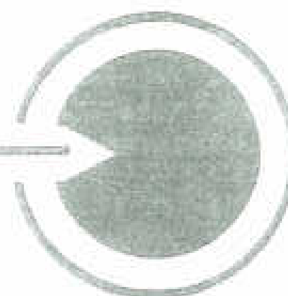
BIO-PROBE NEWSLETTER



Volume 9 March 1993 Issue 2

"SEE-SURP" REPORT CONFLICT!

Michael F. Ziff D.D.S. and Sam Ziff

At what point does factual misrepresentation influence the public health to a degree that demands corrective action?

The misinterpretation of conclusions from the January 1993 CCEHRP ("See-Surp") report is so blatant that nothing less than formal investigation by the United States Congress is warranted!

The closing paragraph of the Preface to the Final Report sums up the veracity of the entire effort: "This report is not intended to serve as the authoritative source on dental amalgam safety, but rather as a planning tool to assist policy-makers in deciding on appropriate risk management actions."

THE CCEHRP DOCUMENT

The Final Report is entitled: *DENTAL AMALGAM: A SCIENTIFIC REVIEW AND RECOMMENDED PUBLIC HEALTH SERVICE STRATEGY FOR RESEARCH, EDUCATION AND REGULATION.*

Table of Contents

PHS CCEHRP REPORT
CCEHRP Report Conclusions 1
PHS Press Release and beyond 2
CCEHRP Report. Why the conflicting views 3
CCEHRP Education Work Group Report 3
CCEHRP Regulatory Work Group Report 4
CCEHRP Evaluation SUMMARY 5
ABSTRACT/REVIEWS
In vitro evidence for the role of glutamate in the CNS toxicity of mercury. Brooks N. 5
FORUM
IAOMT Spring Scientific Session & Board Meeting 6
Consolidated Symptom Analysis of 1569 Patients who eliminated their mercury-containing fillings 7
CHART OF SYMPTOMS 8

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The study represents 25 months of effort by subcommittees from eight Public Health Service (PHS) agencies, including; the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDCP), the Food and Drug Administration (FDA), the Health Resources and Services Administration, and the Indian Health Service. The Environmental Protection Agency (EPA) and non-government "peer reviewers" also participated.

CCEHRP CONCLUSIONS

The conclusion on the safety of dental amalgam, stated on page 3 of the document under the section entitled "Amalgam Risks," is:

- "In the absence of adequate human studies, the Subcommittee on Risk Assessment could not conclude with certainty whether or not the mercury in amalgam might pose a public health risk."

The conclusions of the Subcommittee on Risk Assessment, stated on page 29 of Appendix III, are:

- "Available data are not sufficient to indicate that health hazards can be identified in non-occupationally exposed persons. Health hazards, however, cannot be dismissed."
- "Because there are no scientifically acceptable studies with sensitive standardized measurements for physiological and behavioral changes in non-occupationally exposed populations, we cannot, at present, determine whether such changes observed in persons with low-level occupational exposure to mercury also occur as a result of exposure to mercury from dental amalgams."
- "The margin of safety may, however, be lower

because body burdens of mercury are already high as a result of exposure to other sources; some persons may perhaps respond adversely to the incremental exposure to mercury derived from dental amalgams."

- "At the mercury doses produced by amalgam fillings, the evidence is not persuasive that the wide variety of non-specific symptoms attributed to fillings and "improvement" after their removal are attributable to mercury derived from the fillings. Conversely, the evidence is not persuasive that the potential for toxicity at the levels attributable to dental amalgams should be totally disregarded."
- "The potential for effects at levels of exposure produced by dental amalgam restorations has not been adequately studied."

Further information is derived from the conclusions of the Research Work Group (RWG) Report, found on page 8 of Appendix IV:

- "The available research evidence is not specific enough or strong enough to make sound pronouncements about human health risks from dental amalgam."
- "Given the potential that end effects from low level mercury exposure may well be subtle and non-specific and that the relative importance of various forms and sources of mercury are not clearly established, much work remains."
- "Based on comprehensive scientific reviews of the risks and benefits of dental amalgam, the RWG has identified an extensive list of research opportunities and needs relative to the safety and utility of dental amalgam and alternative dental restorative materials."

