Effective June 19, 2003

BEFORE THE MINNESOTA
DEPARTMENT OF HEALTH
HEALTH OCCUPATIONS PROGRAM

In the matter of David Buschow
Hearing Instrument Dispenser
File 02007

Stipulation and Consent Order

IT IS HEREBY STIPULATED AND AGREED by David Buschow, (hereinafter "Practitioner"), and the Minnesota Department of Health, (hereinafter "Department"), and that without trial or adjudication of any issue of fact or law herein:

Except as otherwise specified herein; this Stipulation and Consent Order, investigative reports, and related documents shall constitute the entire record herein upon which this Order is based and shall be filed with the Department. The Stipulation and Consent Order document is public data pursuant to the Minnesota Government Data Practices Act, Minnesota Statutes, Chapter 13 ("MGDPA"). All other data comprising the record shall not be considered a part of this Stipulation and Consent Order and shall maintain the data classifications to which they are entitled under the MGDPA.

LEGAL AUTHORITY

1. Department has statutory authority to discipline hearing instrument dispensers under Minnesota Statutes, Section 153A.15. The types of disciplinary action the Department may impose include issuance of public reprimands, suspension, revocation, denial of a certificate renewal, revocation or suspension of the right to supervise trainees, the assessment of civil penalties not to exceed $10,000 for each separate violation, or any other action reasonably justified by the individual case. Pursuant to Minnesota Statutes, Section 13.41, disciplinary actions are public data.

2. Minnesota Statutes, Section 153A.15, Subd. 1(5) states the commissioner may take enforcement action against a dispenser of hearing instruments who has been disciplined through revocation, suspension, restriction or limitation by another state for conduct under this chapter.

3. Minnesota Statutes, Section 153A.15, Subd. 1(8) states the commissioner may take enforcement action against a dispenser for demonstrating a willful or careless disregard for the health, welfare, or safety of a consumer.

4. Minnesota Statutes, Section 153A.15, Subd. 1(13) states the commissioner may take an enforcement action against a dispenser for performing services in an incompetent or negligent manner.

5. Minnesota Statutes, Section 153A.15, Subd. 1(21) states the commissioner may take an enforcement action against a dispenser for having been disciplined by the commissioner of health, or the authority, in this or another jurisdiction, if any of the grounds for the discipline are the same or substantially equivalent to those in sections 153A.13 to 153A.19.

FACTS

The Department alleges and the Practitioner unconditionally admits for purposes of these and any future disciplinary proceedings the following allegations:

5. Practitioner was granted status as a hearing instrument trainee on April 9, 1996. Practitioner took the Minnesota hearing instrument dispenser examination exam on August 12, 1996, and received a passing score.

6. Practitioner submitted his application for certification on February 12, 1997, was certified to dispense hearing instruments on April 7, 1997. Practitioner has renewed his certification in 1997, 1998, 1999, and 2000.

7. The Department received Practitioner's renewal application on September 27, 2001, in which Practitioner attached a letter stating that since the time of his last renewal, he was informed that an action was taken against him in Wisconsin and enclosed a Final Decision and Order dated December 6, 2000. The disciplinary action concluded that Practitioner engaged in conduct which evidenced a lack of knowledge or ability to apply principles or skills of the practice of fitting and dealing in hearing aids, and engaged in unprofessional conduct, and practiced in a manner which substantially departs from the standard of care ordinarily exercised by a hearing instrument specialist. The Order required that Practitioner surrender his license and registration as a hearing instrument specialist in Wisconsin and that he could not renew or attempt to renew his license at any time in that state.

8. The Findings of Facts in the December 6, 2002, Wisconsin Order contained the following findings:

A. In May 1995, Practitioner examined Patient 1, performed an audiogram, hearing test, fitted, and sold Patient 1 a hearing aid for his left ear.

