Eppectiv 08/22/2005

BEFORE THE MINNESOTA COMMISSIONER OF HEALTH

In the Matter of John Flake Unauthorized Hearing Instrument Dispenser STIPULATION AND CONSENT ORDER

IT IS HEREBY STIPULATED AND AGREED by John Flake, (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 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 Order 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 Order and shall maintain the data classifications to which they are entitled under the MGDPA.

LEGAL AUTHORITY

- 1. The 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 or be a trainee, 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.13, subdivision 4 defines a dispenser of hearing instruments to be a natural person who engages in hearing instrument dispensing whether or not certified by the commissioner of health or licensed by an existing health-related board. A person who offers to dispense a hearing instrument, or a person who advertises, holds out to the public, or otherwise represents that the person is authorized to dispense hearing instruments must be certified by the commissioner.
- 3. Minnesota Statutes, Section 153A.14, subdivision 4 states it is unlawful for any person not holding a valid certificate to dispense a hearing instrument. A person who dispenses a hearing instrument without the certificate is guilty of a gross misdemeanor.

- 4. Minnesota Statutes, Section 153A.14, subdivision 4b(a), hearing testing protocol, requires a dispenser, to 1) comply with the United States Food and Drug Administration warning regarding potential medical conditions required by Code of Federal Regulations, title 21, section 801.420 when conducting a hearing test for the purpose of dispensing a hearing instrument; 2) complete a case history, 3) inspect the client's ears with an otoscope, and 4) conduct specific tests on both ears, including bone conduction, air conduction, monaural word recognition, loudness discomfort level testing and masking. If any of the tests cannot be performed pursuant to the United States Food and Drug Administration guidelines, an audiologist must evaluate the hearing and need for hearing instruments.
- 5. Minnesota Statutes, Section 153A.14, subdivision 9 states a hearing instrument dispenser shall, at the time of the recommendation or prescription, give a consumer rights brochure, prepared by the Department, which contains information about legal requirements pertaining to sales of hearing instruments, to each potential buyer of a hearing instrument. A sales contract for a hearing must note the receipt of the brochure by the buyer, along with the buyer's signature or initials.
- 6. Minnesota Statutes, Section 153A.19, subdivision 2 states no person shall sell a hearing aid in this state unless the dispenser provides the buyer with a 30-day written money-back guarantee. The guarantee must permit the buyer to cancel the purchase for any reason within 30 days after receiving the hearing aid by giving or mailing written notice of cancellation to the dispenser. Minnesota Statutes, Section 153A.19, subdivision 2(b), requires that buyers of hearing instruments be given a written contract that contains a specific cancellation notice, notifying the buyer of their right to cancel the purchase and which states the dollar amount of the refund.

FACTS

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

- 1. Practitioner conducted business under the name of United Hearing Aid Center, a non-registered Minnesota business, 215 Barbara Avenue, P.O. Box 1417, Detroit Lakes, Minnesota (hereinafter UHAC), and dispensed Starkey and Finetone hearing instruments from 1998 to 2001. United Hearing Aid Center did not have a tax identification number issued by the Minnesota Department of Revenue.
- 2. Practitioner held a valid Department of Health permit to dispense hearing instruments from April 1, 1994 through October 31, 1994.