Finally, even Assistant Secretary for Health and head of the Public Health Service Dr. James O. Mason stated in his introductory letter, dated 15 January 1993:

- "Because the possibility of adverse health effects resulting from the use of dental amalgam cannot be fully discounted based on available scientific evidence, I am requesting the National Institutes of Health, the Centers for Disease Control and Prevention, and the Food and Drug Administration to undertake an expanded and targeted program of research, professional and consumer education and product regulation."

From the above statements, the following facts are clear and obvious:

» Humans with amalgam dental fillings are chronically exposed to mercury from the fillings.

» There is insufficient documented human evidence to clearly determine whether or not this chronic exposure to mercury causes specific adverse health effects.

» The potential for adverse health effects to mercury exposure from amalgam dental fillings is a definite possibility, as well as a cause for concern and a definitive research need.

» Public announcements that the CCEHRP Committee concluded that mercury exposure from amalgam dental fillings has no adverse health effect in humans or that mercury/silver amalgam dental fillings are "safe" or "harmless" are clearly contradictory to the Committee findings, are misrepresentative, and are potentially harmful to the public health.

THE PRESS RELEASE, AND BEYOND

None of the above statements are contrived; they are all direct quotes from the CCEHRP document itself.

However, the press release issued by the Public Health Service on 21 January 1993 is certainly puzzling, if not downright misrepresentative. (HHS NEWS. U.S. Department of Health and Human Services. Public Health Service. Bill Grigg. (202) 690-6867.)

The release stated: "The U.S. Public Health Service today released an evaluation of mercury-containing dental amalgam - silver fillings - that says that amalgam has continuing value in maintaining oral health. According to the report:

- There is no solid evidence of any harm for millions of Americans who have these fillings, and

- No persuasive reason to believe that avoiding amalgams or having them removed will have a beneficial effect on health."

The release further stated:

"James Mason, M.D., who ordered the study as HHS assistant secretary for health and head of the Public Health Service, said, "This report makes clear that, except for a very few people who may be

allergic to substances in the amalgam, there is no scientific justification for refusing to have amalgam fillings or for having them removed."

These statements clearly do not portray the content of the CCEHRP document or the conclusions of the Committee. In point of fact, they convey to the United States public a message contradictory to the findings and conclusions of the Committee and its Document, thereby encouraging the public to accept chronic exposure to mercury from amalgam dental fillings without concern.

Indeed, media articles and reports, as well as an extensive presentation in the ADA News by the American Dental Association closely followed the PHS press release. They all proclaimed that the CCEHRP Committee had determined that amalgam dental fillings are "safe" and "harmless" to humans.

WHY THE CONFLICTING VIEWS?

The direct quotes from the CCEHRP document vividly demonstrate a contradiction with the portrayal of dental amalgam in the PHS press release and subsequent media and ADA presentations. There is an obvious difference of opinion between the CCEHRP scientists and those individuals responsible for the public information. There are even conflicting statements issued by Dr. James O. Mason; his quoted statement in the PHS press release being notably divergent from his statement in the introductory letter in the CCEHRP document.

The extreme disparity of the positions, along with the potential for their effect on the public health, raise profound questions of motivation.

Is it POLITICAL? If so, to who's benefit? The conclusions of the CCEHRP scientists, shown above, clearly demonstrate that public announcements that mercury exposure from amalgam dental fillings is harmless to patients are not to the benefit of the public health!

Is it ECONOMIC? If so, to who's benefit? The study by the Insurance Bureau of the government of Sweden demonstrating a 30% reduction in health care costs two years after removal of amalgam fillings (BPNL July 1992) clearly demonstrates that public announcements that mercury exposure from amalgam dental fillings has no adverse health effect is not an economic benefit to patients, or to the United States taxpayer.

The answer to these questions may well be found in the CCEHRP document itself.

EDUCATION WORK GROUP REPORT

The following revealing statements are found in Appendix V. page 4:

- "The public's concern over the risk of dental amalgams was heightened following the "60 Minutes" television broadcast on December 16, 1990. The report, based on anecdotal information and victim-oriented stories heightened the perception of risk in many viewers."
- "Consumer anxiety and concern were further demonstrated in a 1991 survey of 1,083 adults (543 men, 540 women) sponsored by the American Dental Association. Forty-eight percent of those surveyed responded that they had heard about people possibly developing problems caused by amalgam restorations. Forty-eight percent also believed that people should have concerns about health problems that might develop from amalgam restorations. Finally, 16 percent had considered having their restorations removed while four percent reported having their restorations removed."

