (John Ballantyne et al. eds., 5th ed. 1993).

6. *The Hearing Aid Marketplace: Is the Consumer Adequately Protected? Hearing Before the Special Committee on Aging of the Senate*, 103d Cong., 1st Sess. 155 (1993) (report by the American Association of Retired Persons (AARP)) [hereinafter *Hearings*].

7. *Id.* at 6 (written testimony of the International Hearing Society (IHS)).

8. *Id.* at 155 (report by the AARP).

9. *Id.*

10. *Id.*

11. *Id.* A hearing loss is often a loss of only a certain frequency of sound; however the

Part I of this Comment explores the reasons in favor of hearing aid regulation on both personal and economic levels. Part II of this Comment examines regulations governing the hearing aid, as set forth in the Medical Devices Amendments, and discusses who these regulations affect. Part III of this Comment focuses on important problems that have arisen under current regulations, which have been brought to the forefront by recent actions of the Food and Drug Administration (FDA) and by hearings held before the United States Senate Special Committee on Aging. Finally, Part IV discusses the need for new regulations and considers whether enforcement of current regulations can solve the difficulties now facing the industry and the affected public. This Comment concludes that modification of current regulations, in combination with a renewed effort at enforcement, would greatly enhance the ability of hearing-impaired consumers to receive correct hearing aids, and at the same time enhance the image of the hearing aid industry.

I. WHAT BENEFICIAL EFFECT DOES THE PROPERLY FITTED HEARING AID HAVE ON THE INDIVIDUAL?

A. *Effects on Quality of Life*

A hearing loss can limit an individual in all aspects of daily living. The loss can affect one's ability to communicate in both a professional and social capacity, and can be devastating to a person's ability to function in a society dominated by the hearing.¹² Often, hearing-impaired individuals will gradually withdraw from family members and associates as their ability to understand others diminishes.¹³ Of the estimated 23.5 million Americans with hearing loss, only about 3.78 to 5 million own hearing aids.¹⁴ A market survey conducted by the Hearing Industries Association found that a variety of consumer perceptions of hearing aids and hearing loss may contribute to this low figure.¹⁵

loss of a frequency limits a person's ability to distinguish between different sounds. Thus all sound blends together and spoken language may become incomprehensible. *Id.*

12. See, e.g., Sergei Kochkin, *MarkeTrak III Identifies Key Factors in Determining Consumer Satisfaction*, 45 HEARING J. 39, 40 (1992); Donald Radcliffe, *Hearing Loss and Hearing Restoration: Costs, Benefits, and Quality of Life*, 45 HEARING J. 11, 14 (1992).

13. *Hearings*, *supra* note 6, at 57 (statement of Donald L. Darling, Director, Antitrust/Consumer Protection Division, West Virginia Attorney General's Office).

14. *Id.* at 155 (report by the AARP); *id.* at 106 (written testimony of the IHS). Estimates vary as to the exact number of hearing aid wearers, ranging from the industry figure of almost six million to government estimates that 3.78 million people own one or two hearing aids. *Id.* at 157 (report by the AARP).

15. Sergei Kochkin, *MarkeTrak III: Why 20 Million in US Don't Use Hearing Aids for*

Several recent studies clearly indicate that a hearing aid confers many more benefits than just the ability to hear better.¹⁶ A study on the quality of life for the elderly, conducted at Rush Medical College in Chicago, found that the quality of life for many elderly persons is diminished not by the presence of illness, but by the effect that illness has on their daily lives.¹⁷ "Even if participants had a dozen diseases . . . as long as they could still be active and involved with other people" they were happy with their lives in their later years.¹⁸ The researchers found that improved hearing, in turn, improved the individual's daily activities and thus their quality of life.¹⁹

Another study, reported in the *Annals of Internal Medicine*,²⁰ found that "[h]earing loss is associated with important adverse effects on the quality of life of elderly persons, effects that are reversible with hearing aids."²¹ In this study, one group of elderly veterans was provided with hearing aids; another group was placed on a waiting list for hearing aids.²² The group given the aids "had significantly improved scores for social and emotional function, communication function, cognitive function, and depression."²³

A recent market study examined the effects of presbycusis, a common disorder among the elderly that results in a hearing loss.²⁴ This study found the adverse effects of hearing impairment to include a decline in general health in addition to emotional, behavioral, and social problems.²⁵ Adults with hearing impairments were found to spend more days in bed and to visit a doctor more often than those without hearing

Their Hearing Loss, 46 HEARING J. 20 (1993). Among the reasons cited for not using a hearing aid were that the hearing loss was not substantial, hearing aids do not perform well, and hearing aids cost too much for the value gained from them. *Id.*

16. Radcliffe, *supra* note 12, at 12-14.

17. *Id.* at 12.