- 3. Effective November 1, 1994, hearing instrument dispensers were required to obtain certification from the Department of Health. Practitioner failed to obtain certification to dispense hearing instruments.
- 4. Practitioner was the subject of a disciplinary action by the Department effective June 22, 1998 for engaging in unauthorized hearing instrument dispensing in violation of Minnesota Statutes, Section 153A.14, subdivision 4 when he:
 - a Sold hearing instruments on or about October 2, 1995; June 5, 1996; and June 12, 1996;
 - Entered into a plea agreement with Grant County on July 26, 1996 in which he pled guilty to a misdemeanor charge when Practitioner dispensed hearing instruments without a valid certification. Practitioner was fined \$700.00, plus statutory surcharges and costs, and a 90 day jail sentence. Practitioner's 90 day jail sentence was stayed upon the condition that the fine, surcharges and fees would be paid according to court schedule and that Practitioner have no same or similar violations within two years;
 - c Placed an advertisement in the Detroit Lakes American Legion Post No. 15 newspaper, in January 1997, and held himself out to be a "Licensed Hearing Aid Specialist."
- 5. In the June 22, 1998 Stipulation and Consent Order, the Commissioner ordered the following regarding Practitioner:
 - a. Practitioner shall cease unauthorized hearing instrument dispensing in the State of Minnesota;
 - b. Practitioner shall include the following statement in any advertisements placed in Minnesota, regarding his hearing instrument dispensing services provided in other states, until such time as he obtains a valid Minnesota hearing instrument dispensing certificate or authorized dispenser trainee status issued by the Commissioner: "John Flake is not authorized to dispense hearing instruments in the State of Minnesota."
 - c. Practitioner shall pay a civil penalty of \$991.90 as authorized under Minnesota Statutes, Section 153A.15, subdivision 2(4), to deprive Practitioner of the economic advantage gained by violating one or more provisions of Minnesota Statutes, Sections 153A.13 to 153.15 and to reimburse the Department for the costs of the investigation.

- 6. Effective May 10, 1999, Practitioner completed payment of the civil penalty in the amount of \$991.90.
- 7. In February 2000, the Department received information which indicated Practitioner continued to dispense hearing instruments in the State of Minnesota. On February 9, 1999, Practitioner sold Starkey Laboratories, Inc. (Starkey) hearing instruments to a consumer with the initials AH, who resided in Barnesville, Minnesota, in the amount of \$2800.00; and in December 1999, Practitioner sold Starkey hearing instruments to a consumer with the initials DR, who resided in Campbell, Minnesota, in the amount of \$3,390.00.
- 8. In July 2000, the Department received information which indicated that on May 10, 2000, Practitioner sold Starkey hearing instruments to a consumer with the initials RW, who resided in Big Lake, Minnesota, in the amount of \$1,282.00.
- 9. On November 20, 2000, and in response to a subpoena, the Department received account statements and invoices from Starkey representing hearing instruments Practitioner sold to consumers in Minnesota during the period between June 1998 and November 2000.
- 10. By letter and Subpoena Duces Tecum dated January 29, 2001, John Flake, United Hearing Aid Center, was asked to respond to a notice of complaint and Subpoena Duces Tecum for records about hearing instruments he dispensed since the Stipulation and Consent Order he signed, and effective on June 22, 1998. Practitioner was asked to provide a blank sales contract used by United Hearing Aid Center for the sale of hearing instruments and the consumer rights brochure Practitioner distributed to potential hearing instrument buyers. Practitioner was asked to explain why he continued to dispense hearing instruments after June 22, 1998.
- 11. By letter received February 26, 2001, Practitioner responded to the Department's January 29, 2001 notice of complaint and subpoena for records. In his response, Practitioner stated he had been in the hearing aid business in North Dakota and Minnesota since 1963 and dispensed hearing instruments through referrals made by the Fargo Clinic, Dakota Clinic, Grand Forks Clinic and Grand Forks Rehab and many doctors. Practitioner stated his problems started with "certification," and stated he would "very much like to be certified in Minnesota." Practitioner indicated he was licensed to dispense hearing instruments in North Dakota. Practitioner stated he had "very few" of his old patients in the area and he did not advertise or solicit sales. Practitioner indicated "once in awhile," he contacted patients for repairs or service, and he received calls from patients, but had discontinued this practice. Practitioner stated he was "pressed for payments" on his home and it got him into "trouble." Practitioner stated he got "rid" of his Minnesota files so he would not to be tempted to call or check on former patients.

