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September 16, 1994.

TO: Judge Rotenberg Educational Center, formerly Behavior Research Institute.

SUBJECT: Safety of the GED and the GED-4.

INTRODUCTION.

The GED and the GED-4 are battery-operated electric devices that, worn by the subject, can apply a noxious stimulus to the skin. Delivery of an unpleasant stimulus is triggered by a radio signal from a tiny transmitter under the control of a trained attendant in the same room as the subject and in direct visual contact with the subject. The purpose of the stimulus is to interrupt or to modify actual or incipient self-destructive or retrogressive behavior on the part of the subject.

The stimulus is delivered by electrodes applied to the subject's skin. It requires two electrodes for delivery of any electrical stimulus. The electricity passes from one electrode to the other through the skin.

The electrode assemblies are of two types or configurations. The first type consists of a dime-sized metal button surrounded by a narrow ring; the ring is separated from the first or central electrode by an air-gap or other insulating material. This concentric electrode system is pressed to the skin of the subject's body in areas other than the top of the feet, back of the hands, head, genitals, over the spine, the lower outer quadrant of the buttocks, and directly over the heart. The second configuration of electrode assembly can be likened to the rounded tips of two very short metal rods (rather like protruding rivets) that are mounted on a very sturdy fabric harness. These two electrodes are separated by a maximum of six inches. The distance between the electrodes cannot be changed, nor can the electrodes be separated from each other or from the harness without disassembly by a BRI technician. The harness or bracelet carrying the two electrodes is applied to the subject's skin.

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Regardless of which electrode configuration is employed, the skin of the subject completes the path for electrical current passing between the two electrodes. The current is confined to the shortest path between the two electrodes in each of the two systems. This is a physical principle which is independent of the type of electrode system employed.

In passing through the skin from one electrode to the other, the electrical current directly stimulates sensory nerve endings in the skin. Passage of the current across those nerve endings creates a sensation that most people (in my opinion, having been subjected to the stimulus) would regard as decidedly unpleasant.

METHOD OF INVESTIGATION.

On Wednesday, February 2, 1994, I spent several hours at Behavior Research Institute in the company of Doctors Matthew Israel and Robert von Heyn, engineer Muti Siddiqi, and lead electronics technician Victor Bender. I visited the electronics shop, reviewed equipment logs, handled equipment (disassembled as well as assembled), and reviewed circuit diagrams and operating principles. Nothing that was requested was refused. I was introduced to one of the students refractory to the presently authorized level of therapy.

On a visit to BRI approximately one year earlier, I had had an extensive tour of the facilities, visiting the students in several of their classrooms, and seeing "The Big Reward" (as I believe it is called) during the lunch hour. I also visited an off-campus facility where a dozen or so students were employed in assembling jewelry. It had been particularly interesting to encounter, working in the classroom and in the assembly shop, students whom I had earlier seen on videotape. Indeed, it was impressive now to see students occupied and unrestrained, the same subjects who had been recorded on their arrival at BRI. Pictured then being extracted from delivery vehicles, these subjects had literally been packaged for transport, having been lashed to litters with 4-point restraint, with most wearing protective headgear.

It was on the occasion of this first visit that I requested, and received, a standard stimulus from the GED.

WHAT ARE THE ANTICIPATED PROBLEMS OR COMPLICATIONS OF ELECTRICAL STIMULATION?

Investigations into the effects of exposure to electricity began long before the commercial introduction of electrical power at the end of the last century. Electricity has been applied to the human body with therapeutic intentions for more than 100 years. There exists, then, an extensive body of information, experimental as well as epidemiologic (i.e. accidental exposure, or concerning putative side effects). The wealth of available data is reviewed in some detail in this writer's book on electricity cited below. In brief, there are well-recognized sequelae of electrical stimulation. These sequelae include severe muscular contraction due to direct stimulation of motor nerves, burns, seizures (epileptic convulsions), and ventricular fibrillation (VF). The latter is a condition in which the heart ceases to pump blood. Though spontaneous recovery from VF can occur, VF is the usual mechanism of death associated with exposure to electricity.

BRI is aware of the possibility of direct motor nerve stimulation. Accordingly, attendants are made familiar with the location of major motor nerves in order that these locations may be avoided when applying electrodes to the subject for therapeutic purposes.

Seizures may be produced by electricity, but only if the electrical current is passed directly through the head. The devices under consideration are never employed in this way.

Skin burns are a consideration and have been appropriately addressed by the Institute. In actuality, the power of the stronger device (GED-4) is such that only mild and reversible skin irritation might be expected. Even for

this to occur would require application of many stimuli over a short interval. Cognizant of even this mild risk, the Institute's protocol calls for changing the location of the electrodes at regular intervals.