Further, on page V-6:

- "Public education could lead to increased demands on the dentist by the patient. In the litigious nature of our society, these demands may generate increased concerns over liability for existing amalgam restorations and lead to unnecessary removals."

Finally, on page V-7:

- "In addition, given the number of intergovernmental groups that have been evaluating dental amalgam restoration materials, many groups (consumer and professional) are expecting action on this issue. Credibility will be enhanced by a proactive program, but diminished over the long-term by a failure to respond now."

It would appear that "credibility" may be the key word. In the face of ever increasing scientific and clinical evidence that dental amalgam is not harmless to patients, the only remaining weapon for

the defense of dental amalgam is utilization of governmental "opinion" committees, at taxpayer expense!

REGULATORY WORK GROUP REPORT

Perhaps the most damning section of the CCEHRP document is this report by the Regulatory Work Group, consisting of five employees of the Food and Drug Administration (FDA). The wide perception of the dental community has been that the use of dental amalgam carries with it the full backing and authority of the FDA. Indeed, health-conscious dentists have been punished, some severely, for removal of dental amalgam fillings - a dental device that HAS NOT been evaluated and approved by the FDA.

The report of the FDA Regulatory Work Group verifies that dental amalgam has never been approved and classified. It states, on page VI-1, that dental mercury has been accepted as a safe and effective Class I dental device and amalgam alloy as a safe and effective Class II dental device. [This is also stated on page 19 of the CCEHRP summary.]

Further, the following statements are taken directly from page 2, Appendix VI:

- * "A Class III device is one for which insufficient information exists to assure that general and special controls provide reasonable assurance of safety and effectiveness."
- "While it is clear that mercury vapor is continually released from dental amalgam, it is not clear that this exposure leads to toxicity. However, the potential for toxic effects due to low levels of exposure to mercury vapor from dental amalgam restorations must not be disregarded." [ED Note: Thereby determining, by FDA Rule, that Dental Amalgam must be considered a Class III device!]
- "The Regulatory Work Group recommends that the Food and Drug Administration view dental amalgam as a kit, in that both mercury and alloy must be used together to create dental amalgam restorative material. FDA considers the class of the kit to be that of the component of the kit assigned the highest classification. In this case the kit would be viewed as a Class II device because that is the classification of amalgam alloy."
- "The Regulatory Work Group feels that reclassification of dental amalgam to Class III should not be readdressed until a body of substantial scientific evidence establishes that dental amalgam restorations are a health hazard." [ED Note: Contradicting the FDA Rule that devices of unknown risk must be placed in Class III.]

Considering these admissions on pages VI-1 and VI-2, the following formally published statements by the FDA Regulatory Work Group on page VI-4 are both reprehensible and indefensible:

- "Information dissemination on "mercury-free" dental practices, which advocate removal of dental amalgams and replacement with alternative restorative materials, may be through newsletters published by one of several anti-amalgam organizations, or by word-of-mouth."
- "Advertising is considered to be labeling. [ED Note: Who made that determination? The FDA is clearly usurping, by self-proclaimed edict, the authority of the Federal Trade Commission!] If individual dentists were participating in false advertising such as claiming that dental amalgams are toxic to humans or causative agents for diseases, and if literature purporting these claims were on the premises of the dentist's office, FDA would have the authority to take legal action against that dentist. However, this situation is unusual in comparison to the more common case of illegal use of a device. In view of this, the Regulatory Work Group feels that it would be more appropriate for this issue to be handled by state licensing and regulating bodies, or by the state professional association, i.e., state dental association." [This is also stated on page 20 of the CCEHRP summary.]

"ILLEGAL USE OF A DEVICE!" The FDA has admitted that it has never evaluated and classified dental amalgam! Therefore, by its own admission PLACEMENT of amalgam, not its REMOVAL is illegal! Furthermore, the FDA has now established, by formal published government document, that the previous punishments of dentists for the removal of

dental amalgam fillings was done illegally!

In addition, the FDA statements urging punishment for use of written materials or "word-of-mouth" communication raises serious questions of infringement of Constitutional Rights of Freedom of Speech!

Finally, if claims that dental amalgam mercury exposure presents a potential health risk to patients is a punishable offense (through the FDA, the state licensing boards, or the professional organizations) then, obviously, claims that the CCEHRP Committee determined that the mercury exposure is harmless to patients must be considered equally punishable offenses.

