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To: White House Commission on Complementary and Alternative Medicine

Conventional dental practices have come under increasing scrutiny during the past decade by independent scientific investigators. I enclose a review article by Professors Loscheider, Vimy and Summers, which gently and convincingly explains many of the findings: dental amalgam fillings, which are 50% mercury, on not safe. The mercury used in dental fillings is not safe.

Toxic dentistry is regarded by many independent observers as the leading instance of iatrogenic illness, surpassing even "medical mistakes" and "side effects of properly prescribed drugs." Only examples of toxic dentistry include the use of nickel which, like mercury, is a neurotoxin and is carcinogenic. Other heavy metals that find their way into the mouth in dental work are chromium, copper, tin, zinc, cadmium, fluorides, palladium, titanium and thallium. Adding to this the impacts of root canals, which can be highly toxic, the effects of periodontal disease, which can be promoted by the amalgams and the health impacts of jawbone infections, which are always highly toxic.
The synergistic effects of these many sources of toxins and the infectious conditions means that dentistry can have profound health consequences.

Our best, most innovative dentists have responded by practicing medically sound dentistry; the best dentists regard dentistry as a branch of medicine, because of the interplay between what is happening in the mouth and in the rest of the body, including the brain. They are dubbed "biological" dentists or "holistic" dentists because they look at the underlying biological impacts and at the whole person. Such excellent dentists are in great demand and there are not enough of them.

But, there are two problems in ridding the world of toxic dentistry. One is that the state dental boards have often sat in a state of official denial as to the dire health consequences of toxic dentistry, refusing to investigate, for example, charges of mercury poisoning by unsafe amalgam removal practices while in the dental chair. As a result, the dental consumer feels that he/she receives no understanding from the state dental board, which is usually dominated by handpicked members of the American Dental Association, a private trade group. The second problem is that these same dental boards harass, intimidate and even pull the licenses of the more prominent, more outspoken holistic dentists. Dozens of top holistic dentists have been forced to spend hundreds of thousands of dollars and years of their lives in order to defend themselves from the unchecked powers of the dental board's complaint committee, which is able to meet in private and to operate with accountability to no one. Often the holistic dentist collaborates with a holistic doctor or naturopath, and those doctors also find themselves subject to harassment by the states' medical boards. As a result may states have lost their finest holistic MDs.

Solutions. Congress should hold hearings on the health harm inflicted on the public by mercury and other features of toxic dentistry. They should the harm done to people's mental and physical

health, and the damage done to children and to infants and the unborn. They should hear about the damage inflicted on the professional lives of many of our best dentists by unfair and unjust regulatory actions by the state boards.

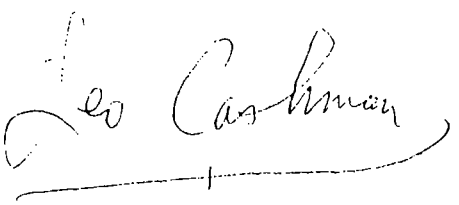
The Food and Drug Administration has a dental division which, ideally, should be curbing the use of amalgam fillings (as Canada has done) or imposing an outright ban (as Sweden has done). But our FDA's dental division has been dominated by the same ADA dentists that are the heart of the deception and cover-up. Congress and the president should rid the FDA of all who have conflicts of interest and appoint independent scientists and leaders whose commitment is only to the public health. Dental amalgams should be banned. Health plans and insurance companies should be prevented from forcing insured people to accept toxic dental options, and should be allowed to choose safer, more holistic dentists for their care.

Congress should establish a $200 million dollar fund as a preliminary measure, to pay for the safe replacement of amalgam fillings with biocompatible alternative materials. Since mercury has left many of its victims in ill health and financially devastated, the government, having failed to protect the public health in the past, should now make it possible for the victims to get their lives back. It should also fund new institutes for biological dentistry so that dentists can be re-trained to use safer materials and methods, and to replace the old amalgam fillings safely, without further poisoning the patient.

Congress should also conduct hearing on the scam of water fluoridation, which is mandatory in Minnesota and in many other states. It should investigate the corrupt politics of water fluoridation, which is a form of "mandatory medication," and which forces millions to drink and bath in the water to which the toxic byproducts from the phosphate fertilizer plants has been added (hydro-fluosilicic acid). The water fluoridation does not help dental status but does harm bones, connective tissue and brain and behavioral patterns.

The commission should take courage and represent people, rather than power. It should blow the whistle on the toxic dentistry, the fluoridation scam and the corrupt agencies and boards that help make this all possible. The commission's report will be heard by the congress and the American people, not just the president, and that will mobilize the demand for the change that is needed.

In ten days, on March 26th, Professor Fritz Lorscheider, PhD, will announce new research findings that further implicate dental mercury as the major cause of Alzheimer's Disease. Watch for that.



REVIEW

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Mercury exposure from "silver" tooth fillings: emerging evidence questions a traditional dental paradigm

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Abstract: For more than 160 years dentistry has used silver amalgam, which contains approximately 50% Hg metal, as the preferred tooth filling material. During the past decade medical research has demonstrated that this Hg is continuously released as vapor into mouth air; then it is inhaled, absorbed into body tissues, oxidized to ionic Hg, and finally covalently bound to cell proteins. Animal and human experiments demonstrate that the uptake, tissue distribution, and excretion of amalgam Hg is significant, and that dental amalgam is the major contributing source to Hg body burden in humans. Current research on the pathophysiological effects of amalgam Hg has focused upon the immune system, renal system, oral and intestinal bacteria, reproductive system, and the central nervous system. Research evidence does not support the notion of amalgam safety.—Lorscheider, F. L., Vimy, M. J., Summers, A. O. Mercury exposure from "silver" tooth fillings: emerging evidence questions a traditional dental paradigm. *FASEB J.* 9, 504–508 (1995)

KeyWords: mercury toxicity · dental amalgam

HISTORICAL OVERVIEW OF MERCURY USE IN DENTISTRY

As early as the 7th century, the Chinese used a "silver paste" containing mercury (Hg) to fill decayed teeth. Throughout the Middle Ages, alchemists in China and Europe observed that this mysterious silvery liquid, extracted from cinnabar ore, was volatile and would quickly disappear as a vapor when mildly heated. Alchemists were fascinated that at room temperature Hg appeared to "dissolve" powders of other metals such as silver, tin, and copper. By the early 1800s, the use of a Hg/silver paste as a tooth filling material was being popularized in England and France and it was eventually introduced into North America in the 1830s. Some early dental practitioners expressed concerns that the Hg/silver mixture (amalgam) expanded after setting, frequently fracturing the tooth or protruding above the cavity preparation, and thereby prevented proper jaw closure. Other dentists were concerned about mercurial poisoning, because it was already widely recognized that Hg exposure resulted in many overt side effects, including dementia and loss of motor coordination. By 1845, as a reflection of these concerns, the American Society of Dental Surgeons and several affiliated regional dental societies adopted a resolution that members sign a pledge not to use amalgam. Consequently, during the next decade some members of the society were suspended for the malpractice of using amalgam. But the advocates of amalgam eventually prevailed and membership in the American Society of Dental Surgeons declined, forcing it to disband in 1856. In its place arose the American Dental Association, founded in 1859, based on the advocacy of amalgam as a safe and desirable tooth filling material. Shortly thereafter, tin was added to the Hg/silver paste to counteract the expansion properties of the previous amalgam formula (1–3).

There were compelling economic reasons for promoting dental amalgam as a replacement for the other common filling materials of the day such as cement, lead, gold, and tinfoil. Amalgam's introduction meant that dental care would now be within the financial means of a much wider sector of the population, and because amalgam was simple and easy to use, dentists could readily be trained to treat the anticipated large number of new patients. By 1895, the dental amalgam mixture of metals had been modified further to control for expansion and contraction, and the basic formula has remained essentially unchanged since then (2, 3). Scientific concerns about amalgam safety initially surfaced in Germany during the 1920s, but eventually subsided without a clear resolution. At the present time, based on 1992 dental manufacturer specifications, amalgam (at mixing) typically contains approximately 50% metallic Hg, 35% silver, 9% tin, 6% copper, and a trace of zinc. Estimates of annual Hg usage by U.S. dentists range from approximately 100,000 kg in the 1970s to 70,000 kg today. Hg fillings continue to remain the material preferred by 92% of U.S. dentists for restoring posterior teeth (4,5). More than 100 million Hg fillings are placed each year in the U.S. Presently, organized dentistry has countered the controversy surrounding the use of Hg fillings by claiming that Hg reacts with the other amalgam metals to form a "biologically inactive substance" and by observing that dentists have not reported any adverse side effects in patients. Long-term use and popularity also continue to be offered as evidence of amalgam safety (6).

In light of the medical research evidence that has accumulated primarily over the past decade, the purpose of this review is to examine the traditional dental paradigm that maintains that amalgam is a biologically safe and appropriate tooth restorative material.

