

404.7(a)(1)(i), that the National Institutes of Health (NIH), Department of Health and Human Services, is contemplating the grant of an exclusive worldwide license to practice the invention embodied in: E-181-2002; U.S. Provisional Patent Application 60/413,773 entitled "Methods and Devices for Intramuscular Stimulation of Upper Airway and Swallowing Muscle Groups," to the Alfred Mann Foundation, a non-profit organization having a place of business in Valencia, California. The United States of America is an assignee to the patent rights of these inventions.

The contemplated exclusive license may be limited to the use of the Alfred Mann Foundation BION® system for treating dysphagia and dysphonia.

DATES: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before September 12, 2003 will be considered.

ADDRESSES: Requests for a copy of the patent application, inquiries, comments and other materials relating to the contemplated license should be directed to: Michael A. Shmilovich, J.D., Technology Licensing Specialist, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5019; Facsimile: (301) 402-0220; e-mail: shmilovichm@od.nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of the patent application.

SUPPLEMENTARY INFORMATION: The patent application covers devices and methods for intramuscular stimulation (stimulation of the geniohyoid, mylohyoid, and thyrohyoid muscles) in patients with neuromuscular disorders. The invention provides autonomous control of both hyolaryngeal elevations, anterior hyoid motion and opening of the upper esophageal sphincter for swallowing, vocalization and speech. Primarily, the technology allows self-stimulation of swallowing and can return oral feeding to dysphagia patients. Electrodes are attached to the appropriate musculature of the neck and an electrode stimulator or subcutaneous signal generator modulates electrostatic pulses through the electrodes that cause the attached muscles to contract simulating natural swallowing or vocalization depending on placement.

The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7. The prospective exclusive license may be granted unless, within 60 days from the date of this

published Notice, NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Properly filed competing applications for a license filed in response to this notice will be treated as objections to the contemplated license. Comments and objections submitted in response to this notice will not be made available for public inspection, and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: July 7, 2003.

Steven M. Ferguson,

Acting Director, Division of Technology development and Transfer, Office of Technology Transfer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443-7978.

The Family Treatment Drug Court Evaluation—New—The Substance Abuse and Mental Health Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) will conduct an evaluation of Family Treatment Drug Courts. The Family Treatment Drug Court Evaluation will examine the effectiveness of family treatment drug courts in four settings: Suffolk County, New York; Washoe County, Nevada; San Diego County, California; and Santa Clara County, California. The study will employ a multi-method, quasi-experimental research design to investigate several key child welfare outcomes for family treatment drug courts as compared to traditional case processing, including whether the time to permanency for children is different in a family treatment drug court program than in traditional case processing.

In addition, the study will investigate rates of reunification and termination of parental rights; types, frequency, and

length of out-of-home placements; and child welfare recidivism. The study will investigate the key mediators of program success, including the effect of family treatment drug courts on treatment access, treatment completion, parent motivation, and family well-being, among other key mediators.

The project consists of an outcome evaluation that includes administrative data collection and client interviews with a sample of treatment and comparison participants. The target population for the family treatment drug court consists of substance abusing parents who have a current child abuse or neglect case. The outcome evaluation will document whether family treatment drug courts are more effective than traditional court settings in decreasing the time needed to reach permanent placements for children; increasing the frequency of successful parent-child reunifications and decreasing the frequency of terminations of parental rights; decreasing the time children spend in foster care; and reducing child welfare recidivism. An intent-to-treat sampling model will be used for the treatment groups at each site during a 2-year recruitment window. Comparison groups will be recruited in two of the four sites; no comparison group will be used in San Diego and Santa Clara because the counties have implemented a system-wide reform. Interview data will be sought from all persons included in the administrative datasets in Suffolk and Washoe Counties, and from a sample of individuals included in the San Diego and Santa Clara County administrative datasets.

Interview participants will take part in a baseline interview within one month of their dispositional hearing and three follow-up interviews. Follow-up One will take place six months later, Follow-Up Two will take place 12 months after baseline, and Follow-Up Three will take place 18 months after baseline. The interview tool will assess participants' perceptions of the services they are receiving and their interactions with the court, treatment, and child welfare systems; their understanding of what they need to do in order to be reunified with their children; and their feelings of empowerment and control over the process. Each interview will last approximately one hour. Administrative data, including child welfare and treatment data, will be collected up to 24 months after baseline to ascertain the type, frequency, and timeliness of services received and to capture the crucial child welfare outcomes of interest, including the timing and type of permanency plans for children, the length of time children