SUMMARY

- It is clear from the documented statements of the CCEHRP Committee, its Risk Assessment Subcommittee, its Research Work Group, its (FDA) Regulatory Work Group, and Dr. James O. Mason, himself, that there is insufficient human evidence to publicly proclaim mercury exposure from dental amalgam fillings to be harmless.
- Public pronouncements, by government representatives or anyone else, that the CCEHRP Committee concluded that dental amalgam fillings are safe or harmless to humans constitute misrepresentation and could have a detrimental effect on the public health.
- It is now formally documented and established that dental amalgam has never been evaluated and classified as dental device, a clear dereliction of the mandate issued to the Food and Drug Administration by the President and Congress in 1976.
- The openly inflammatory and inciting statements formally published by the FDA Regulatory Work Group and the CCEHRP Committee might be flagrant violations of law, as well as the constitutional rights of citizens of the United States.
- The actions and statements of employees of the United States government involved in this issue clearly call for executive and/or congressional investigation.

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ABSTRACTS/REVIEWS

Brooks N. In vitro evidence for the role of glutamate in the CNS toxicity of mercury. Toxicology. 76:245-256, 1992.

SUMMARY

Intoxication with elemental mercury vapor or with methylmercury results in the accumulation of mercuric mercury (Hg^{2+}) in the brain. Submicromolar concentrations of Hg^{2+} were shown previously to inhibit glutamate uptake in astrocyte cultures selectively and reversibly. This finding suggests that blockade of the inactivation of synaptically released glutamate is a potential mechanism of the CNS toxicity of Hg^{2+}. The present study shows further that Hg^{2+} ($\leq 1\ \mu M$): (i) markedly inhibits the clearance of extracellular glutamate both by astrocyte cultures and by spinal cord cultures; (ii) reduces glutamine content and export in astrocyte cultures; (iii) has little effect on neuronal viability in spinal cord cultures in the absence of excitotoxic accumulations of glutamate. Also, it is noted that Hg^{2+} ($\leq 1\ \mu M$) has not been shown to impair transmitter release acutely in existing studies of presynaptic actions. Thus, the available evidence from in vitro studies is consistent with the hypothesis that low concentrations of mercuric mercury in the brain can cause neurotoxicity by selectively inhibiting the uptake of synaptically released glutamate, with consequent elevation of glutamate levels in the extracellular space.

In addition to the above summary we would like to quote the last paragraph of the article: "The proposed role of glutamate has some implications for the neurotoxicology of mercuric mercury that merit attention. An environmental or occupational exposure to mercury that is of itself insufficient to cause overt CNS toxicity, by diminishing the safety factor for inactivation of glutamate could nevertheless accelerate processes of excitotoxic neurodegeneration associated with disease or aging. 'Silent' impairment of this kind is suggested by the delayed emergence of neurologic dysfunction following remote occupational exposure to elemental mercury vapor."

BIO-PROBE COMMENT:

We believe that the hypothesis expressed by Dr. Brooks in the closing paragraph of his article is fully applicable to dental personnel. Scientific studies are presently demonstrating the latent neurotoxic effects to dental personal of being chronically exposed occupationally to elemental mercury vapor. Moreover, we believe that future scientific studies will also confirm the same type of delayed emergence of neurologic dysfunction in patients chronically exposed to elemental mercury vapor and mercury particulate from their mercury-containing dental fillings. This statement is strongly supported by the increased frequency of clinical evidence being reported by physicians, dentists, researchers and patients. Clinical evidence that is clearly demonstrating remarkable curative effects directly attributable to the elimination of mercury containing dental fillings and their replacement with non-mercury containing dental materials. This fact is very evidential in the Consolidated Symptom Analysis appearing on the last page of this newsletter.

Glutamic Acid (GA), Gamma-Aminobutyric Acid (GABA) and Glutamine (GAM) are referred to by Braverman and Pfeiffer[1] as "The Brain's Three Musketeers." "Among the three musketeers, glutamate (the salt form of GA) is the most prolific neurotransmitter. It exists everywhere in the body and is present in almost all nerve cells. GA, an amino acid, is involved in all the brain cells and in photoreceptor transmission in the retina, an extension of the brain. GAM and GABA can be formed from GA, and GABA and glutamate can also be formed from GAM;..." Hence, the Three Musketeers motto of "one for all and all for one."[1]

"GA and its metabolites, GAM and GABA have been found to have therapeutic value in the treatment of hypertension, schizophrenia, chorea, aging , dyskinesia, Parkinson's, epilepsy, alcoholism and many other conditions."