MERCURY EXPOSURE FROM AMALGAM FILLINGS

During the early 1980s several laboratories established that Hg vapor (Hg^0) is continuously released from amalgam tooth fillings, and that the rate of release into human mouth air is increased immediately after chewing (7–9) or tooth brushing (10). Mouth air levels of Hg^0 correlate significantly with the number of occlusal (biting) amalgam surfaces in molar teeth. Continuous chewing for 10–30 min results in a sustained elevation of the mouth Hg^0 level, which eventually declines to a baseline level 90 min

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after chewing cessation (11). Blood Hg levels also display a positive correlation with the number and total surface area of amalgam fillings (12).

A single amalgam filling with an average surface area of only 0.4 cm^2 is estimated to release as much as 15 μg Hg/day primarily through mechanical wear and evaporation, but also through dissolution into saliva (13). Recent electron microscopy images and electrochemistry data show direct evidence of amalgam Hg corrosion and leakage into saliva as free ions (14). Thus, for an average individual with eight occlusal amalgam fillings (11), a total of 120 μg Hg could be released daily into the mouth and a portion of this amount would be inhaled or swallowed. These estimations are consistent with a recent report showing that human subjects with an average number of amalgam fillings excrete approximately 60 μg Hg/day in feces (15), a portion of which is microparticles of amalgam. Various laboratories have estimated that the average daily body absorption of amalgam Hg in humans ranges between 1.2 and 27 μg (16), with levels for some individual subjects being as high as 100 μg/day. At the present time the consensus average estimate is 10 μg of amalgam Hg (range 3–17 μg) absorbed per day (17), an uptake amount corroborated by a more recent daily estimate of 12 μg (15). By way of contrast, estimates of the daily absorption of all forms of Hg from fish and seafood is 2.3 μg, and from other foods, air, and water is 0.3 μg (17). Thus, it is now proposed that dental amalgam tooth fillings are the major source of Hg exposure for the general population (17, 18). This position has been clearly validated by a recent demonstration that at least 65% of excretable Hg in human urine is derived solely from dental amalgams, and that amounts of Hg excreted also correlate with total amalgam surface area (19).

BODY TISSUE UPTAKE OF AMALGAM MERCURY

The degree to which body tissues can sequester amalgam Hg after exposure has been demonstrated in a variety of human and animal experiments. Human autopsy studies reveal significantly higher Hg concentrations in brain and kidney of subjects with aged amalgam fillings than in subjects who had no amalgam tooth restorations (20). When amalgam fillings containing a radioactive Hg tracer were placed in sheep molar teeth, a whole-body image scan performed 4 wk later demonstrated several possible uptake sites for Hg including oral tissues, jaw bone, lung, and gastrointestinal tract, with major localization of Hg in the kidney and liver (21). A similar whole-body image study repeated in a monkey (whose teeth, diet, feeding regimen, and chewing pattern more closely resemble those of humans) clearly demonstrates high levels of amalgam Hg in kidney, intestinal tract, and other tissues. The brain/CSF Hg ratio had increased threefold by 4 wk after amalgam fillings had been installed (22). The primate kidney will continue to accumulate amalgam Hg for at least 1 year after installation of such fillings (23).

Repeated observations in adult sheep (21, 24) demonstrate that after placement of amalgam fillings the blood Hg levels remain relatively low even though the surrounding body tissue concentrations of Hg become many fold higher than blood. This suggests that tissues rapidly sequester amalgam Hg at a rate equivalent to its initial appearance in the circulation. Such a phenomenon may explain why monitoring blood levels of Hg in humans is a poor indicator of the actual tissue body burden directly attributable to continuous low-dose Hg exposure from amalgam.

In pregnant sheep, which received amalgam fillings containing a radioactive Hg tracer, it was demonstrated that both maternal and fetal tissues began to accumulate amalgam Hg within several days after such fillings were installed. Maternal-fetal transfer of amalgam Hg was progressive with advancing gestation, and amalgam Hg also transferred to breast milk postpartum (24). More recently, human fetal/neonatal studies have likewise demonstrated that Hg concentrations in fetal kidney and liver, and cerebral cortex of infants, correlate significantly with the number of amalgam filled teeth of their mothers (25). This latter finding is consistent with previous animal studies that show greater Hg concentration in rat fetal tissues (and less placental retention) when the source of exposure was Hg^0 rather than mercuric salts (26).

CELL METABOLISM OF MERCURY

Major metabolic pathways

Figure 1 illustrates the major metabolic pathways for the three species of Hg. The principal source of Hg^0 is vapor from dental amalgam tooth fillings, whereas organic Hg (Hg^+) is derived principally from fish and seafood, and inorganic Hg (Hg^{2+}) originates from other foods, water, and air. Approximately 80% of inhaled Hg^0 is absorbed across the lung and converted to Hg^{2+} intracellularly by catalase oxidation. In contrast to other Hg species, the high lipid solubility of Hg^0 permits it to cross cell membranes readily, including the blood–brain barrier, and easily enter the brain. However, the kidney eventually becomes the major site of Hg accumulation during compartmental redistribution after exposure to Hg^0. Some Hg^0 is also dissolved in saliva and swallowed, converted to Hg^{2+} by peroxidase oxidation, and the majority is eliminated by fecal excretion. Other Hg^{2+} that is ingested in the diet is poorly absorbed across the intestinal tract and most is excreted in the feces. Although the majority of Hg^+ from the diet is also eliminated in the feces, a substantial portion is absorbed intracellularly as methyl-Hg^+. Both intracellular Hg^{2+} and Hg^+ are ultimately bound covalently to glutathione (GSH) and protein cysteine groups. Hg^{2+} is the toxic product responsible for the adverse effects of inhaled Hg^0. Body tissues have various retention half-lives for Hg^+ and Hg^{2+} ranging from days to years (15, 17, 26–28). After Hg is released from tissues, fecal excretion becomes the predominant route for elimination of Hg from the body. Human fecal excretion of

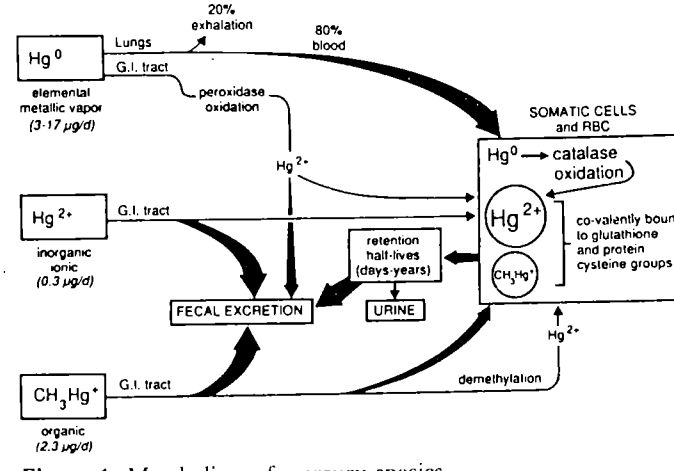

Figure 1. Metabolism of mercury species.

Hg correlates significantly with the number of amalgam fillings, and the excretion rate for Hg in feces is 20 times higher than its corresponding excretion rate in urine. Even though fecal excretion of amalgam Hg predominates, this principal excretory route in humans shows a high correlation with urinary excretion of Hg. Fecal excretion rates for Hg in human subjects with amalgam tooth fillings can be as much as 100-fold higher than in subjects without such fillings (15).

Significance of glutathione and other sulfhydryl compounds

The major low molecular weight sulfhydryl compound in mammals is GSH, present at approximately 5 mM in cells, serum, and bile (29). Other low molecular weight sulfhydryls present at lower concentrations in cells include cysteine, biotin, lipoic acid, and coenzyme A. The major targets in proteins for binding of transition metals, including Hg, are the sulfhydryl group of cysteine and the imino nitrogen of histidine. The aromatic ring nitrogens of the nucleotide bases also form Hg complexes, with thymine and uracil being more reactive than cytosine, guanine, and adenine (30).

Whereas Hg^0 from amalgam is lipid soluble and freely passes through cell membranes, methyl and ionic Hg from food and other sources are both charged and therefore must be complexed with counter-ions or low molecular weight sulfur compounds in order to pass freely through the cell membrane.

The major cellular reaction potentiating the toxicity of Hg^0 is its oxidation by catalase, an enzyme found in all normal mammalian cells (31). This oxidation process can take place in any of the "barrier tissues" of the body as well as in the blood. Once generated within the cell by catalase, highly reactive Hg^{2+} will interact with a variety of nucleophilic ligands, the most abundant single nucleophile reactant being GSH. The sulfhydryl groups of proteins are next in abundance and avidity for Hg^{2+}, with the imino nitrogens of histidine and the nucleobases being substantially less reactive.

Despite the large molar excess of GSH, many proteins compete very effectively for binding of transition metals such as Zn, Ni, and Cu. The precise chemical basis for the high affinity of such metalloproteins is not understood; many of the currently well-defined members of this group, including important regulatory proteins, use cysteines and histidines as ligands to their respective metal cofactors (32). Thus, these proteins may exchange metals, including Hg, bound to GSH.