- By letter dated March 2, 2001, the Department provided Practitioner with instructions on the procedures to become certified in the State of Minnesota as a hearing instrument dispenser. Practitioner was again asked to submit a blank sales contract used by United Hearing Aid Centers since June 22, 1998 and the consumer rights brochure he distributed to potential buyers of hearing instrument. Practitioner was asked to explain the period of time in which he was "pressed for payments" on his home and what type of "trouble" it caused. Practitioner was asked to explain how and when he destroyed files related to Minnesota sales. Finally, Practitioner was also asked to provide invoices for thirty-five transactions as noted on account statements provided by Starkey.
- 13. By letter dated March 14, 2001 to the Department, Practitioner stated he was "pressed for income" because the clinics that previously referred patients to his business started dispensing hearing aids and no longer referred patients. Practitioner stated he "never" fit aids to new clients that had not previously been to his business. Practitioner stated he conducted hearing tests to "screen" clients for hearing loss and to make referrals to physicians. Practitioner stated his files were burned in December 2000. Practitioner provided a list of thirty-five transactions, of which sixteen represented new hearing instruments sales. Practitioner also provided a blank purchase agreement, but did not provide the consumer rights brochure.
- 14. On April 9, 2001, and in response to a subpoena, the Department received account statements and invoices from Finetone representing hearing instruments Practitioner sold to consumers in Minnesota during the period between June 1998 and November 2000.
- 15. By letter and Subpoena Duces Tecum dated April 13, 2001, Practitioner was asked to provided copies of all account statements, invoices, purchase records, names and address of consumers, related to hearing instruments purchased through Finetone; and other hearing instruments manufacturers, except Starkey. Practitioner was also asked to provided invoices and purchase orders which represented twenty-two consumers who purchased Finetone hearing instruments.
- By letter dated May 14, 2001, and received May 16, 2001, Practitioner responded to the Department's Subpoena Duces Tecum and provided copies of Finetone and Prairie Labs invoices representing hearing instrument sales and services, and consumer purchase agreements dated between the period January 1998 and April 2001. Practitioner stated the invoices represented "all the invoices I could find." Practitioner made notations on a copy of the Department's April 13, 2001 letter and indicated the state in which each of the twenty-two consumers resided, and whether the sale represented new hearing instruments or repairs to existing hearing instruments. Practitioner indicated his reason for conducting business with each individual was because "these people have been patients I have taken care of for many years. They have all been referred to me, in fact . . by Merit Care of Fargo, North Dakota."

- 17. Practitioner has not submitted an application to become certified as a hearing instrument dispenser in the State of Minnesota and Practitioner has not applied to take the certification examination.
- 18. Between the period June 6, 1998 and April 7, 2001, Practitioner dispensed hearing instruments to twenty-one consumers as listed below, which represent transactions that occurred in the State of Minnesota. Practitioner signed the purchase agreements, and in a space entitled, "License number," Practitioner wrote in the number "19." Practitioner knowingly wrote this invalid number on each illegal contract.

Consumer Initials	Date Sold	No. Aids	Purchase Price	Practitioner Cost
AR	06/10/98	2-Starkey	3792.00	631.95
NH	06/15/98	1-Finetone	1793.00	298.75
KR	08/04/98	2-Finetone	2363.00	393.75
FB	09/24/98	1-Finetone	722.00	120.25
AJ	09/28/98	1-Finetone	1604.00	267.25
MG	01/13/99	2-Finetone	3584.00	597.25
AH	02/09/99	2-Starkey	2800.00	184.94
SJ	04/02/99	2-Finetone	2558.00	426.25
LA	08/06/99	1-Starkey	1590.00	264.97
JO	11/05/99	1-Starkey	4500.00	749.95
TT	11/05/99	2-Finetone	3165.00	527.50
LK	10/19/99	1-Starkey	1200.00	199.97
DR	12/22/99	2-Starkey	3390.00	849.91
HA	01/13/00	2-Starkey	3360.00	559.93
НО	04/19/00	2-Generic	1488.00	247.94
AN	08/07/00	2-Starkey	3186.00	530.95
BE	08/22/00	1-Starkey	1626.00	270.97
CH	10/03/00	1-Starkey	1386.00	230.97
WR	04/07/01	2-Finetone	1700.00	549.50
19		30	45,807.00	7902.95