18. *Id.*

19. *Id.* The study found that if a person with a hearing loss was assisted with hearing aids the result was a "positive impact on a person's functional abilities, particularly in everyday living situations." *Id.*

20. William S. Bentson, *Hearing Aids and Life Benefits*, 34 ANNALS OF INTERNAL MED. 56 (1990).

21. *Id.*

22. *Id.*

23. *Id.*

24. Michael D. Lichtenstein, *Hearing Aids: A Market Study*, 45 J. GEN. INTERNAL MED. 82 (1991). Presbycusis is the gradual loss of hearing brought about by old age and caused by continual wear on the inner ear. DEAFNESS, *supra* note 5, at 212-13.

25. Lichtenstein, *supra* note 24, at 82.

impairments.²⁶ The study concluded that treating hearing-impaired adults with hearing aids leads to improved psychological functioning.²⁷

These studies clearly illustrate that a hearing aid greatly enhances the quality of life for the hearing impaired, especially for the elderly. Not only does a proper hearing aid improve the user's quality of life, it actually plays a role in reducing overall health costs by reducing the number of doctor visits and improving general health. The benefits of hearing aids are an important consideration in the ongoing debate over the health care system in the United States. For these reasons, it is necessary that persons seeking to purchase a hearing aid be assured that they are getting the best possible aid for their specific hearing impairment.

B. *The Needs of the Elderly Consumer*

In any discussion of hearing aids, it is important to note that sixty percent of potential hearing aid users are over the age of sixty-five.²⁸ Furthermore, the over sixty-five population in the United States is rapidly increasing.²⁹ These factors make health policy regarding hearing aids especially timely. The over sixty-five population is a specialized market and, as such, has unique characteristics that must be considered when discussing hearing aids and policy issues relating to their use.³⁰

The elderly hearing aid purchaser is often more trusting than the average consumer.³¹ Older consumers are "more oriented to internal knowledge and experience" than to "external knowledge and experience."³² Often this internal knowledge is outdated in our rapidly changing society or is incomplete when compared to the knowledge of the younger consumer.³³ Moreover, the elderly consumer is more susceptible to high

26. *Id.*

27. *Id.*

28. *Hearings, supra* note 6, at 155 (report of the AARP).

29. George A. Gates et al., *Hearing in the Elderly: The Framingham Cohort, 1983-1985*, 11 *EAR & HEARING* 247 (1990). "The over-65 age group is the most rapidly growing segment of the United States and hearing loss is its fourth most prevalent major chronic disability." *Id.*

30. H. Keith Hunt, *Consumer Satisfaction, Dissatisfaction, and Complaining Behavior*, 47 *J. Soc. ISSUES* 107, 111 (1991).

31. *Id.*

32. *Id.*

33. *Id.* Older consumers may often be more trusting of those held out as health care dispensers because they look upon these people as trained professionals. *Id.* It is likely that in an elderly person's "internal knowledge" he assumes that someone with a license to dispense hearing aids has the necessary professional training to do an adequate job. *Id.*

pressure sales tactics,³⁴ especially when the sale takes place in the consumer's home, a common practice employed by door-to-door hearing aid dispensers.³⁵ Furthermore, the hearing aid is often a major purchase for many elderly consumers.³⁶ The average cost of one hearing aid is over \$600, and often a person will need two.³⁷ Because most hearing aids are not covered by Medicare or most insurance policies, hearing aid purchasers have to rely on their own savings and resources.³⁸ The financial burden assumed by the hearing impaired purchaser may significantly deplete an older individual's savings.

II. REGULATIONS GOVERNING HEARING AID SALES

The manufacture, sale, and distribution of hearing aids is governed by three overlapping bodies of law.³⁹ These three bodies of law, which also oversee the advertising claims made by hearing aid manufacturers and dispensers, include federal laws, state laws, and state licensing board requirements.⁴⁰ The federal laws are policed by the Food and Drug Administration (FDA) and the Federal Trade Commission (FTC), state laws are enforced by states' attorneys general, and licensing boards enforce their own licensing criteria.⁴¹

A. Current Federal Regulations Governing the Sale of Hearing Aids

1. Promulgation of the 1977 Regulations

Federal regulations governing the sale, distribution and advertisement of hearing aids are set forth in Volume 21 of the Code of Federal Regulations⁴² and in the Federal Trade Commission Act.⁴³ The most controversial section of the current federal regulations is section 801.421(a),⁴⁴ which provides for the conditions of the sale of hearing aids. This section states that any seller of hearing aids is directed by law not to sell a hearing aid unless "the prospective user has presented to the hearing aid dis-

34. *Id.* Elderly consumers are less likely to seek redress of their grievances and are also less aware of their rights as consumers than are younger consumers. *Id.*

35. See *Hearings*, *supra* note 6, at 144-47 (written testimony of IHS).

36. See *id.* at 152 (report of the AARP).

37. *Id.*

38. *Id.*

39. *Id.* at 160-63.