Once bound to GSH, Hg can leave the cell to circulate in serum or lymph and be deposited in other organs or tissues. GS-Hg-SG is eventually eliminated via either the kidney or downloaded via bile into the intestinal lumen and excreted in feces. After Hg leaves cells, its major route of elimination in any form (inorganic or organic) is via feces, with less than 10% of Hg normally exiting the body in urine (26). Experiments in sheep (21, 24) and monkey (22) indicate that 99% of amalgam Hg is excreted in feces, and in humans with 30 amalgam surfaces the average 24 h excretion rate for Hg in feces is 60 μg (95% of total daily excretable Hg) in contrast to 3 μg/24 h in urine (15). In mammals, half-lives from acute single doses of Hg^{2+} or methyl-Hg^+ range from months to years. Half-lives may differ with chronic Hg exposure as a result of compromised cellular function (e.g. kidney Hg turnover deceases with age and duration of exposure) (17, 26).

EFFECTS OF AMALGAM MERCURY ON CELL AND ORGAN SYSTEM FUNCTION

The overt clinical effects resulting from toxic exposure to the three species of Hg have been described (26, 28). Various animal and human experiments over the past several years have addressed the possibility of more subtle pathophysiological effects of amalgam Hg upon the function of several organ systems or cell types, including the immune system, renal system, oral and intestinal bacteria, reproductive system, and central nervous system.

Immune system

Ionic Hg has been shown to be antigenic and capable of inducing autoimmunity in rats (33, 34). In a very recent report, gelatin-encapsulated dental amalgam pieces were implanted intraperitoneally in an inbred strain of mice known to be genetically susceptible to Hg-induced immune pathology. Within 10 wk to 6 months the animals displayed hyperimmunoglobulinemia, serum autoantibodies that targeted nucleolar proteins, and systemic immune complex deposits. Similar changes were observed when only dental alloy (not containing Hg) was implanted, and these immune aberrations were attributed to the silver component of the alloy. This study concluded that both Hg and silver dissolution from dental amalgam can chronically stimulate the mouse immune system with subsequent induction of systemic autoimmunity (35). In humans, fecal excretion of silver is also correlated with the number of amalgam fillings (15). This would suggest that further investigation of the potential molecular effects of amalgam metals on the human immune system is warranted.

Renal system

Because human (20), monkey (22, 23), and sheep (21) kidney display significantly increased Hg concentrations after exposure to dental amalgam, some investigations have focused on what these concentrations may imply for renal function. Sheep with amalgam tooth filling implants show a reduced filtration rate of inulin, increased urinary excretion of sodium, and a decrease in urinary albumin (36). An increased sodium excretion has also been observed in monkeys similarly treated with amalgam fillings (unpublished data). Because Hg^{2+} accumulates primarily in the proximal tubule of rat (37) and rabbit (38) kidney and amalgam Hg in the proximal tubule of monkey kidney (23), where the majority of sodium is normally reabsorbed, increased excretion of sodium after placement of amalgam fillings in sheep (36) may reflect a reduced tubular capacity to conserve sodium selectively. Urinary albumin levels increased 1 year after removal of amalgam fillings in humans (12), whereas urine albumin levels fell in sheep after amalgam placement (36). It is uncertain whether these differences in albumin excretion patterns may reflect a Hg-induced reduction in renal blood flow due to the presence of amalgam fillings.

Oral and intestinal bacteria

It is well established that some human intestinal bacteria carry plasmids encoding resistance to both Hg and antibiotics (39). In a population subgroup of 356 persons who had no recent antibiotic exposure, those individuals with a high prevalence of Hg resistant bacteria in their intestinal flora were significantly more likely to display multiple antibiotic resistance in these same bacteria. A parallel investigation in monkeys demonstrated a marked in-

crease in the proportion of Hg-resistant bacteria in the floras of the intestine and oral cavity soon after installation of dental amalgam tooth fillings, an increase that persisted until the amalgam fillings were removed. The majority of these primate Hg resistant bacteria were also resistant to one or more commonly used antibiotics. Results show that Hg released from dental amalgam can enhance the prevalence of resistance to multiple antibiotics in the bacteria of the primate normal flora (40).

Reproductive system

The relationship of occupational exposure to Hg^0 and fertility of female dental assistants has recently been examined, because it is well established that long-term exposure to Hg^{2+} will alter reproductive cyclicity in rodents. Epidemiological screening by questionnaire of 7000 dental assistants showed that within an eligible subgroup of 418 women who were subsequently interviewed, fertility was reduced to only 63% that of control women not occupationally exposed to Hg^0. The study, while open to the criticism of all data that rely upon subject observation and opinion, concluded that dental assistants who prepared 30 or more amalgam fillings per week, and who also had poor Hg hygiene habits, were at risk of lowered fecundity (41).

Central nervous system

Initially suggestions occurred within medicine that neurodegenerative diseases could perhaps be linked to Hg from dental amalgam, but no experimental evidence was available at that time (42). However, it is now established that uptake and accumulation of amalgam Hg occur in monkey and human brain tissues (22, 27). Studies have demonstrated that Hg is selectively concentrated in human brain regions (medial basal nucleus, amygdala, and hippocampus) involved with memory function, and have suggested that Hg may be implicated (by mechanisms as yet unexplained) in the etiology of Alzheimer's disease (AD) (43, 44). Abnormal microtubule formation in AD brains has been associated with a defect in the tubulin polymerization cycle (45), which may increase the density of neurofibrillary tangles. A similar tubulin defect can be induced in the brain of $HgCl_2$-treated rats (46, 47), suggesting a connection between exposure to inorganic Hg and AD. $HgCl_2$ also markedly inhibits in vivo ADP-ribosylation of two rat brain cytoskeletal proteins, tubulin and actin, and thus alters a specific neurochemical reaction involved in maintaining brain neuron structure (48).

It is well established that Hg^+ will interact with tubulin resulting in disassembly of microtubules, and that microtubules function to maintain neurite structure (49). In a current investigation, recently reported, rats were exposed to Hg^0 4 h/day for as long as 14 consecutive days. Vapor exposure was maintained at 300 μg Hg/m^3 air, a level detectable in mouths of some human subjects with large numbers of amalgam fillings. Average brain Hg concentrations increased significantly with duration of Hg^0 exposure. Photoaffinity labeling of the β-subunit of the tubulin dimer with $[\alpha^{32}P]8N_3GTP$ in brain homogenates was diminished by 75% after 14 days of Hg^0 exposure. An identical neurochemical lesion of similar magnitude was seen in human AD brain homogenates, but no direct evidence exists to prove that this lesion is the result of human exposure specifically to amalgam Hg. Because the rate of tubulin polymerization is dependent on binding of tubulin dimers to GTP, it was concluded that chronic inhalation of low-level Hg^0 in rats can inhibit the polymerization of tubulin essential for formation of microtubules (50).

Another recent report demonstrates subclinical neuropsychological and motor control effects from an occupational exposure to Hg^0 over 1 year in a subpopulation of dentists with high urinary Hg levels (51). A more extensive report, evaluating dental technicians and dentists who received occupational exposure to Hg^0 and nondental personnel controls, demonstrated that after a chelation drug (DMPS) challenge test urinary Hg levels were 16-fold higher in technicians and 6-fold higher in dentists compared to control subjects. Baseline urinary porphyrin levels measured before DMPS treatment were associated with urinary Hg levels obtained after the DMPS challenge. Urinary Hg was also adversely associated with several neurobehavioral changes in Hg-exposed subjects including impairment of attention tasks and motor perceptual tasks. The utility of a DMPS challenge to assess renal Hg burden was established (52).

CONCLUSIONS

The collective results of numerous research investigations over the past decade clearly demonstrate that the continuous release of Hg^0 from dental amalgam tooth fillings provides the major contribution to Hg body burden. The experimental evidence indicates that amalgam Hg has the potential to induce cell or organ pathophysiology. At the very least, the traditional dental paradigm, that amalgam is a chemically stable tooth restorative material and that the release of Hg from this material is insignificant, is without foundation. One dental authority states that materials are presently available that are suitable alternatives to Hg fillings (4). Based on recent immunology investigations (35), electrochemical corrosion experiments (14), and human metabolic studies (15) it appears that the use of silver in amalgam may be almost as questionable as is Hg, and this evidence suggests that it may be inappropriate to alternatively use recently developed Hg-free silver-containing dental metals (53) to fill teeth. It would seem that now is the time for dentistry to use composite (polymeric and ceramic) alternatives (4) and discard the metal alchemy bestowed on its profession from a less enlightened era. Although human experimental evidence is incomplete at the present time, the recent medical research findings presented herein strongly contradict the unsubstantiated opinions pronounced by various dental associations and related trade organizations, who offer assurances of amalgam safety to dental personnel and their patients without providing hard scientific data, including animal, cellular and molecular evidence, to support their claims (54). FJ

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REFERENCES

1. American Academy of Dental Science. (1876) *A History of Dental and Oral Science in America* (Dexter, J.E., ed) S.S. White Publ., Philadelphia
2. Bremner, M.D.K. (1954) *The Story of Dentistry, 3rd Ed.,* Dental Items of Interest Publ. Co., Brooklyn
3. Ring, M.E. (1985) *Dentistry: An Illustrated History.* H.N. Abrams Inc. Publ., New York