B. In January 2000, Patient 1 went to see an Ear Nose and Throat (ENT) doctor to have earwax removed that was interfering with the operation of his hearing aid. The ENT was unable to remove the earwax. The ENT recommended that Patient 1 use olive

oil and mineral oil in his ears to soften the earwax then return for a follow up appointment.

C. Five days later Patient 1 returned to the ENT for ear wax removal. Patient 1's ear wax was removed. The ENT observed in Patient 1's left ear a large area of eroded bone and made a diagnosis of a cholesteatoma.

D. The ENT determined that the cholesteatoma had been in Patient 1's left ear for at least the last ten years and that the cholesteatoma was the cause of the hearing loss.

E. Patient 1 told the ENT that Practitioner had fitted him with a hearing aid several years before, but that Practitioner never recommended that he see a physician before purchasing the hearing aid. Patient 1 said that the only option he was given was to purchase a hearing aid for his left ear.

F. Patient 1 did not sign any waiver statement stating that he did not want a medical exam before purchasing a hearing aid, as required by federal law.

G. In February 2000, Patient 1 had cartilage tympanomastoidectomy with ossicular reconstruction surgery on his left ear to correct the cholesteatoma.

H. Two months later, Patient 1 returned to the ENT and reported a significant improvement in his hearing. An audiogram was obtained, which showed a significant improvement in Patient 1's left-sided conductive hearing loss.

I. Patient 1 did not require the use of a hearing aid after his surgery.

9. The Minnesota Department of Health renewed Practitioner's certification on November 1, 2001, and Practitioner was notified in his issuance letter dated October 25, 2001, that the issuance of his renewal would not affect the pending investigation or the Department's right to impose sanctions against his credential.

10. On December 10, 2001, the Department questioned Practitioner about his dispensing activities in 1995 in Wisconsin, and requested him to describe in detail what criteria he uses to recognize any unilateral hearing loss, a conductive hearing loss and unilaterally poor speech discrimination in order to properly refer a consumer to a physician. Practitioner was also questioned about his knowledge of cholesteatoma and his ability to recognize this condition including any training he had received on this disease or any other diseases of the ear which would enable him to properly refer consumers for a medical evaluation.

11. On January 10, 2002, the Department received Practitioner's response in which he stated "a unilateral hearing loss is a loss of hearing only on one side. The criteria I use to recognize any unilateral hearing loss is: When testing, if bone conduction thresholds are within the normal range of

0 dB to 25dB and air conduction threshold exhibit a hearing loss, we have what is referred to as a conductive hearing loss, (an air bone gap). When testing the other ear we find near normal air conduction thresholds and near normal bone conduction thresholds, we then have unilateral hearing loss. When there is an air bone gap equal to or greater than 15dB at 500, 1,000, 2000 Hertz, it is a red flag meaning I would send to a physician. Any medical problems of the ear, if there were any question, would be refereed to a physician before purchasing a hearing aid. In the case when a patient may be found to have an air bone gap equal to or greater than 15 dB at 500, 1,000, 2,000 Hertz, I would refer to a physician. I would also refer to an ENT if one or both ears had pain or drainage or if there were anything unusual seen on my otoscopic observation."

12. Practitioner responded to the Department's question about his knowledge of cholesteatoma and his ability to recognize this condition including any training he had received on this disease or any other diseases of the ear which would enable him to properly refer consumers for a medical evaluation. Practitioner stated that "Cholesteatoma is a pouch of skin formed by a retracted eardrum, which fills with sloughing skin cells and invades the middle ear space. As it grows in size it can erode the mastoid bone and ossicle chain. Normally, a perforated tympanic membrane heals by creating a smooth thin continuous membrane across the area of perforation. Occasionally, the edges of the perforation grow inward into the middle ear and trapped epithelial skin cells create white "pearls" of epithelium, which can form congenitally or after traumatic or surgical perforations. Some cholesteatoma sacs grow in the middle ear behind the eardrum. These are observable with a good otoscope and appear as white masses. Other Cholesteatomas grow into a nonvisible part of the middle ear. These are more dangerous as their detection is quite difficult. Cholesteatomas produce conductive hearing loss which increases with time, and client whose ear exhibits such growth should be referred immediately to a physician. Audiometric indicators approximate normal test results when the Cholesteatoma pocket is small. As the pocket grows, conductive indicators become positive. These include: rounded or flat tympanograms, elevated or absent reflexes, small air bone gaps and elevated MCLS and UCLS."