That leaves only ventricular fibrillation (VF) to be addressed. VF, while a major risk in some applications of electricity, can easily be disposed of in the present context. For VF to occur, current must pass through the heart. This means that, for electrical exposure through electrodes applied to the surface of the body, the electrodes must be so configured that the path of current from one electrode to the other passes at least in part through the heart. The spacing of the GED electrodes precludes this possibility.

Here it seems prudent to emphasize an unyielding principle demonstrated by electricity: It tends to flow through the path of least resistance. In general, that path would be the shortest distance between the points of application. It is true that, in moving from a point contact into a conductor of greater volume, current does tend to "spread out", while the current density in the volume conductor diminishes apace. Electricity, however, doesn't "make detours" or take capricious turns. Electricity applied from one hand to the other, for example, doesn't veer off into the head; similarly, no part of a current applied from one leg to the other would pass through the heart.

Returning to the GED, the bulk of the current passes through the skin - which is where it is perceived by nerve endings. Some current may pass through underlying structures, including subjacent muscle. However, observation of a number of stimuli being delivered (BRI personnel willingly submit to demonstrating the devices on themselves) revealed minimal or zero muscle stimulation. There certainly can be no stimulation of the heart or brain by pairs of closely spaced electrodes applied to any one part of the body.

An highly unlikely "worst case" scenario has been anticipated by BRI: The subject has managed to dislodge the strap electrode assembly and is grasping one electrode in each hand. A protocol established for the use of the GED specifically states that the GED shall not be activated if the subject is even perceived as attempting to manipulate or dislodge an electrode pair.

CONCLUSION AND OPINION REGARDING THE GED AND GED-4.

Operated in accordance with a protocol established by BRI, there is no conceivable way that the GED or GED-4 might be a physical threat to the subjects. This is true regardless of any underlying medical conditions such as pre-existing seizures.

On the evidence of the test facilities and equipment logs, the design of the device, and the configuration of the electrodes, the GED-4 appears to operate as designed, safely, and with a high index of reliability.

QUALIFICATIONS OF THE AUTHOR OF THIS REPORT.

My curriculum vitae and bibliography have been separately submitted. Though steeped in electricity and electronics for decades, this author lays no claim to being an engineer. Furthermore, that issue is not germane. Electrical safety is not necessarily a part of the expertise of the electrical engineer for two closely related reasons. First, the adverse effects of electricity on the human organism are primarily subjects and concerns of physiology and pathology; these fields are not a regular part of the engineering curriculum. Further, the bulk of our knowledge about the effects of electricity on the human organism stems from the work of physicians, physiologists, and a very few specialized engineers (Dalziel, Kouwenhoven) whose primary aims were to ameliorate the adverse effects of electricity, define safe limits, employ electricity for therapeutic purposes, or undo the adverse effects of accidental exposure to electricity. The bulk of this work is published in journals of medicine and physiology. A later engineering objective came to be the design of safe medical equipment - according to specifications developed in considerable degree by physicians who were not engineers. Electrical engineers have, surely, made great contributions;

but appreciation of the effects of electricity, along with pursuit of electrical safety, have primarily been the fields of physiologists and of physicians with specialized interests.

There exists no credentialing body for the certification of "expertise" in the field of electrical safety. Regarding publication and peer-recognition as proxy criteria for calibration of expertise, it is pertinent, therefore, that my first paper bearing on electrical safety was published in 1967. Here follows a quotation from the preface of the 1989 publication on Electricity, Safety and the Patient by Bruner and Leonard, considered by some as the definitive work in the field:

"Participation [in national standards] committee activities meant...that we became the beneficiaries of exposure to information and opinion from diverse geographic sources and expertise. We feel that there is little that we haven't heard on the subject of electrical safety, an assertion not based on immodest arrogation of omniscience, but because we have had the privilege of years of association with learned colleagues and experts in fields beyond our realm of personal experience."