40. *Id.*

41. *Id.*

42. FDA Hearing Aid Devices Rules, 21 C.F.R. § 801.420-421 (1994).

43. 15 U.S.C. § 45 (1988).

44. 21 C.F.R. § 801.421(a).

penser 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."⁴⁵ In addition, the required evaluation must have taken place within the six months preceding the written statement.⁴⁶ The regulations also state that the purchaser may waive this medical evaluation so long as the dispenser informs the purchaser that waiving the examination is "not in the user's best health interest."⁴⁷ In addition, the dispenser cannot encourage the purchaser to waive the examination.⁴⁸ The purchaser must also be given the opportunity to sign a statement informing him that the waiver is not in his best medical interest and that he wishes nevertheless to waive the examination.⁴⁹

Section 801.421(a) became effective on August 15, 1977, after several Senate subcommittees investigating the matter heard testimony on the issues and the FDA received comments on the proposed rules.⁵⁰ These comments ranged from calls for stricter rules to demands for more lenient requirements.⁵¹ Among the proposals advocating stricter control of the hearing aid marketplace was the request that a physical examination be required of potential hearing aid recipients.⁵²

After hearings before the Senate Permanent Subcommittee on Investigations were conducted, Subcommittee Chair Senator Charles H. Percy observed that, "[t]wenty million hearing-impaired Americans are being denied top-flight treatment by a delivery system that simply is not working."⁵³ Senator Percy recommended a rule that would "restrict the sale of hearing aids to those patients who ha[d] undergone a medical evaluation."⁵⁴ Those who opposed the required examination argued that it was an infringement of individual rights, it would impose hardship on potential hearing aid users not in the vicinity of a health care provider, and that

45. *Id.*

46. *Id.*

47. *Id.*

48. *Id.*

49. *Id.*

50. 42 Fed. Reg. 9286 (1977) (to be codified at 40 C.F.R. § 801) (proposed Apr. 21, 1976). For an in-depth history of the Medical Devices Amendments of 1976 see H.R. REP. No. 94-853, 94th Cong., 2d Sess. (1976). Comments were received from audiologists, consumer groups, hearing aid dispensers, manufacturers, and trade associations.

51. 42 Fed. Reg. 9286 (1977) (to be codified at 40 C.F.R. § 801) (proposed Apr. 21, 1976).

52. *Id.* at 9287-88.

53. *Id.* at 9286.

54. *Id.*

it violated certain philosophical and political beliefs.⁵⁵ In its final decision, the FDA decided to require a physical examination with the caveat that it could be waived only by a "fully informed adult."⁵⁶ The FDA Commission stated that because "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."⁵⁷ The FDA anticipated that the waiver would constitute the exception rather than the rule, thereby allowing individuals objecting to the physical examination the opportunity to receive hearing aids without an examination.⁵⁸

In addition to calls for requiring a physical examination of potential hearing aid users were requests for more federal involvement in the licensing of hearing aid dispensers.⁵⁹ Proponents argued that where state licensing laws were weak, federal licensing statutes would "protect the public against unfit and inept practitioners."⁶⁰ After reviewing the comments from both sides, the FDA concluded that the regulation of licensing hearing aid dispensers should be left almost entirely to the states.⁶¹ The Commissioner stated: "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."⁶² The federal rules omitting licensing regulation went into effect in 1977, and, to date, "strong" state licensing laws have failed to materialize.

2. *Misleading Advertising Violations Within the Jurisdiction of the Federal Trade Commission*

The federal laws governing misleading advertisements and claims made concerning hearing aids are enforced by the FTC under § 45(a) of the Federal Trade Commission Act (FTCA).⁶³ The relevant part of the section provides that "unfair or deceptive acts or practices in or affecting commerce, are declared unlawful."⁶⁴ If a violator is notified through a cease and desist order that its hearing aid advertisements are false or mis-

55. *Id.* at 9288.