4. Reinhardt, J.W. (1988) Risk assessment of mercury exposure from dental amalgams. *J. Pub. Hlth. Dent.* **48,** 172–177
5. Berry, T.G., Nicholson, J. and Troendle, K. (1994) Almost two centuries with amalgam: Where are we today? *J. Am. Dent. Assn.* **125,** 392–399
6. American Dental Association Divisions of Communication and Scientific Affairs (1990) When your patients ask about mercury in amalgam. *J. Am. Dent. Assn.* **120,** 395–398
7. Svare, C.W., Peterson, L.C., Reinhardt, J.W., Boyer, D.B., Frank, C.W., Gay, D.D. and Cox, R.D. (1981) The effects of dental amalgams on mercury levels in expired air. *J. Dent. Res.* **60,** 1668–1671
8. Vimy, M.J. and Lorscheider, F.L. (1985) Intra-oral air mercury released from dental amalgam. *J. Dent. Res.* **64,** 1069–1071
9. Aronsson, A.M., Lind, B., Nylander, M., and Nordberg, M. (1989) Dental amalgam and mercury. *Biol. Metals* **2,** 25–30
10. Patterson, J.E., Weissberg, B., and Dennison, P.J. (1985) Mercury in human breath from dental amalgam. *Bull. Environ. Contam. Toxicol.* **34,** 459–468
11. Vimy, M.J., and Lorscheider, F.L. (1985) Serial measurements of intra-oral air mercury: Estimation of daily dose from dental amalgam. *J. Dent. Res.* **64,** 1072–1075
12. Molin, M., Bergman, B., Marklund, S.L., Schutz, A., and Skerfving, S. (1990) Mercury, selenium and glutathione peroxidase before and after amalgam removal in man. *Acta Odontol. Scand.* **48,** 189–202
13. Gross, M.J., and Harrison, J.A. (1989) Some electrochemical features of the *in vivo* corrosion of dental amalgams. *J. Appl. Electrochem.* **19,** 301–310
14. Masi, J.V. (1995) Corrosion of amalgams in restorative materials: the problem and the promise. In *Status Quo and Perspectives of Amalgam and other Dental Materials* (Friberg, L., Schrauzer, G. N., eds) Thieme-Verlag, Stuttgart. In press
15. Skare, I., and Engqvist, A. (1994) Human exposure to mercury and silver released from dental amalgam restorations. *Arch. Environ. Hlth.* **49,** 384–394
16. Vimy, M.J., and Lorscheider, F.L. (1990) Dental amalgam mercury daily dose estimated from intra-oral vapor measurements: A predictor of mercury accumulation in human tissues. *J. Trace Elem. Exp. Med.* **3,** 111–123
17. World Health Organization (1991) *Environmental Health Criteria 118, Inorganic Mercury* (Friberg, L., ed) WHO, Geneva
18. Clarkson, T.W., Friberg, L., Hursh, J.B., and Nylander, M. (1988) The prediction of intake of mercury vapor from amalgams. In *Biological Monitoring of Toxic Metals* (Clarkson, T.W., Friberg, L., Nordberg, G.F., and Sager, P.R., eds) pp. 247–260. Plenum, New York
19. Aposhian, H.V., Bruce, D.C., Alter, W., Dart, R.C., Hurlbut, K.M., and Aposhian, M.M. (1992) Urinary mercury after administration of DMPS: correlation with dental amalgam score. *FASEB J.* **6,** 2472–2476
20. Nylander, M., Friberg, L., and Lind, B. (1987) Mercury concentrations in the human brain and kidneys in relation to exposure from dental amalgam fillings. *Swed. Dent. J.* **11,** 179–187
21. Hahn, L.J., Kloiber, R., Vimy, M.J., Takahashi, Y., and Lorscheider, F.L. (1989) Dental "silver" tooth fillings: A source of mercury exposure revealed by whole-body image scan and tissue analysis. *FASEB J.* **3,** 2641–2646
22. Hahn, L.J., Kloiber, R., Leininger, R.W., Vimy, M.J., and Lorscheider, F.L. (1990) Whole-body imaging of the distribution of mercury released from dental fillings into monkey tissues. *FASEB J.* **4,** 3256–3260
23. Danscher, G., Hørsted-Bindslev, P., and Rungby, J. (1990) Traces of mercury in organs from primates with amalgam fillings. *Exp. Mol. Pathol.* **52,** 291–299
24. Vimy, M.J., Takahashi, Y., and Lorscheider, F.L. (1990) Maternal-fetal distribution of mercury (203-Hg) released from dental amalgam fillings. *Am. J. Physiol.* **258,** R939–R945
25. Drasch, G., Schupp, I., Höfl, H., Reinke, R., and Roider, G. (1994) Mercury burden of human fetal and infant tissues. *Eur. J. Pediat.* **153,** 607–610
26. Clarkson, T.W., Hursh, J.B., Sager, P.R., and Syversen, T.L.M. (1988) Mercury. In *Biological Monitoring of Toxic Metals* (Clarkson, T.W., Friberg, L., Nordberg, G.F., and Sager, P.R., eds) pp. 199–246. Plenum, New York
27. Goering, P.L., Galloway, D.W., Clarkson, T.W., Lorscheider, F.L., Berlin, M., and Rowland, A.S. (1992) Toxicity assessment of mercury vapor from dental amalgams. *Fundam. Appl. Toxicol.* **19,** 319–329
28. Klaassen, C.D. (1990) Heavy metals and heavy-metal antagonists. In *The Pharmacological Basis of Therapeutics, 8th Ed.* (Gilman, A.G., Rall, T.W., Nies, A.S., and Taylor, P., eds) pp. 1598–1602, Pergamon Press, New York
29. Meister, A., and Anderson, M.E. (1983) Glutathione. *Ann. Rev. Biochem.* **52,** 711–760
30. Bloomfield, V.A., Crothers, D.M., and Tinoco, I., Jr. (1974) *Physical Chemistry Nucleic Acids,* pp. 420–429, Harper & Row Publ., New York
31. Magos, L., Halbach, S., and Clarkson, T.W. (1978) Role of catalase in the oxidation of mercury vapor. *Biochem. Pharmacol.* **27,** 1373–1377
32. O'Halloran, T.V. (1993) Transition metals in control of gene expression. *Science* **261,** 715–725
33. Druet, P., Bernard, A., Hirsch, F., Weening, J.J., Gengoux, P., Mahieu, P., and Berkeland, S. (1982) Immunologically mediated glomerulonephritis induced by heavy metals. *Arch. Toxicol.* **50,** 187–194
34. Hirsch, F., Kuhn, J., Ventura, M., Vial, M-C., Fournie, G., and Druet, P. (1986) Autoimmunity induced by $HgCl_2$ in Brown-Norway rats. I. Production of monoclonal antibodies. *J. Immunol.* **136,** 3272–3276
35. Hultman, P., Johansson, U., Turley, S.J., Lindh, U., Enestrom, S., and Pollard, K.M. (1994) Adverse immunological effects and autoimmunity induced by dental amalgam and alloy in mice. *FASEB J.* **8,** 1183–1190
36. Boyd, N.D., Benediktsson, H., Vimy, M.J., Hooper, D.E., and Lorscheider, F.L. (1991) Mercury from dental "silver" tooth fillings impairs sheep kidney function. *Am. J. Physiol.* **261,** R1010–R1014
37. Zalups, R.K. (1991) Autometallographic localization of inorganic mercury in the kidneys of rats: Effect of unilateral nephrectomy and compensatory renal growth. *Exp. Mol. Pathol.* **54,** 10–21
38. Zalups, R.K., and Barfuss, D.W. (1990) Accumulation of inorganic mercury along the renal proximal tubule of the rabbit. *Toxicol. Appl. Pharmacol.* **106,** 245–253
39. Gilbert, M.P., and Summers, A.O. (1988) The distribution and divergence of DNA sequences related to the Tn21 and Tn501 mer operons. *Plasmid* **20,** 127–136
40. Summers, A.O., Wireman, J., Vimy, M.J., Lorscheider, F.L., Marshall, B., Levy, S.B., Bennett, S., and Billard, L. (1993) Mercury released from dental "silver" fillings provokes an increase in mercury- and antibiotic-resistant bacteria in oral and intestinal floras of primates. *Antimicrob. Agents & Chemother.* **37,** 825–834
41. Rowland, A.S., Baird, D.D., Weinberg, C.R., Shore, D.L. Shy, C.M., and Wilcox, A.J. (1994) The effect of occupational exposure to mercury vapour on the fertility of female dental assistants. *Occup. Environ. Med.* **51,** 28–34
42. Ingalls, T.H. (1983) Epidemiology, etiology and prevention of multiple sclerosis. *Am. J. Forensic Med. Path.* **4,** 55–61
43. Thompson, C.M., Markesbery, W.R., Ehmann, W.D., Mao, Y.-X. and Vance, D.E. (1988) Regional brain trace-element studies in Alzheimer's disease. *Neurotoxicology* **9,** 1–7
44. Wenstrup, D., Ehmann, W.D., and Markesbery, W.R. (1990) Trace element imbalances in isolated subcellular fractions of Alzheimer's disease brains. *Brain Res.* **533,** 125–131
45. Khatoon, S., Campbell, S.R., Haley, B.E., and Slevin, J.T. (1989) Aberrant guanosine triphosphate-β-tubulin interaction in Alzheimer's disease. *Ann. Neurol.* **26,** 210–215
46. Duhr, E., Pendergrass, C., Kasarskis, E., Slevin, J., and Haley, B. (1991) Hg^{2+} induces GTP-tubulin interactions in rat brain similar to those observed in Alzheimer's disease. *FASEB J.* **5,** A456
47. Duhr, E.F., Pendergrass, J.C., Slevin, J.T. and Haley, B.E. (1993) HgEDTA complex inhibits GTP interactions with the E-site of brain β-tubulin. *Toxicol. Appl. Pharmacol.* **122,** 273–280
48. Palkiewicz, P., Zwiers, H., and Lorscheider, F.L. (1994) ADP-ribosylation of brain neuronal proteins is altered by *in vitro* and *in vivo* exposure to inorganic mercury. *J. Neurochem.* **62,** 2049–2052
49. Falconer, M.M., Vaillant, A., Reuhl, K.R., Laferriere, N., and Brown, D.L. (1994) The molecular basis of microtubule stability in neurons. *Neurotoxicology,* **15,** 109–122
50. Lorscheider, F.L., Vimy, M.J., Pendergrass, J.C., and Haley, B.E. (1994) Toxicity of ionic mercury and elemental mercury vapor on brain neuronal protein metabolism. 12th International Neurotoxicology Conference, Hot Springs, AR, October 31, 1994. *Neurotoxicology,* **15,** 955
51. Escheverria, D., Heyer, N., Martin, M.D., Naleway, C.A., Woods, J.S., and Bittner, A.C. (1995) Behavioral effects of low level exposure to Hg^0 among dentists. *Neurotoxicol. Teratol.* **17,** 161–168
52. Gonzalez-Ramirez, D., Maiorino, R.M., Zuniga-Charles, M., Xu, Z., Hurlbut, K.M., Junco-Munoz, P., Aposhian, M.M., Dart, R.C., Gama, J.H.D., Escheverria, D., Woods, J.S., and Aposhian, H.V. (1995) Sodium 2,3-dimercaptopropane-1-sulfonate (DMPS) challenge test for mercury in humans: II – Urinary mercury, porphyrins and neurobehavioral changes of dental workers in Monterrey, Mexico. *J. Pharmacol. Exp. Ther.* **272,** 264–274
53. Dariel, M.P., Lashmore, D.S., and Ratzker, M. (1994) New technology for mercury free metallic dental restorative alloys. *Powder Metallurgy,* **37,** 88
54. Lorscheider, F.L., and Vimy, M.J. (1993) Evaluation of the safety issue of mercury release from dental fillings. *FASEB J.* **7,** 1432–1433