Totals

- 19. Of these nineteen transactions, only one of the consumers was given the 30-day written money-back guarantee as required by Minnesota Statutes, Section 153A.19, subdivision 2; one consumers was given the refund amount for cancellations made within 30 days as required by Minnesota Statutes, Section 153A.19, subdivision 2(b); and one consumer signed the waiver, which indicated receipt of the FDA warning regarding potential medical conditions as required by Minnesota Statutes, Section 153A.14, subdivision 4(b)(1). None of the consumer were received the MDH consumer rights brochure as required by Minnesota Statutes, Section 153A.14, subdivision 9.
- 20. By letter dated February 3, 2005, the Department sent an inquiry to the North Dakota Board of Hearing Instrument Specialist (NDBHIS) and requested information regarding the status of Practitioner's licence to dispense hearing instruments in the State of North Dakota. On February 11, 2005, the Department was advised that Practitioner was no longer licensed as a Hearing Instrument Dispenser in North Dakota, but had been "grand fathered" in for license number "19" when licensure was first required.
- By letter dated March 14, 2005, the Department received additional information from the NDBHIS regarding John Flake, United Hearing Aid Center. According to the NDBHIS, Practitioner's license to sell hearing instruments in the State of North Dakota expired January 1, 2004. NDBHIS indicated Practitioner's original license to dispense hearing instruments in North Dakota was issued prior to changes in the law which required individuals to pass a practical examination. Further, effective March 8, 2004, and in response to a complaint, the NDBHIS determined Practitioner did not provide adequate and proper testing, as required by the State of North Dakota, before dispensing hearing instruments to the consumer. By same letter, Practitioner was advised he would be required to take and pass the practical audiometric portion of the Hearing Aid Dispenser's examination. According to the NDBHIS, Practitioner has not made arrangements to take the examination. Practitioner's last correspondence to NDBHIS, dated March 2003, indicated he was no longer selling hearing instruments.
- 22. On February 11, 2005, the Department received a copy of the Detroit Lakes/Fergus Falls Yellow Book telephone directory. According to the telephone directory, United Hearing Aid Center, 12000 Ravenswood Beach Road, Detroit Lakes, Minnesota was listed under the title "Hearing Aids." On February 17, 2005, a search of the name "John Flake" was conducted through the internet search engine "Switchboard." The results found John Flake, 12000 Ravenswood Beach Road, Detroit Lakes, Minnesota 56501. A search of the business name "United Hearing Aid Center" was conducted through the internet search engine "Yellow Book." The results found "United Hearing Aid Center, 12000 Ravenswood Beach Road, Detroit Lakes, Minnesota 56501."

- On February 22, 2005, Department staff investigator contacted Practitioner via telephone at the phone number found via internet search without identifying himself as being from the Department. Department staff asked Practitioner about purchasing hearing instruments. Practitioner stated he "semi-retired" approximately one year ago. Practitioner stated he provides service, but no longer tests or sells hearing instruments because he was no longer licensed. Practitioner referred caller to a licensed hearing instrument dispenser in the Detroit Lakes area.
- 24. Practitioner admits and acknowledges that, for purposes of this Stipulation and Consent Order and any future disciplinary proceedings, that he has engaged in unauthorized hearing instrument dispensing and has violated the provisions of the Stipulation and Consent Order, as referenced in paragraph 11, which constitutes a violation of Minnesota Statutes, Section 153A.14, subdivision 4 and 153A.15, subdivision 2, and which justifies enforcement action by the Commissioner under Minnesota Statutes, Section 153A.15, subdivision 2, against Practitioner.