56. *Id.*

57. *Id.*

58. *Id.*

59. *Id.*

60. *Id.* at 9287.

61. *Id.*

62. *Id.*

63. 15 U.S.C. § 45 (1988).

64. *Id.* § 45(a)(1).

leading, the FTC may seek civil penalties.⁶⁵ Despite the FTC's broad power, it has taken little action against hearing aid dispensers. In fact, the FTC has enforced its authority over deceptive advertisers of hearing aids in only two cases between 1985 and 1993.⁶⁶ Such agency inaction does not further the cause of accurate advertising in the sale of hearing aids.

B. State Regulation of Hearing Aid Dispensers

Licensing boards differ from state to state. In some states they are comprised of both professionals and consumers; in other states, the boards are composed solely of professionals.⁶⁷ Although the composition of licensing boards may differ, they all serve the same basic purpose:⁶⁸ to "set standards for minimum competency, licensure, and practice; investigate complaints; and discipline practitioners."⁶⁹ A consumer survey of those licensing boards found that licensing boards possessed "adequate oversight, disciplinary, and enforcement powers, but seldom use[d] them."⁷⁰ Because these boards lack the funding to aggressively enforce their regulations, they are often referred to as "reactive boards," meaning that they only act in response to consumer complaints.⁷¹ The failure of these boards to be pro-active further illustrates the weakness of the other mechanisms.

C. What Defines the Hearing Aid Dispensers?

Licensing boards, along with federal and state laws, govern three basic groups of hearing aid dispensers,⁷² which include physicians, audiologists, and hearing instrument specialists.⁷³ Each group is distinct, in that differing requirements must be fulfilled before a licensee is permitted to prac-

65. *Id.* § 57b(b) (1988). Relief that the FTC may seek "include[s], but [is] not limited to, rescission or reformation of contracts, the refund of money or return of property, the payment of damages, and public notification respecting the rule violation or unfair or deceptive act or practice." *Id.* The only remedy the FTC may not seek is exemplary or punitive damages. *Id.*

66. *Hearings*, *supra* note 6, at 161 (report of the AARP).

67. *Id.* at 162.

68. *Id.*

69. *Id.*

70. *Id.* at 163. A study of state boards from 1988 to 1990 found that 10 boards took no disciplinary action and 12 others were only "minimally active." *Id.*

71. *Id.*

72. *Id.*

73. *Id.*

tice as a hearing instrument specialist, an audiologist, or a physician.⁷⁴

Physicians who diagnose and treat ear dysfunction and hearing loss are divided into three groups: otologists, otorhinolaryngologists, and aotolaryngologists.⁷⁵ These physicians must complete four years of medical school, and fulfill the general requirements for professional licensure in their particular states.

Dispensing audiologists conduct tests to determine the proper hearing aid and fit, and also provide aural rehabilitation.⁷⁶ Audiologists are usually certified by the American Speech-Language-Hearing Association (ASHA) and possess a Certificate on Clinical Competence (CCC-A).⁷⁷ Forty-three states provide licensing boards for audiologists; most requiring CCC-A certification.⁷⁸ In order to be certified, an audiologist must possess a master's degree in audiology, complete a nine-month, post-graduate clinical internship, and pass a national examination.⁷⁹ Approximately two-fifths of U.S. audiologists work in private practice, with the remaining three-fifths practicing in clinics.⁸⁰

Hearing instrument specialists, also known as hearing aid dealers, may also dispense hearing aids.⁸¹ Forty-eight states have established licensing boards for hearing instrument specialists.⁸² Although requirements for qualification as a hearing aid dealer vary greatly from state to state, several common requirements must be met. A hearing aid dealer must be a high-school graduate or possess a general equivalency degree (GED), must be at least eighteen years old, and must "be in good health and of good moral character."⁸³ Some states require a limited training program, and there may be a licensure examination with a degree of difficulty that varies from state to state.⁸⁴ A hearing aid dealer's primary place of business is a retail establishment specializing in testing hearing and selling

74. *Id.* at 159.

75. *Id.* Otologists specialize in treating the ear; otorhinolaryngologists specialize in treating the ear, nose, and throat; and otolaryngologists specialize in treating the ear and throat. *Id.*

76. *Id.* Audiologists perform tests to determine the type of hearing aid that is suitable for each patient. They also provide aural rehabilitation for hearing aid users. *Id.*

77. *Id.*

78. *Id.* at 19.

79. *Id.* at 159.

80. Karen S. Cranmer-Briskey, *The Consumer Connection: Value + Benefit*, 43 HEARING INSTRUMENTS 58 (1992).

81. *Hearings*, *supra* note 6, at 159 (report of the AARP).