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001. testimony	Gayle Bowler (partial) (1 page)	03/16/2001	b(6)

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[001]

Testimony

White House Commission
3/16/01
Minneapolis Minnesota

From: Gayle Bowler
(b)(6)
Jordan, Minnesota 55352
bowlerg@minn.net

My name is Gayle Bowler. I am a satisfied consumer of several alternative modalities. Please protect my right to choose and the right to get information about those treatments.

The problems I encountered in my healing journey are what I hope lawmakers will protect other health seekers from. There was a period when a local dentist and homeopath were being harassed in a manner with lots of publicity and no unsatisfied clients. This put me in fear of discussing my treatment plan with my MD. Would my traditional doctor set in motion political terrorism of my herbalist? As I participated in a class of energy healing, the MD sitting next to me said he would lose his license if his colleagues saw him there. Licensed doctors should be allowed to access information about complementary practices and use those techniques with patients.

I sought information about nutritional supplements and spent hours reading labels in health food stores trying to intuit what something was good for. I resented rules that make that information hard to obtain. I am afraid when I hear demands from some to protect the public by banning or controlling all herbal substances. The prescription drugs that are the alternative are advertised with the side effects that often sound worse than the symptom being treated.

Objective research should be conducted on the effectiveness of nutritional supplements and other products and practices. I have heard research workers tell how the results of studies by drug manufacturers are suppressed if they don't have an outcome in the financial interest of the company that funded the research. This reminds me of the cigarette scandals where knowledge of health risks were hidden from the public for decades. I would support tax dollars to conduct research.

The new Minnesota law provides the protections that I need as a consumer. I am pleased that there are not standards for licensure as many of the modalities are best taught person to person rather than in a structured class. I note that the law passed in Minnesota without much opposition in the final form.

It is important the allopathic and the complementary healing arts not be competitive. There is a need for both. There never is an excess of good health. Information to the consumer is needed so they can make informed choices about the health care received by their families

Public Comment/Testimony from Jeanne Hollingsworth to the White House Commission on Complementary and Alternative Medicine. March 13, 2001

As a consumer and a natural healthcare bodyworker I strongly believe that all people have the right to go to the natural healthcare practioner of their choice regardless of that practitioner's academic training. I believe people have the right to full access to all natural healthcare modalities so that they may choose those which best facilitate their healing process.

I believe my healthcare is my own personal choice and responsibility. It is one of the most personal choices I make.

From my own experience I know that a person with a lot of academic training may not be the most appropriate one to assist with certain health issues. I have found that someone with a natural gift for healing or who has studied with a mentor can be far more effective in my healing process than a person with only academic training.

In my 19 years of experience with natural healthcare I have found that it produces good results in a safe and non-invasive manner. I do not need any protection from it.

I fully support Minnesota Statute 146A, The Complementary and Alternative Health Care Freedom of Access Bill because this is a good solution to the concerns of consumers and practitioners alike. It requires that all practioners disclose their education and training along with information about the modalities and care that they give. This helps people make well-informed choices regarding their heathcare.

This bill provides consumers freedom of access to all healthcare practitioners while holding those practitioners accountable to the MN Department of Health. Appropriate consumer protection and healthcare access are provided simultaneously.This bill is exactly what we need and is an excellent model for the needs of the expanding natural healthcare industry.

Thank you for your time and attention regarding this important matter.

Acupuncture for Nature Healing

250 W 57th Street Suite 831 New York NY 10107
Telephone: (212) 974-2880 fax: (212)974-2880

February 21, 2001

James Gordon, M.D
Chair, White House commission on complementary and
Alternative Medicine Police
2934 Macomb Street NW
Washington DC 20008

Dr. Gordon:

My name is Zhao Yang Chen, a licensed acupuncturist of New York and I had the great pleasure of meeting you at the New York Town Meeting on January 23, 2001.

I thought the meeting was very successful in many regards. The meeting demonstrated that the government pays a great deal of attention to alternative medicine and the role it will play in the future of public health care. I also feel that the meeting offered caring people a chance to voice their thoughts to the Government. Due to the nature of your work, I feel that it is fitting for me to tell you about Active Acupuncture.

Active acupuncture is a combination of Cheng De Gu's exercise program and acupuncture. Mr. Gu's exercises are currently being taught at our office at Manhattan, Dorot, a non-profit senior center located at west 85th street, Manhattan; YHMA at east 14th street of New York City and Senior Center of Westport, Connecticut. There has been an overwhelming positive response from Mr. Gu's student, most of them are elderly. After you read the reports that I handed to you at the meeting you have had some impression about this exercise. Ms karen Fuller, the director of Dorot, also spoke of the benefits of Mr. Gu's exercise in the meeting of January 23, 2001. All of us strongly encourage you and your colleagues to visit Dorot, Y14 and /or the Senior Center of Westport, Connecticut, so that you can see for yourselves how Mr. Gu's exercises promotes health.

In conjunction with Gu's exercises, acupuncture is much more effective in treating different kind of diseases. Because the acupuncture needles are inserted at the time that nervous system of the body is highly excited by exercise will greatly enhance and extend the power of the acupuncture on stimulating the systems of the body. Because of this point, a hospital is showing their interest to have some research on treatment of some difficult to be treated diseases by Active Acupuncture. Once there have any results, I will mail the information to you.

If you have any suggestion, please contact me at (212) 974-2880 from Monday to Friday between 12:30-6:30 PM.

Thank you.

Sincerely

Zhao Yang Chen L. Ac.

Remarks of Michele Forzley, J.D.
to
The White House Commission
on
Complementary and Alternative Medicine Policy
Washington, D.C.
February 23, 2001

The Commission has an opportunity in its policy recommendations in the area of education and training to accomplish many goals. First and foremost, I urge that it recommend that a system be developed to harmonize guidelines to be followed by states and professional associations in the development of legislation and requirements for education and training of CAM providers. As a consequence, the Commission will take a giant step towards harmonized licensing and credentialing standards.

Currently, there are conflicting educational standards between states and countries outside the US and in the case of several modalities, no standards. The conflicts lead to some modalities being legislated out of existence, such as recently occurred in Maryland with massage therapists versus other touch healers. Another problem lies with the lack of cohesion and capacity amongst practitioners to politically articulate on their behalf. This is so either while a legislature or administrative body is considering a rule or when it becomes desirable to posture to develop applicable rules such as the case when one modality needs to be distinguished from another.