There is also scientific evidence showing that increased levels of GA have been found in patients with Alzheimer's disease.

Research has shown the placental passage of mercury vapor from amalgam dental fillings and subsequent uptake by the fetus. The in utero exposure problem may be compounded by the fact that nursing mothers with amalgams have increased quantities of mercury in their breast milk. It is also known that learning deficits and delayed mental development in children can be caused by mercury exposure during pregnancy and nursing. It would appear that these facts readily fit the 'Silent" delayed neurological dysfunction proposed by Dr. Brooks.

There is unmistakable scientific evidence showing positive correlations of brain mercury content with the numbers and surfaces of amalgam dental fillings. What has been missing has been a working hypothesis showing how this mercury in the brain may be causing the myriad of symptoms supporting the latent subtle neurological dysfunctions being confirmed all over the industrialized world by clinical case histories.

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FORUM

INTERNATIONAL ACADEMY OF ORAL MEDICINE AND TOXICOLOGY (IAOMT) SPRING SCIENTIFIC SESSION AND BOARD MEETING

Date: 1 May 1993 (Scientific Session)-2 May 1993 (Board Meeting)

City: Arlington, Virginia

Hotel/Reservations: Hyatt Arlington at Key Bridge. 1325 Wilson Blvd. Arlington, VA 22209-9990. Tel: (703) 525-1234. Fax: (703) 875-3393.

Room rates: $89.00/night (Specify IAOMT).

Saturday Program:

Murray J. Vimy, D.M.D.: "Amalgam Mercury Exposure - Is There Still a Controversy?" Private practitioner, researcher, and Clinical Associate Professor in the Department of Medicine at University of Calgary's Medical School. Dr. Vimy has published numerous peer reviewed scientific papers and served as a scientific consultant to WHO.

John Lee, M.D.: "Fluoride and Bone Physiology - An Update." Dr. Lee has been a practicing physician for 30 years and has served as Clinical Instructor in Medicine at the University of California Medical

1 Braverman ER with Pfeiffer CC.The Healing Nutrients Within. Page 189-210, Keats Publishing, Inc. New Canaan, CT.

School in San Francisco. He has published original scientific research on fluoride and osteoporosis and pioneered an effective treatment for osteoporosis

James V. Masi, Ph.D.: "Minimizing Heavy Metal Ion Production in the Oral Cavity." Dr. Masi is a professor of engineering and bioengineering at Western New England College. He is the author of over 120 articles and papers, two books and serves as a consultant to several companies.

Walter "Jess" Clifford, M.S.: "Effects of Low-level Toxins on Human Blood as Viewed with Naessens' Microscopy." Over 25 years of clinical experience in microbiology, immunology and hematology.. Jess pioneered the world's first biomaterials reactivity testing via immunologic complex detection.

Berkley Bedel "Opportunities for alternative Health Care." Congressman Bedell served as Iowa's Representative from 1975 to 1987. He was instrumental (together with Senator Harkins) in forming the new Office of Alternative Medicine at NIH and currently serves as a member of the Advisory Committee for that Office.

Tony Martinez, J.D.: "Strategies for Legislative and Political Action." Mr. Martinez is currently the legislative advisor to Nutritional Health Alliance, the organization that was formed to protect freedom of chico in health care.

Fee: $150.00 (Non-IAOMT members)

Meeting Registration: Richard D. Fischer, D.D.S. 4222 Evergreen Lane. Annandale, VA 22003. Tel: (703) 256-4441.2

CONSOLIDATED SYMPTOM ANALYSIS OF 1569 PATIENTS

Reference is made to our original analysis, by symptom, of the 762 Patient Adverse Reaction Reports (PARR) submitted to the Food and Drug Administration. (BPNL Jan 1993) The reports were submitted by patients who had undergone amalgam replacement and reflect the individual's assessment of any changes that may have occurred in their health status as a direct result.

In addition to the PARR, several other studies have been completed assessing any effects of amalgam replacement on an individuals health. These are: 519 patients in Sweden performed by Mats Hanson, Ph.D.; 100 patients in Denmark performed by Henrik Lichtenberg, D.D.S.; 80 patients in Canada performed by Pierre Larose, D.D.S.; 86 patients in Colorado performed by Robert L. Siblerud, O.D., M.S. as partial fulfillment of a Ph.D. requirement and 22 patients reported by Alfred V. Zamm, MD, FACA, FACP. Combined total 1569.