82. *Id.*

83. *Id.*

84. *Id.*

hearing aids.⁸⁵ The dealer performs no aural rehabilitation. The variety of state licensing schemes makes it difficult to extrapolate any common licensing scheme.

III. PROBLEMS UNDER CURRENT FEDERAL REGULATIONS

A. *Misleading Advertising As a Major Impediment to Effective Use of Hearing Aids*

Several serious problems must be corrected before the hearing aid can adequately benefit the millions of hearing-impaired persons now suffering from a hearing loss. These problems are not new to the hearing aid industry and were actually examined when the current federal regulations went into effect in 1977.⁸⁶ The most serious and widely recognized of these problems is false and misleading advertisements made to the public regarding the benefits received from the use of a hearing aid.⁸⁷ Another serious problem is the potential and apparent abuse of the current regulations under which a consumer may waive the physical examination required to purchase a hearing aid.⁸⁸ Moreover, some hearing aid dispensers apparently lack the training necessary to properly examine potential hearing aid users.⁸⁹ Often these dispensers do not conduct adequate tests, or understand the results of the tests they do conduct.⁹⁰ Finally, there is an increasing call for "laws . . . at the state or federal level which ban or restrict home solicitation sales of hearing aids."⁹¹ Home sales present an inherently difficult problem to both the seller and the

85. *Id.*

86. *Id.* at 161. In 1975 the FTC sought to develop a Trade Rule for the hearing aid industry. *Id.* at 160. It was thought at the time that case-by-case litigation within the industry was ineffective and did not serve the purpose of notifying the consumer. *Id.* In 1982, the Commission staff set forth several proposals, including a 30 day free trial period for hearing aid purchasers, a requirement that retail dispensers disclose their status as sellers and not just prescribers, and a prohibition against deceptive claims and advertising. *Id.* Following a 1985 survey conducted by the FTC's Bureau of Consumer Protection, finding a high rate of consumer satisfaction with hearing aids, the Trade Rule hearings were terminated and no rule was promulgated. *Id.* Although the survey was challenged by both AARP and ASHA, the Commission refused to leave the hearings open. *Id.* at 161.

87. *Hearings, supra* note 6, at 59 (statement of Donald L. Darling). "[False and misleading] advertisements give elderly consumers, grasping for solutions to their hearing problems, false hopes and false expectations as to the technological ability of a hearing aid." *Id.*

88. *Id.* at 61; *id.* at 63 (statement of Donna L. Sorkin, Executive Director, Self Help for Hard of Hearing People, Inc. [SHHH]).

89. *Id.* (statement of Donna L. Sorkin).

90. *Id.* at 54 (statement of Donald L. Darling).

91. *Id.* at 61 (statement of Donald L. Darling).

purchaser.⁹²

Misrepresentation of the capabilities of hearing aids only tarnishes the reputation of the entire hearing aid industry. Such misrepresentation also improperly leads those who might benefit from the use of a hearing aid to develop unrealistic expectations about the capabilities of current technology.⁹³ Misleading advertisements in the hearing aid industry were first recognized and prohibited in 1934.⁹⁴ In April of 1993, the FDA sent letters to six hearing aid manufacturers warning them to cease making false claims regarding the capabilities of hearing aids to consumers.⁹⁵ These manufacturers were charged with making claims that hearing aids could eliminate background noise.⁹⁶ In addition, the FDA alleged that manufacturers made claims that were unsubstantiated by clinical data, failed to disclose material information, and overstated the quality and value of the hearing aids.⁹⁷

Two of these six manufacturers, Beltone Electronics Corp. and Dahlberg Electronics, Inc., had consent orders issued against them by the FTC in 1976 directing them to cease making unreasonable claims as to their products' abilities.⁹⁸ These two manufacturers were also issued consent orders for their misleading advertising practices prior to the 1976 orders.⁹⁹ These manufacturers appear to be representative of a pattern

92. *Id.* (statement of Donald L. Darling).

93. David Kirkwood, *In Hearing Aid Advertising, How Much is Too Much?*, 45 HEARING J. 4 (1992).

94. *Hearings*, *supra* note 6, at 160 (report of the AARP).

95. U.S. DEP'T OF HEALTH & HUMAN SERV., P93-14 HHS News 1 (April 26, 1993). Warning letters were sent to the following manufacturers: Dahlberg Inc., Golden Valley, Minnesota; Electone Inc., Longwood, Florida; Siemens Hearing Instruments, Piscataway, New Jersey; Omni Hearing Systems, Carrollton, Texas; Starkey Laboratories Inc., Eden Prairie, Minnesota; and Beltone Electronics Corp., Chicago, Illinois. *Id.* at 1.