13. On April 23, 2002, Department staff met with the Hearing Instrument Dispenser Advisory Council Competency Review Committee (CRC) to review this matter. CRC members defined cholesteatoma as a growth of cells that erodes the bones. It is a growth on both sides of the eardrum. A patient may or may not have any symptoms and it is a serious condition that could become life threatening if it is malignant.

14. CRC members advised the Department that it was conceivable that Practitioner might not have seen the cholesteatoma in 1995; however, the ability to see the cholesteatoma is irrelevant because Practitioner should have referred the patient to and ENT physician, based solely on the audiogram. CRC members also stated that based on the unilateral hearing loss, Practitioner violated the FDA regulations by not referring Patient 1 to a physician. CRC members stated that in Practitioner's explanation to the Department, he did not provide the definition of unilateral hearing loss and that Practitioner did not follow the criteria he described when testing Patient 1.

15. CRC members also evaluated Practitioner's explanation to the Department of the criteria he uses to recognize any unilateral hearing loss, a conductive hearing loss and unilaterally poor speech discrimination in order to properly refer a consumer to a physician. The CRC stated that Practitioner did not answer the question and it further appeared that Practitioner did not take the audiogram of Patient 1 seriously because Practitioner should have seen that there was an air-bone gap result on the audiogram and should have referred the patient immediately to a physician. CRC members stated that based on the unilateral hearing loss, Practitioner violated the FDA regulations by not referring to a physician and that Practitioner was not able to provide the definition of unilateral hearing loss. CRC members stated that the audiogram also showed that Practitioner did not do a UCL speech test.

16. The Department contacted Practitioner's current supervisor regarding Practitioner's dispensing activities and level of supervision. Practitioner's supervisor informed the Department that he has supervised Practitioner since April 15, 1997, and that Practitioner calls him during the week to review hearing tests results and fitting recommendations prior to Practitioner recommending to the patient, especially for unusual audiograms. The order forms from Practitioner for hearing instruments along with the test results, case histories, ear impressions etc, are funneled through the company's business office and reviewed for completeness, appropriate testing procedures, adequate impressions and appropriateness of the hearing instruments selected for the hearing loss and other patient related factors before being sent to the factory.

17. The Department questioned Practitioner's supervisor whether or not he had any concerns regarding Practitioner's dispensing activities and/or patient care. Practitioner's supervisor stated that he did not have any concerns and that Practitioner, like all audiologists and specialists, when new technologies and/or equipment are introduced, require some time to master computer software or equipment procedures and his company has worked with Practitioner, and he has responded and mastered the software and procedure in a reasonable period of time. Practitioner's supervisor stated that they require real ear test on all deliveries that are not recent digital technology. Practitioner's employer purchased equipment to conduct this test and have it available in every office. Practitioner's supervisor stated that two years ago, Practitioner was not making a consistent practice of performing real ear tests and sound field word verification at delivery and Practitioner was given a written Employee Warning Notice regarding these procedures on September 30, 2000. Practitioner's supervisor also stated that Practitioner has improved greatly in this area since that time.

18. Practitioner's supervisor advised the Department that their company has previously seen clients with a cholesteatoma. Their testing procedures and questioning requires their specialists to refer to a physician whenever anything unusual is discovered that warrants a physician referral from otoscope observation, inquiry and testing including an air bone gap, pain in the ear, dizziness and other red flag questions mandated by the FDA. Those referral forms are given to the patient directly by the clinicians and the company encourages practitioners to make note of the medical referral in the file or on our audiogram form. The patient is referred to a physician with a completed Referral for Medical Examination form.