In addition to the benefits a system of harmonized education and training guidelines will offer the world of CAM, there is indeed a larger community that will benefit from this work. That community is the world of all health care professionals who face differing requirements from state to state and from country to country. While you may be thinking that this is not a problem, I would suggest you consider the practice of telemedicine, made possible through technology. There is no national system to ensure that physicians and other health care practitioners are able to practice across state and lines through the medium of telemedicine. Also, we should not forget the geographic areas of the US, such as DC metro, where it is almost impossible to not cross state lines in a practice, whether telemedicine or not. I might add this issue is not unique to health care. It beleaguers lawyers too.

Models do exist on how to bridge conflicting state and national rules and the equivalencies integral to the process already exist. The first model is European Council Directive 92/51 and amendments, which in 1992 began the European wide system by which the education for all trades would be recognized by neighboring states. Coincidentally, the Directive was specifically determined to be applicable to practitioners

of complementary and alternative medicine in November 1998.

The second model is the International Treaty on Telemedicine, for which I am one of the drafters, as a member of the International Bar Association Committee 2. The treaty is now being considered by the World Health Organization and establishes a harmonized system to recognize educational and licensing standards across national lines.

The third item is a tremendous body of work, which identifies the equivalencies in education and training. Alternative Link, Inc has done that work. There is no need to see how differing state rules can be compared. That is done. The Commission need only determine the rules it wishes to recommend.

Lastly, I refer the Commissioners to the Business Model Pilot Study I reported in my written remarks for December 4, 2000. That study reported that the basics of business should be at least an elective in coursework for all practitioners. As a result of that finding, my office has developed a curriculum which is being tested in Boston on March 15, 2001 and a similar element has been added to the program this August 4 on CAM law and business issues at the annual meeting of the American Bar Association.

For further information, Michele Forzley may be contacted at 301-565-1693 or mforzley@tiac.net.

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002. bio	Michele Forzley (partial) (1 page)	nd	b(6)

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[002]

Biography of Michele D. Forzley, J.D.

Michele Forzley is an attorney and business consultant with 24 years of experience, who focuses her practice on new directions in health care, shaping health care policy and practice, alternative and complementary medicine, international health law and public health issues and health care business practices. She also is an international business transactions lawyer and serves as independent general counsel to her client companies and institutions.

Michele is Vice Chair of the American Bar Association International Health Law Committee and Chairs the Committee on Complementary and Alternative Medicine (CAM) Law, which she founded. Michele edits the American Bar Association International Health Law News. She was a member of the International Bar Association Medicine and Law Drafting Committee on Telemedicine which authored the International Telemedicine Treaty, presented to the World Health Organization. She has also served as a Jessup International Moot Court Practice Judge.

She began The Center for Complementary and Alternative Medicine Law and Business in 1999, whose mission is to be a source of guidance and information on the legal, ethical, regulatory and business issues confronting the complementary and alternative medicine community. The Center does this through its web site, special projects, speaking and consulting services. The community includes all persons, governmental agencies, providers, regulators, patients, practitioners, and organizations who are involved in complementary and alternative medicine.

Michele earned her J.D. from New England School of Law and her B.A. in Sociology and Economics from Simmons College, both in Boston. She has studied private international law at the Hague Academy of International Law at the International Court of Justice in the Netherlands, Mind-Body Medicine and Spirituality and Medicine at Harvard Medical School and Health and Human Rights at the Harvard School of Public Health. She has been an adjunct professor at the Lubin School of Business at Pace University in New York and an adjunct professor of international business transactions law at New England School of Law.

Michele speaks, writes and consults worldwide on topics related to the changes in health care. She serves on one of the special international boards of the St. Jude Children's Research Hospital and has served on the boards of the Lower East Side Service Center and the Arab American Family Support Center; both healthcare organizations located in New York City.

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Silver Spring, MD 20910 USA
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003a

GERALD F. KARNOW, M.D.
(b)(6)
Spring Valley, NY 10977
(b)(6)

$45 $45

To: WHCCAMP

Ms. Chang

FAX 301-480-1691

Dear Ms. Chang:

Enclosed my summary for the meeting. I realize I will possibly not be able to present - but just in case. I also attached a position statement on AEM.

Thanks,

G Karnow MD.

4 pages including this.

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b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

0036

Summary of oral statement to the White House Commission on Complementary and Alternative Medicine Policy by the representative of the Physicians' Association for Anthroposophical Medicine (PAAM) speaking for the community of practitioners of anthroposophically extended medicine and therapies.

I will describe some concrete actions already enacted by the world-wide community of physicians striving to practice an anthroposophically extended medicine and express views on other requirements for a successful integration of CAM into our health care system. A major goal would be prohibition of discrimination against CAM providers in federal programs. Further, to pass legislation that would give all consumers the right for equal access to all licensed or accredited health care providers, and give health care providers the right to provide the care they feel is necessary.

Re 1 of suggested focus topics: By virtue of having academic chairs in at least three academic institutions, research efforts, in cooperation with conventional colleagues, to evaluate anthroposophically extended CAM practices have been done and continue to be done. Results are made available in peer reviewed literature.
Needed : a) encouragement of openness for new paradigms which are based on salutogenesis rather than pathogenesis, human centered rather than disease centered medicine. b) funding to support investigations.

Re 2 of suggested topics: Needed here is first of all protection from harassment by State and Federal and private agencies. Then needed is a change in licensing boards, insurance boards, HMO boards, all agencies having to do with the regulation of medical practice, to allow the incorporation of CAM practices. As many of these practices do not have the maturity or financial support of conventional practices, provision should be made for tolerance and support provided quality standards and accountability issues are met.

Re 3. of suggested topics: A prerequisite for the practice of anthroposophical medicine is a conventional training and licensure; training in anthroposophically extended medicine (AEM) complements conventional training. Anthroposophical therapies require physician contact and supervision of diplomats of specialty therapy trainings, e.g. massage, therapeutic eurythmy, art therapy, etc. Certification criteria have been or are being developed world-wide. In the USA, AEM has established criteria for certification and has certified physicians. Continuing education courses are ongoing.
Needed: Recognition that uniformity of standards needs to respect the diversity of CAM practices and not be determined by dogma or paradigmatic disagreements. Criteria for accountability should be uniform for all but include the consumer as having major input. Focus on moral issues.

Re 4. of suggested topics: Reliable and useful information is being made available through a variety of literature, published and web-based, for consumer and provider by AEM, worldwide and local.
Needed: Structuring of channels of information to support emerging CAM practices in presenting ever improving quality of useful information.

Gerald F. Karnow MD PAAM representative.
(b)(6)
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Anthroposophical Medicine – Position Statement

Anthroposophical medicine is based conventional scientific medicine and is practiced by fully qualified members of the medical profession only. To the existing scientific knowledge are added research findings concerning the nature of human life, the soul and the spirit. These are gained by the methods of the anthroposophical spiritual science developed by Rudolf Steiner based on and as an extension of the principles of the methods of natural science.

Training includes both the regular study of medicine and further training in specialist disciplines. Study of anthroposophical spiritual science and its research methods is an addition, as are the training in the arts and the basics of eurythmy therapy and art therapy.

Training in both theory and practice takes a minimum of three years. Training places are available in hospitals in Germany, Switzerland, England, Sweden, Holland and Italy.

Opportunities for further training in medical practices are given in more than 40 countries in the northern and southern hemispheres.

The clinical spectrum

Apart from general medical practice and family doctor provisions, the practice of anthroposophical medicine covers all medical disciplines from surgery through internal medicine, pediatrics, gynecology and obstetrics to neurology and psychiatry.

Anthroposophical medicines are produced by special methods. Reviewed by a special commission (Commission C for medicines and medical products) in Germany, their pharmaceutical monographs have been published. Indications for medicines, their manufacture and use are based on the anthroposophical view of the human being and of nature. The mistletoe preparations developed on this basis for the treatment of cancer (Abnoba viscum, Helixor, Iscar/Weleda, Iscusin/Wala, Visorel/Novipharm) are particularly well known.

Other forms of treatment are:

modelling and sculpture, painting, therapeutic speech formation, music and singing therapies as well as eurythmy therapy, a new form of movement therapy.

New developments in physical include rhythmic massage, rhythmic medicated rubs and a wide range of highly effective external applications which are part of nursing care. A special form of remedial gymnastics is being developed on the basis of Bothmer gymnastics which go back to 1920. It is known as 'remedial Bothmer gymnastics' and 'spatial dynamics.'

Therapeutic conversation between doctor and patients and biography work, including counseling for personal development and meditative work.

Internationally acknowledged treatment program for addicts.

Close collaboration with teachers (promoting the role of the school doctor) and worldwide work in curative education and social therapy based on out approach in more than 350 establishments worldwide (including those of the Camphill Movement(in 26 European and 12 other countries.)