96. *Id.* at 2.

97. *Id.* at 3. Promotional materials distributed by these manufacturers made such claims as, "[i]f you have nerve deafness, hearing again is no big thing." *Id.* at 3.

98. Beltone Electronics Corp., 88 F.T.C. 336 (1976); Dahlberg Electronics, Inc., 88 F.T.C. 319 (1976). Four other consent decrees were issued that year against other hearing aid manufacturers. *See* Maico Hearing Instruments, Inc. 88 F.T.C. 298 (1976); Qualitone, Inc., 88 F.T.C. 287 (1976); Radioear Corp., 88 F.T.C. 308 (1976); Sonotone Corp., 88 F.T.C. 368 (1976). Prior to 1976, Beltone already had two FTC orders against it, Dahlberg not only had two orders against it, but had signed two assurances of voluntary compliance with the FTC as well. Of the other four manufacturers, Maico already had been issued one previous consent order against it and one voluntary compliance; Qualitone had been issued one previous order against it; and Sonotone had been issued two previous consent orders and two voluntary compliance citations. *Hearings*, *supra* note 6, at 160 (report of the AARP).

99. *Hearings*, *supra* note 6, at 160 (report of the AARP).

of abuse of unenforced hearing aid regulation: misleading advertisements that overstate a hearing aid's capabilities.

A recent editorial by David Kirkwood, editor-in-chief of *The Hearing Journal*, aptly represents the attitude of the hearing aid industry toward false advertising. Mr. Kirkwood states that it is too much to expect hearing aid advertisers to "present a full and objective picture of the product being promoted."¹⁰⁰ Mr. Kirkwood states that the hearing aid industry uses "hype" in its advertisements no more than any other industry in promoting its products in order to attract customers.¹⁰¹ Despite the fact that companies do use hype in the promotion of their products, this still is not a license to mislead consumers.

B. The Option of Waiving a Medical Examination Has Led to Consumer Misinformation

The second major problem impeding the adequate use of hearing aids is evidenced by the regulations themselves, specifically, the FDA regulation allowing a hearing aid purchaser to waive a medical examination, which is essential to determining whether the purchaser is a proper candidate for a hearing aid.¹⁰² Unfortunately, the option of waiver has produced a breeding ground for fraud and misinformation.¹⁰³ This problem was clearly expressed by Donald Darling, director of West Virginia's Antitrust/Consumer Protection Division:

The most pervasive problem I have encountered in my investigation of hearing aid dispensers is the falsification of waiver of medical evaluation forms and the omission to inform prospective users that it is in their best health interest to have a medical evaluation by a licensed physician prior to purchasing a hearing

100. Kirkwood, *supra* note 93, at 4.

101. *Id.* Mr. Kirkwood's response was to a letter published in *The Hearing Journal* in January of 1992 from John Zeigler. A dispensing audiologist, Mr. Ziegler stated that false advertising by the hearing aid industry would hurt the industry in the long run because of dissatisfied customers. *Id.* According to Mr. Kirkwood, reader response to the letter was "remarkably strong" from "all segments of the hearing healthcare community," and unanimously in agreement with Mr. Zeigler. *Id.* Mr. Kirkwood states that the advertising used in the hearing aid industry is no worse than advertising in other industries, and that advertising must "grab the hearing-impaired listener's attention" or it is of little use. *Id.*

102. 21 C.F.R. § 801.421(a) (1994). This waiver is subject to certain conditions. *See id.* § 801.421(a)(i)-(iii); *see also* notes 42-49 and accompanying text.

103. *See Hearings, supra* note 6, at 29 (statement by David Kessler, M.D., Commissioner, Food and Drug Administration); *id.* at 61 (statement of Donald L. Darling); *id.* at 64 (statement of Donna L. Sorkin).

aid.¹⁰⁴

If the examination is waived, and the dispenser either fails to perform the necessary tests or fails to understand the results of a test, a dispenser may sell an ineffective aid to a purchaser, or may misdiagnose the purchaser's need for a hearing aid.¹⁰⁵ In addition to potentially burdening the consumer with a heavy financial obligation, the dispenser may prevent the purchaser from discovering a surgically correctable hearing impairment. Waiver of the medical examination undoubtedly has produced repercussions for the individual who suffers a hearing loss. "[S]erious medical conditions are overlooked by non-physician providers [dispensers] subsequently necessitating more extensive medical and or surgical treatment than would have been necessary originally, adding additional cost and suffering to the patient and cost to the health care system."¹⁰⁶