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1949 M.D., Harvard Medical School
 1949-1950 Surgical Intern, Pennsylvania Hospital, Philadelphia
 1950-1951 Medical Intern, Pennsylvania Hospital
 1951-1952 Research Fellow and Resident in Hematology, Pennsylvania Hospital.
 1952-1954 Lieutenant, Medical Corps, U.S. Naval Reserve.
 U.S. Naval Shipyard, Philadelphia.
 Armed Forces Examination Service, Fort Hayes, Ohio.
 Destroyer Escort Squadron 14.
 1954-1962 Family medicine in Groton, Massachusetts.
 1955-1962 Physician to Students at The Lawrence Academy, Groton.
 1959-1962 Chief of Anesthesia, Groton Community Hospital.
 1959-1962 Associate Chief of Anesthesia, Community Memorial Hospital, Ayer
 1960-1963 Groton Board of Health, member.
 1963-1964 Peter Bent Brigham Hospital, Resident, Department of Anesthesia.
 1965 Harvard Medical School, Research Fellow in Anesthesia.
 1965-1967 Private practice of anesthesiology and acute medicine.
 1966-1967 Partner, Mount Auburn Associates, anesthesiologists.
 1967-1968 Assistant in Anesthesia at Harvard Medical School.
 1967-1969 Assistant in Anesthesia at Massachusetts General Hospital.
 1968-1971 Instructor in Anesthesia, Harvard Medical School.
 1969-1972 Assistant Anesthetist, Massachusetts General Hospital.
 1971-1983 Assistant Professor of Anesthesia, Harvard Medical School.
 1972-1977 Associate Anesthetist, Massachusetts General Hospital.
 1978-1992 Anesthetist, Massachusetts General Hospital.
 1983-1992 Associate Professor of Anesthesia, Harvard Medical School.
 1992- Writer; editorial and technical consultant.

At Massachusetts General Hospital (through 1992):

Associate Director of Respiratory Therapy Department, 1969-1972.
 Committee on Monitors, Chairman, 1969-1972.
 Laboratory Safety Committee, 1967-1972.
 Safety Committee, 1967-1972.
 Executive Committee, Anesthesia Staff, 1970 passim.

Hospital Staff Appointments, former:

Mount Auburn Hospital, Cambridge, Massachusetts.
 The Nashoba Community Hospital, Ayer, Massachusetts.
 Emerson Hospital, Concord, Massachusetts.

Medical Licenses: Massachusetts, 1954 Pennsylvania, 1951
 For both: Retired status, October 1, 1992.

Societies and memberships:

National Fire Protection Association, Delegate from American Society of Anesthesiologists, 1970-1980. Liaison Member, 1980-1983. Delegate 1984-1992.

National Fire Protection Association:

Committee on Hospitals (alternate), 1970-1976.
Technical Committee on Anesthetizing Agents (alternate), 1970-1992.
Sectional Committee on Inhalation Therapy (alternate), 1970-1976.
Sectional Committee on Safe Use of Electricity in Hospitals (ad hoc), 1971.
Technical Committee on Safe Use of High-Frequency Electricity in Patient Care Areas of Health Care Facilities, 1972-1992.

American Society of Anesthesiologists:

Committee on Flammable Hazards and Electrical Equipment, Member, 1970-1979; Consultant, 1979-1982. Reappointed member for 1983, but committee disbanded October, 1982.
Committee on Equipment and Standards, 1982-1988.
Committee on Equipment, Monitoring, and Engineering Technology 1983-1988.

Massachusetts Society of Anesthesiologists:

Ad Hoc Committee on Massachusetts Safety Standards for Anesthetic Equipment, Chairman, 1974-1977.
Massachusetts Anesthesia Study Commission, 1977.

Middlesex North District Medical Society.

Massachusetts Medical Society.

American Medical Association.

Alpha Omega Alpha.

American Society of Anesthesiologists.

Massachusetts Society of Anesthesiologists.

Institute of Electrical and Electronics Engineers, Professional Group on Bio-Medical Engineering.

Diplomate of the American Board of Anesthesiology.
April 5, 1969. Certificate #4313.

Fellow of the American College of Anesthesiologists.

Fellow of the Faculty of Anaesthetists of the
Royal Australasian College of Surgeons. 1985.
Reconstituted as the Australian and New Zealand College of Anaesthetists.

National Fire Protection Association Awards:

1992: Certificate of Appreciation "in recognition of dedicated service to the development of NFPA codes and standards. Subcommittee on Anesthesia Services 1970-1992".

1994: Committee Service Award "in recognition and appreciation of distinguished service to the National Fire Protection Association in the development of NFPA codes and standards".

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Health Devices 1971;1:123-125.

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Presented at the Annual Meeting of the American Society of Anesthesiologists,
October, 1986, Las Vegas. Awarded Exceptional Merit.
Presented, by invitation, at the Annual Meeting of the
International Research Society, March, 1987, Orlando.

Leonard PF, Bruner JMR. Electrosurgery and patient safety.
Presented at the Annual Meeting of the American Society of Anesthesiologists,
October, 1989, New Orleans. Awarded First Prize.

U. S. Patent No. 3,459,935 on a lighting device.

Privately published:

Bruner JMR. A Manual on Monitors, 1970.

Bruner JMR. Telemetry at the Massachusetts General Hospital: A look at the future, 1970.

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