ORDER

- 1. Upon this Stipulation, and without any further notice of proceedings, the Division Director hereby ORDERS:
 - a. Practitioner cease unauthorized hearing instrument dispensing in the State of Minnesota.
 - b. Practitioner cease advertising and representing, in writing or orally, that he can dispense legally in Minnesota.
 - c. Within 14 days of the effective date of the Stipulation, Practitioner will mail a letter to Starkey and to Finetone stating he is not certified to dispense in Minnesota nor has he ever been. Practitioner shall provide a copy of the letter to the Department within 21 days of the effective of the Stipulation.
 - d. Within twenty-one days of the effective date of the Stipulation, Practitioner shall send a letter to all of his United Hearing Aid Center customers informing them he is not authorized to dispense hearing instruments in the State of Minnesota. This letter must be pre-approved by the Department. The Department will provide Practitioner with a list of names and addresses.
 - e. Within three days of complying with the letter (d) above, Practitioner will provide the Department of a copy of the letter mailed plus a list of the names and mailing address of consumers who were sent the letter.

- f. Practitioner shall pay a civil penalty of \$ 9,947.00 as authorized under Minnesota Statutes, Section 153A.15, subdivision 2(4) to deprive Practitioner of the economic advantage gained by violating one or more provisions of Minnesota Statutes, Section 153A.13 to 153A.15 and to reimburse the Department of the costs of its investigation. Of the total civil penalty amount, \$ 1,917.00 reimburses the Department for costs incurred in investigating the circumstances described in paragraph 1. Practitioner shall remit the civil penalty, by check or money order, made payable to "State of Minnesota, Treasurer," to Catherine Peterson, Health Care Program Investigator, Health Occupations Program, Minnesota Department of Health, 85 E 7th Place, P.O. Box 64882, Saint Paul, Minnesota 55164-0882.
- g. Practitioner is responsible for providing the Department with his current home and business mailing address(es) and telephone number(s). Within seven days of any address change, Practitioner will inform the Department in writing of his new information by mailing or faxing notice to Health Occupations Program, Minnesota Department of Health, 85 East 7th Place, P.O. Box 64882, St. Paul, Minnesota 55164-0882, or by fax at 651/282-3839.
- 2. Regarding the civil penalty described in paragraphs 1 and 2 above, the penalties may be referred to the Minnesota Collection Enterprise (MCE) in the Minnesota Department of Revenue, or other source for collection if Practitioner misses a monthly payment by 14 calendar days after the deadline. When this Order for a penalty becomes public and the Department refers the matter to MCE. MCE is authorized by Minnesota Statutes, section 16D.17 to obtain a judgement against the practitioner without further notice or additional proceedings.
- 3. 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.
- 4. 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 Statute Chapter 14 and Minnesota Statutes, Section 153A.15, 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.
- 5. 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.

6. A copy of the Stipulation and Consent Order when issued by the Division Director, shall be served by first class mail on Practitioner, at Practitioner's attorney's office at Paul Thorwaldsen, Thorwaldsen, Malmstrom, Sorum and Donehower, PLLP, 1104 Highway 10 East, Detroit Lakes, Minnesota 56502. 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 Commissioner, enter its decree enforcing the Order of the Commissioner.

CONSENT:	
Practitioner hereby acknowledges that hat Consent Order and has freely and volunta	as read, understood, and agreed to this Stipulation and arily signed it.
Dated: $\frac{7/6/05}{}$, 2005	John Flake
Dated: 8/1/, 2005	Susan Winkelmann Investigations and Enforcement Manager Health Occupations Program
Upon consideration of this stipulation an Division Director, IT IS HEREBY ORI and implemented by the Division Director.	d all the files, records and proceedings herein by the DERED that the terms of this stipulation are adopted
	STATE OF MINNESOTA DEPARTMENT OF HEALTH
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David Giese, Director

Division of Compliance Monitoring