C. *The Need for Stricter Training and Licensing of Dealers*

A troubling aspect of the current hearing aid industry is that aid dispensers are unable to diagnose adequately a hearing loss, and they are unable to prescribe the correct type of hearing aid in conjunction with rehabilitative training necessary to adjust to the aid and to communicate more clearly.¹⁰⁷ Hearing aid dispensers are often given inadequate training on the physiology and anatomy of the inner ear.¹⁰⁸ Dispensers are generally trained in sales tactics that may cause a consumer to purchase a costly hearing aid that may not be appropriate to compensate for his or her hearing loss.¹⁰⁹

Although some states require a licensed hearing aid dispenser to supervise the sale of hearing aids by trainees or salespeople, "the supervision requirement has been abused by dealers and in most instances the supervision is so attenuated that it is nonexistent."¹¹⁰ In order to avoid this abuse, state licensing and regulatory boards should prohibit the sale of

104. *Id.* at 61 (statement of Donald L. Darling).

105. *Id.* at 28 (statement of David Kessler); *id.* at 63 (statement by Donna L. Sorkin).

106. *Hearings, supra* note 6, at 88 (statement of Jerome C. Goldstein, M.D., Executive Vice President, American Academy of Otolaryngology-Head and Neck Surgery [AAO-HNS]).

107. *Id.* at 63 (statement of Donna L. Sorkin).

108. *Id.* at 54 (statement of Donald L. Darling).

109. *Id.* at 29 (statement of David Kessler) (pointing out that the hearing aid industry is becoming an "increasingly aggressive, competitive business," where pressure is placed on salespeople to sell hearing aids, which in turn leads salespeople to encourage consumers to sign the waiver and forego the critical medical evaluation).

110. *Id.* at 55 (statement of Donald L. Darling).

hearing aids by anyone except a licensed hearing aid dispenser. Until these conditions are enforced, the same abuses of the rules will continue to occur as has occurred under the false advertisement regulations. Suspending the licenses of abusive dealers would send a clear message that inadequate examination services provided to the hearing aid consumer will not be tolerated.

D. Dangers of Door-to-Door Hearing Aid Sales

Door-to-door sales of hearing aids is another problem with providing adequate hearing aids to the hearing-impaired consumer.¹¹¹ The high pressure sales tactics,¹¹² may be particularly abusive if used on elderly individuals, especially when used at an elderly consumer's home, because the individual with the hearing impairment has no opportunity to walk away from the transaction.

Other medical assistive devices, such as eyeglasses and dentures, are not sold in the home; however high pressure hearing aid dispensers are allowed to influence elderly individuals into making a substantial purchase with little or no supervision.¹¹³ Moreover, dispensers may wear white coats leading the consumer to believe that they are doctors.¹¹⁴ The elderly consumer may fail to differentiate between a trained professional, such as an optometrist or audiologist, and the dispenser in the white coat.¹¹⁵

Proper testing of an individual is essential to the effective fitting of a hearing aid. These tests cannot accurately be performed in the home because of background noise and/or a lack of the necessary equipment carried by the door-to-door salesperson.¹¹⁶ If this testing is not adequately performed, the hearing aid will likely be of little value to the wearer, just as an incorrect eyeglass prescription would not benefit someone with impaired vision. Because a majority of persons with hearing loss have what is known as "progressive or fluctuating losses," an outdated audiological examination will also be of little benefit.¹¹⁷ It is necessary to perform the

111. See *supra* notes 33-34 and accompanying text.

112. Hunt, *supra* note 30, at 111.

113. *Hearings*, *supra* note 6, at 69 (statement of Donna L. Sorkin).

114. *Id.*

115. *Id.*

116. *Id.* at 7 (statement of Donald L. Darling). Audiological examinations performed in the hearing-impaired person's "kitchen or living room" have very little chance of getting an accurate reading in order to prescribe the appropriate aid. *Id.*

117. *Id.* at 69 (statement of Donna L. Sorkin). "Sixty percent of persons with hearing loss have progressive or fluctuating losses . . ." *Id.*

essential tests within six months of the time the aid is obtained. In addition, this essential testing cannot be performed in the home.