Art therapy, eurythmy therapy and rhythmic massage are currently the subject of a study by two federal health insurance companies in Germany (IKK Hamburg, PKK Post) to assess their usefulness, indications and economic viability. The study is supervised by the Institute of Industrial and Social Medicine and Epidemiology of the Humboldt University in Berlin (Prof. N. S. Willich) and the Institute of Applied Epistemology and Medical Methodology in Freiburg (Dr. Helmut Kiene).

History and current availability

Anthroposophical medicine was developed by Ita Wegman, MD, and Rudolf Steiner, PhD, in collaboration with other members of the medical profession in the early 1920's. The first institutes of clinical medicine

with their own pharmaceutical laboratories opened in Stuttgart/Germany and Arlesheim/Switzerland in 1921. They were the precursors of the present Weleda and Wala pharmaceutical manufacturers. Steiner and Wegman wrote the fundamental work *Extending Practical Medicine, Fundamental Principles based on the Science of the Spirit*. Research and clinical practice relating to both diagnosis and treatment have continued to develop. Anthroposophical medicine does not claim to be an alternative form of medicine but an approach that includes the methods of conventional medicine. This is also why the term 'anthroposophically extended medicine' is widely used.

At the present time, about 2,000 medical practitioners are working in most European countries and many other countries worldwide. They are supported by hundreds of art therapists and eurythmy therapists, counselors, etc. the number of patients receiving anthroposophical medical treatment is currently approximately five million a year.

Ethical Issues

The focus is on the patient and individual treatment. Because of this, standardized methods of treatment are the exception, and work is in progress to develop documentation methods based on representative single cases and outcome studies. Randomized double blind trials are not considered acceptable for ethical reasons. The doctor-patient relationship is an integral part of this approach to treatment. The medical ethics base of Rudolf Steiner's main philosophical work: *The Philosophy of Spiritual Activity, A Philosophy of Freedom*. The concept of ethical individualism is the focus, and a view of the human being that recognizes the eternal individual nature of man even in a body that may be sick or handicapped This ethical concept is complemented by that of reincarnation and the certainty that the human mind and spirit is capable of infinite development.

Health Policy Aspects

The International Association of Anthroposophical Medical Societies (IVAA) is working for freedom of medical treatment for both members of the medical profession and patients, and for medical pluralism. It collaborates with all medical associations that pursue the same aims.

The IVAA and the European patients' association EFNMU are especially also asking for EU research funds to be made available for work in complementary medicine, and that it will be made easier for representatives of anthroposophical medicine to continue their work on documentation to establish and evaluate the efficacy of their approach by applying their own criteria or criteria inherent in the method.

Anthroposophical medical practitioners and patients are seeking to have experts in anthroposophical medicine included in all bodies responsible for the registration and licensing of medicines and for decisions concerning reimbursement for these medicines.

Today only three lectureships in and chairs of anthroposophical medicine exist, in San Francisco/USA, Hamburg/Germany and Bern/Switzerland. The ultimate ideal would be to have chairs of complementary medicine, including anthroposophical medicine, at all universities.

Anthroposophical medical practitioners, pharmaceutical manufacturers and patients are collaborating to develop a regional care provision system to meet existing needs, one aim being to strengthen patients' rights of self-determination also with medical insurance bodies, medical services, etc.

Contact in the USA:
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Ann Arbor, MI 48104

American College of Women's Health Physicians, Inc.
OFFICE OF THE PRESIDENT
Kelley L. Phillips, M.D., MPH
1626 34th Street NW•Washington, D.C. 20007
(202)337-8051• Fax: (202)338-2291

IN THIS CASE: January 2001

IN THIS CASE is a monthly publication exclusively for members of the American College of Women's Health Physicians.

NEWSFLASH!! Practical Reviews in Women's Health ACWHP Announces the First Audio Tape Series/CD-Rom on Comphrehensive Care for Women

The American College of Women's Health Physicians, in collaboration with Albert Einstein College of Medicine & Montefiore Medical Center, announces *Practical Reviews in Women's Health*, the first audiotape series dedicated to keeping physicians up to date on comprehensive care for women. This innovative survey of the literature, co-coordinated by ACWHP Board members Dr. Barbara Levy, and Dr. Elizabeth Lee Vliet, features 12 sixty-minute audio reviews with commentary from the foremost experts on women's health.

Each monthly issue contains 12-15 summaries of carefully selected and analyzed published articles. Each article highlights the most significant clinical considerations related to women's care. Tapes are accompanied by 4" x 6" printed cards with brief reviews of the selected articles. Up to 36 hours of category 1 CME credit is available with an annual subscription. *Practical Reviews in Women's Health* is also available on CD-ROM. Discounted cost for members is $299, additional discount provided for residents and students. For more information, or to subscribe, call (800) 633-4743, or (205) 991-5188, or visit our website www.acwh.org.

THIS MONTH'S AUTHOR: Lynne Firpo, MT

Lynne Firpo, MT, is a certified and licensed massage therapist. She holds a BA from Loyola Marymount University in Los Angeles. Her interests in alternative healing techniques have led her to study various forms of massage both in the U S and abroad. Some of the manual healing systems she has training in include Chinese, Thai, Hawaiian, as well as a South Indian form of massage called Varamum. Ms. Firpo's ten years of practice have included work with athletes and their related injuries, and she has been part of a chiropractic team treating soft tissue and muscular injuries. A mother of three, she shares here various tried and true massage techniques for relief of common complaints during pregnancy and menstruation.

Editor of In this Case: Francesca Taylor, M.D.

Can't find the right gift for your coworker, (best) friends, mother, grandmother, sister, aunt? Consider making a charitable donation to the Foundation for Women's Health in her name. Please remember as you approach your financial and estate planning for the new millennium, we hope you will consider the Foundation for Women's Health among your giving options.

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IN THIS CASE

American College of Women's Health Physicians

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monthly case study from a women's health physician's perspective

January 2001

Massage Modalities for Common Women's Health Concerns

Lynne Firpo, MT

Vignette: Back Pain in Late Pregnancy: AB is a 32 year old G3 P2 at 33 weeks gestation who notes much dull, aching pain in her lower back, worsening at the end of the day. She occasionally takes Tylenol for this, and has sought massage for more relief.

For alleviation of low back and sciatic pain I suggested the purchase of a body-length pillow. They can be found at a department store, or any bed and bath specialty store. A king-sized pillow, while not preferred, may be used. The mother lies on her side with her standard pillow under her head. The body-size pillow is placed along the anterior aspect of her body. Her lower leg, the one in contact with the mattress, remains extended, in alignment with her body. Her upper leg is bent at the knee and rests on the pillow. This posture allows the gluteal muscles to rest in a relaxed position, decreasing pressure on the sciatic nerve. Gentle circular motions can be applied to the area between the greater trochanter and the sacrum. This can provide tremendous relief for hip aches, low back pain, and sciatic pain. For maximum comfort and to ease turning over in the middle of the night, a body pillow can be placed on both sides of the mother. Thus, she only has to turn her own body, and the other pillow is there ready for her. This *does* work better in a large bed, and/or with an understanding/accommodating bed partner.

Vignette: Massage for Mastitis: CD is a 29 year old G1 P1 at four weeks post-partum who has been breastfeeding successfully since her baby's birth. One day, unexpectedly, she develops a low grade fever, and then notices a small area of redness and warmth on her left breast, about the size of a quarter. She describes the area as hard, like a knot, and wants to know what she can do for it.

Engorgement and mastitis can occur within the first week after birth, at the time of weaning, or during periods of time when the nursing mother is away from her baby. It can also occur without any apparent cause, but when the mother-baby dyad is separated it is time to be aware of measures to prevent the infection. Using the flat surface of the finger tips make circular motions to loosen the skin from the breast tissue. Secondly, support the breast underneath with one hand, and stroke from the areola out toward the torso. Use as much steady pressure as possible without causing discomfort. I also suggested applying lotion to the skin. Finally, use the fingertips to apply pressure in small circular strokes superiorly and laterally toward the area where lymph drains. Throughout the childbearing years there may be many times when the woman can feel the early signs of a breast infection. If these massage techniques are begun immediately and repeated as often as possible, it can help considerably to prevent recurrence.

Vignette: Massage and Dysmenorrhea: EF is a 36 year old G1 P0 who has had mild to moderately painful menses on and off during most of her reproductive years. She treats this often with typical doses of NSAIDs (non-steroidal anti-inflammatory drugs) but is looking for something more natural for aid. She has been found to have simple dysmenorrhea; more serious etiologies for menstrual pain have been ruled out.

These next techniques give relief for the back ache and lower abdominal pain that often occur with menstruation. Using duct tape, or wide masking tape, completely wrap two tennis balls so they are attached. Lying down supine (face up), place the tennis balls beneath the lower back. With the balls on either side of L5 relax the back and let the body weight take the pressure of the balls into the paravertebral muscles. After about a minute, move the balls up to L4 and repeat the relaxation. I also taught that if the pressure feels too great, try lying on a bed for this technique. A warm pack can be placed over the anterior lower abdominal/pelvic area during this procedure. A warm water bottle, a hand towel soaked in warm water, or a heat pack which can be warmed in the microwave all serve as good sources for moist relaxing heat.