A consolidated statistical summary of major symptoms reported is presented on page 8. One statistic which you may find extremely interesting relates to the incidence of allergies. The January 1993 CCEHRP Report states: "Only a small proportion of mercury-sensitized individuals respond adversely to the placement of amalgam restorations. The few case reports of adverse allergic reactions to amalgam involve skin reactions, such as rashes and eczematous lesions..." Statements of this nature totally ignore valid peer reviewed scientific studies demonstrating an allergic reaction to dental amalgam ranging from 16.5% for non-allergic patients to 44% for fourth year dental students. More importantly, as this symptom analysis demonstrates, the question is not whether the patient is allergic to dental amalgam but rather the direct causal relationship of mercury/amalgam dental fillings to the development of allergies to food, chemicals, and environmental factors. In our analysis, this is supported by the fact that 14% of the individuals reported some type of allergy and that after replacement of their mercury/amalgam dental fillings, 89% reported their condition had improved or was totally eliminated. If you were to extrapolate this data to the approximately 140 million amalgam bearers in the United States, there should be 19.6 million people (14%) with amalgam causally related allergies. Of this number 89% or approximately 17.4 million would have their allergies ameliorate or disappear simply by having their mercury dental fillings exchanged for non-mercury ones.

No doubt critics of this information will claim that it is "anecdotal" and of no value. However, it cannot be denied that these experiences did occur in human beings and was of immeasurable value to them.

Further, these critics questioning the data should not lose sight of the historical fact that clinical experience data always precedes "establishment" acceptance of the scientific facts. New human research soon to be published will add significant scientific validation of the clinical evidence.

SELECTED HEALTH SYMPTOM ANALYSIS OF 1569 PATIENTS WHO ELIMINATED MERCURY-CONTAINING DENTAL FILLINGS

The following represents a partial statistical symptom summary of 1569 patients who participated in six different studies evaluating the health effects of replacing mercury-containing dental fillings with non-mercury containing dental fillings. The data was derived from the following studies: 762 Patient Adverse Reaction Reports submitted to the FDA by the individual patients; 519 patients in Sweden reported on by Mats Hanson, Ph.D.; 100 patients in Denmark performed by Henrik Lichtenberg, D.D.S.; 80 patients in Canada performed by Pierre Larose, D.D.S.; 86 patients in Colorado reported on by Robert L. Siblerud, O.D., M.S., as partial fulfillment of a Ph.D. requirement and 22 patients reported on by Alfred V. Zamm, M.D., FACA, FACP. The combined total of all patients participating in the six studies was 1569.

% OF TOTAL REPORTING	SYMPTOM	NUMBER REPORTING	NO. IMPROVED OR CURED	% OF CURE OR IMPROVEMENT
14%	ALLERGY	221	196	89%
5%	ANXIETY	86	80	93%
5%	BAD TEMPER	81	68	89%
6%	BLOATING	88	70	88%
6%	BLOOD PRESSURE PROBLEMS	99	53	54%
5%	CHEST PAINS	79	69	87%
22%	DEPRESSION	347	315	91%
22%	DIZZINESS	343	301	88%
45%	FATIGUE	705	603	86%
15%	GASTROINTESTINAL PROBLEMS	231	192	83%
8%	GUM PROBLEMS	129	121	94%
34%	HEADACHES	531	460	87%
3%	MIGRAINE HEADACHES	45	39	87%
12%	INSOMNIA	187	146	78%
10%	IRREGULAR HEARTBEAT	159	139	87%
8%	IRRITABILITY	132	119	90%
17%	LACK OF CONCENTRATION	270	216	80%
6%	LACK OF ENERGY	91	88	97%
17%	MEMORY LOSS	265	193	73%
17%	METALLIC TASTE	260	247	95%
7%	MULTIPLE SCLEROSIS	113	86	76%
8%	MUSCLE TREMOR	126	104	83%
10%	NERVOUSNESS	158	131	83%
8%	NUMBNESS ANYWHERE	118	97	82%
20%	SKIN DISTURBANCES	310	251	81%
9%	SORE THROAT	149	128	86%
6%	TACHYCARDIA	97	68	70%
4%	THYROID PROBLEMS	56	44	79%
12%	ULCERS & SORES IN ORAL CAVITY	189	162	86%
7%	URINARY TRACT PROBLEMS	115	87	76%
29%	VISION PROBLEMS	462	289	63%