IV. SOLUTIONS TO CURRENT PROBLEMS WITH HEARING AID INDUSTRY REGULATION

Although many problems confront both the hearing aid industry and hearing-impaired consumers, viable solutions do exist. Some of the solutions are simple and thus more easily implemented; others, however, are more controversial due to the fact that they will involve additional costs. Regardless of whether the solution is painless or fraught with controversy, it must be remembered that the overarching goal of the hearing aid industry should be to provide an effective medical assistive device to millions of Americans whose lives would be enhanced by its use.

Fraudulent misrepresentation of the capabilities of hearing aids must be stopped. An enforcement mechanism that does no more than cause the violator to simply cease making claims for a short period of time should not be tolerated. Federal regulations already exist to stop fraudulent advertising,¹¹⁸ but, unless the laws are enforced, hearing aid manufacturers have little to fear when making false statements about their products.¹¹⁹ Civil penalties available to enforce the current regulations¹²⁰ should be used to alert the industry that ads claiming that “[n]erve deafness can be helped! Nerve deafness, a common cause of hearing impairment, *can be helped*, even though there is no surgical or medical cure available”¹²¹ will not be tolerated. Although the recent letters sent by the FDA are a welcome step, they appear to have been a step taken only at the behest of FDA Commissioner David Kessler; consequently, it is a very real possibility that they will be ignored once this active Commissioner leaves office.¹²² Consistent enforcement of the regulations now in place must become a priority of the agencies involved, in order to stop the recurrence of false advertising in the hearing aid industry.

To prevent hearing aid dispensers from abusing the availability of the medical waiver, the waiver option should be eliminated. The rationale

118. 15 U.S.C. § 45 (1988). The current code is broadly written and allows for enforcement against manufacturers making fraudulent claims.

119. See, e.g., *Hearings*, *supra* note 6, at 160-63 (report of the AARP).

120. 15 U.S.C. § 57b (1988).

121. *Beltone Electronics Corp.*, 88 F.T.C. 336, 338 (1976).

122. *Hearings*, *supra* note 6, at 161-62 (noting that the FDA focused minimal attention on the regulation of hearing aids, and only after Commissioner David Kessler launched an investigation did the FDA issue warning letters in April of 1993 to six hearing aid manufacturers).

accepted upon passage of the waiver was not to create a loophole for dispensers wishing to make a quick sale, the waiver option was in fact intended to be the exception to the rule, not the norm.¹²³ The medical examination waiver was originally intended to allow those with specific religious beliefs against medical examinations to opt out, yet to still have the option of using a hearing aid if they wished.¹²⁴ Today, more than 85% of adults who purchase a hearing aid make use of the waiver.¹²⁵ In order to reverse this trend, the ease with which the waiver is obtained must be eliminated. The FDA is currently considering either eliminating the waiver option, or, at a minimum, substantially limiting the availability of the waiver.¹²⁶

To avoid the seemingly widespread problem of misdiagnosing a hearing loss, the solution is straightforward: dispensing hearing aids should be limited to those who are specially trained to do so, such as audiologists or physicians. Hearing aid specialists, dealers, and others without adequate training should not be allowed to dispense aids. This would eliminate the majority of inappropriate aids provided to persons with hearing loss.¹²⁷ The economic problem this would present for the hearing aid manufacturer is obvious: suddenly, a large portion of the manufacturers' sales force would be prohibited from participating in the market. In contrast, this elimination would benefit the consumer, who would receive a higher standard of care from dispensing audiologists and physicians.

The problem of door-to-door sales of hearing aids has two possible solutions. Either this type of sale could be prohibited altogether, or hearing aid dispensers performing this type of sale could be required to provide a bond with the state in which they practice.¹²⁸ Prohibition of the practice would be the more effective solution, considering the factors previously discussed regarding elderly consumers in the home.¹²⁹

V. CONCLUSION

The hearing aid can be a valuable medical assistive device if the appropriate steps are taken to assure that the person with the hearing loss receives the appropriate aid. Misleading advertising, the option to waive a

123. *Id.* at 29 (statement of David Kessler).

124. *Id.* at 88 (statement of Jerome C. Goldstein).

125. *Id.* (statement of Jerome C. Goldstein).

126. *Id.* at 29 (statement of David Kessler).

127. *Id.* at 67 n.2 (statement of Donna L. Sorkin).

128. *Id.* at 61 (statement of Donald L. Darling).

129. *See supra* notes 33-34 and accompanying text.

medical examination, the need for stricter training and licensing of dealers, and the improper door-to-door selling of hearing aids are all major obstacles to the efficient distribution of hearing aids to hearing-impaired persons. As the elderly population in the United States grows ever larger, the problems facing the hearing aid industry grow ever greater and their effect widens. The solutions to these problems are readily available, and now is the time to act.

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