19. Practitioner's supervisor stated that he was not aware of any formal complaints or serious matters experienced with Practitioner.

20. By signing this Stipulation, Practitioner expressly waives the formal hearing and all other procedures before the Department of Health to which Practitioner may be entitled under the Minnesota or United States constitutions, statutes, or rules.

ORDER

Upon this Stipulation record, and without any further notice of proceedings, the Division Director hereby ORDERS:

1. Practitioner must obtain and report ten continuing education (CE) units related to the causes and diagnosis of unilateral hearing loss, conductive loss and testing for poor speech discrimination within one year. These ten hours will be in addition to the CE units Practitioner is required to report for renewal of his certification and cannot be used for that reporting requirement.

2. Practitioner must reimburse the Department $522.00 for its cost of investigation and proceedings to date.

3. If Practitioner leaves his current employment where he is supervised directly, he must do the following:

A. Practitioner must provide any employer who hires him as a hearing instrument dispenser with a copy of this Stipulation and Consent Order;

B. Notify the Department within two weeks of his starting a new job and provide name, address, telephone number of both his employer and supervisor, including their names:

C. Practitioner must be supervised in any new job for a period of one year. Practitioner's supervisor will submit quarterly reports to the Department about Practitioner's hearing testing for the purposes of dispensing hearing aids, specifically including cases where the Practitioner should have referred the client to an ENT for follow up;

D. If the Practitioner does not have a supervisor at his new job, he must obtain an offsite supervisor who will agree to consult with Practitioner regarding his clients and audiogram results and testing on a regular basis and who will provide quarterly reports to the Department for a period of one year;

4. Practitioner will also sign whatever releases are necessary for the supervisor to report Practitioner's work directly to the Department. Practitioner shall cooperate fully during the process of Department's enforcing and monitoring compliance with this Stipulation;

5. If the same or similar evidence about Practitioner's conduct is substantiated, the Department will suspend or revoke Practitioner's certification.

6. This Stipulation and Consent Order shall not in any way or manner limit or affect the authority of the Commissioner to proceed against Practitioner by initiating a contested case hearing or by other appropriate means on the basis of any act, conduct, or admission of the Practitioner, justifying disciplinary action which occurred before or after the date of this stipulation and which is not directly related to specific acts and circumstances set forth herein;

7. In the event the Division Director in his discretion does not approve this settlement or a lesser remedy than specified herein, this Stipulation and Order shall be of no evidentiary value and shall not be relied upon or used for any purpose by either party. If this should occur and thereafter an administrative contested case is initiated pursuant to Minnesota Statutes, Chapter 14, Practitioner agrees he will assert no claim that the Division Director was precluded by his review and consideration of this Stipulation or any records relating hereto;

8. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation. Practitioner understands that this agreement is subject to the Division Director's approval. If the Division Director either approves the Stipulation or makes changes acceptable to the Practitioner, an Order will be issued by the Division Director, upon this Stipulation and Consent Order and all other evidence made available to the Division Director, once the Division Director has approved it, the Division Director may issue the Stipulation and Consent Order to Practitioner at any time without further notice;

9. A copy of the Stipulation and Consent Order when issued and signed by the Division Director, shall be served by first class mail on Practitioner, at Practitioner's last known address. Service via first class mail shall be considered personal service upon Practitioner, at which time this Stipulation and Consent Order shall become effective. Any appropriate federal or state court shall, upon application of the Department, enter its decree enforcing the Order of the Department.

CONSENT: Practitioner hereby acknowledges that he has read, understood, and agreed to this Stipulation and Consent Order and has freely and voluntarily signed it.

Dated: 6/19, 2003 David Buschow
David Buschow, Practitioner

Dated: 6/17, 2003 Susan Winkelmann
Susan Winkelmann, Investigations and Enforcement Manager
Health Occupations Program