Vignette: A Tip for Women Working on Weight Loss: GH is a 42 year old G1P1 who is 6 months post-partum and has been dedicated in her efforts to lose the extra weight gained during pregnancy. She has accomplished a loss of about half of what she had gained. She notes at a check-up that she "wishes the skin on her thighs were more smooth". She doesn't want to seek specialist techniques immediately, but wonders if "anything can be done?"

This final technique works most effectively for women who have lost some weight, but did not decrease the appearance of 'cellulite'. This stroke is called "skin rolling." In theory when connective tissue layers are lifted from the adipose tissue, dimples and lines will become more shallow and can disappear. Begin at the hip and use both hands. Pinch about an inch of skin between the thumbs and forefingers. Slide the hands down the thigh by using a walking motion with the forefingers, keeping the thumbs steadily in contact with the skin. (I demonstrate that the motion is akin to rolling down a leg of panty hose) A roll of skin will remain pinched in between the fingers and the thumbs as you travel down the thigh. Repeat this stroke enough times to cover the entire thigh. Perform this stroke regularly two to three times a day. Look for results after a few weeks. Some people find that they need to do maintenance strokes a couple times a week to keep the desired results. The same stroke can be used across the forehead to diminish horizontal wrinkles. Try it on frown lines or deep, dimpled scars. This technique can have notable satisfactory results.

References

1. Curties, Debra. Breast Massage. Overzet Publications, Moncton, New Brunswick, Canada. 1999.
2. Stillerman E. Mother Massage: touch for happier, healthier pregnancies. Massage Magazine; #87 Sept-Oct 2000: pp82-94.
3. Nichols, Frank. Theory and Practice of Body Massage. Milady Publishing Company, Bronx, NY, 1987.

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004. letter	Constance Malaambo to Commission re homeopathy (partial) (1 page)	04/12/2001	b(6)

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WHCCAM Town Hall Meeting Testimony, Minneapolis, Minnesota, March 16, 2001
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b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

[004]

Constance Malaambo, R.N., M.Hom
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Signal Hill, California 90806-5816
Email: cmalaambo@yahoo.com

April 12, 2001

Dear Commission,

As a Registered Nurse with over 30 years experience in traditional emergency medicine, I wanted to take this occasion to share with you my encounter with homeopathy.

Several years ago I developed a debilitating carpal tunnel syndrome that caused intense pain and decreased muscle mass in my right arm thus leading to a diminished work and social life. By chance, I happened to meet a homeopath and she suggested I cancel my next day Orthopedic surgery allowing her an opportunity to heal my wrist.

After one month with her homeopathic remedy, the pain I had been living with for over a year had improved by 50%, allowing me to resume my normal activities. Within 5 months my symptoms were nearly gone and they have been completely gone for 7 years.

The remarkable outcome I have experienced first hand inspired me to research and study this amazing form of "alternative" medicine. As a homeopathic practitioner myself, I can now say that I have seen this treatment work for many disorders, not the least of which include ADHD, cholecystitis, Irritable Bowel Syndrome, and trauma.

My personal goal for homeopathy is to have it integrated into a system of complete holistic medicine which will "restore health rapidly, gently, permanently, to...destroy the whole disease in the shortest, surest, least harmful way..." (Organon of Medicine, Samuel Hahnemann, paragraph 2). I believe the first step in this process is to end the bias that many traditional medical practitioners have regarding the efficiency of this modality.

Thank you for your consideration in the importance of alternative treatments.

Sincerely,

Constance Malaambo, RN, M. Hom

We have many legislators to thank for helping us pass this first-of-a-kind, precedent-setting legislation. They did so with wisdom and courage. We encourage you to thank them with a note, call, or e-mail.

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Our House Author

Heroes For Health Freedom!

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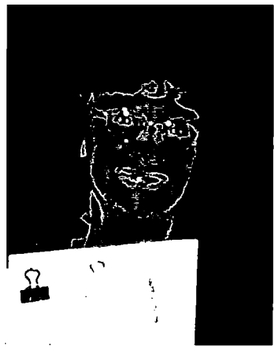

Our Senate Author

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Ensuring Freedom of Access to Natural Health Care

May 2000

Complementary and Alternative Health Freedom of Access Act Signed into Law

Statute 146A Signed by Governor Jesse Ventura on May 11, 2000

Legislature Votes: House 110-23; Senate 58-1

How Does the New Act Work?

Nuts and bolts: Firstly everyone should know that this statute goes into effect on July 1st, 2001, so we have some time to adjust. The number of the new statute is Minnesota Statute 146A. Currently you can find the text of our bill on our web site (www.minnesotanaturalhealth.org) imbedded in Conference Committee Report 3839 beginning at Section 9. However after the conference committee report is statutorized and made into Minnesota Statute 146A you will also be able to find that on our web site. You can also call House Information at the capitol at 651-296-2146 and they will send you a copy of House of Representatives Conference Committee Report 3839.

There are three important components to this statute:

The first is jurisdiction. The question is: Which practitioners will be available to consumers and will be able to practice as unlicensed complementary and alternative health care practitioners under the Department of Health's jurisdiction and be exempt from charges of practice of medicine without a license? The answer is twofold. First a practitioner must, in fact, be practicing unlicensed complementary and alternative health care as defined in the new statute. The practitioner cannot be practicing modalities that are outside the limits set forth within the law. A practitioner, for example, cannot engage in practices such as surgery, administering or dispensing controlled substances, practices that puncture the skin, etc. Secondly, it will be relevant whether a practitioner is currently an unlicensed or a licensed health care practitioner and if they are licensed whether they hold themselves out as a licensed professional. A close read of the new statute will help you discern whether this statute relates to your situation.

The second important component is grounds for disciplinary actions of practitioners. The question is: If a practitioner is under the jurisdiction of the Department of Health under this new statute, are they abiding by the proper conduct code or are they practicing prohibited conduct. The grounds for disciplinary action are spelled out clearly in the statute and are important for consumers and practitioners alike to be aware of.

Thirdly, and most importantly, is the Client Bill of Rights. The question is: If you are a consumer, did your practitioner provide you with the Client Bill of Rights before treatment commenced and did they have you sign an acknowledgment of receipt of the Bill of Rights before treatment commenced. The Client Bill of Rights mandates that every practitioner provides the client with 17 areas of information before treatment begins, including for example: the name, complementary and alternative health care title, business address, and telephone number of the practitioner; the degrees, training, experience, or other qualifications of the practitioner regarding the complementary and alternative health care being provided; a disclosure in bold letters that reads "THE STATE OF MINNESOTA HAS NOT ADOPTED ANY EDUCATIONAL AND TRAINING STANDARDS FOR UNLICENSED COMPLEMENTARY

Continued on next page

COME CELEBRATE OUR VICTORY!!

When: Sun. June 11, 2000; 2 pm-6 pm

Where: St. Stephen's School Gymnasium, 2123 Clinton Ave. S. in South Minneapolis. Use entrance on Clinton closest to 22nd St.

Directions: 35W to I-94 West to Lyndale Ave. Exit turning left (south) to first stop light at Franklin Ave. Turn left (east) on Franklin going about 1/2 mile to Clinton Ave. Turn right on Clinton Ave. and go less than one block to St. Stephen's School. Park in lot or on the street.

Who: All of you Health Freedom Fighters

MEET THE AUTHORS, MOVERS AND SHAKERS WHO MADE THIS A REALITY.

The church requests no alcoholic beverages.

QUESTIONS? Call 612-721-3305

How Does the New Act Work continued from previous page

AND ALTERNATIVE HEALTH CARE PRACTITIONER. THIS STATEMENT OF CREDENTIALS IS FOR INFORMATION PURPOSES ONLY." Every consumer should be aware of this practitioner mandate to distribute a Client Bill of Rights so that they can reap the benefits from the helpful information that practitioners will be providing. You can find the complete Client Bill of Rights in the new Minnesota Statute at Sections 146A.11.

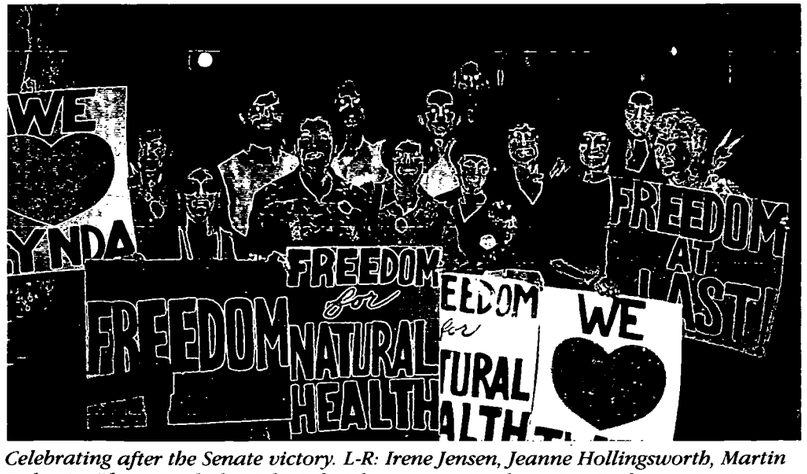
It is not the intent of this article to cover every aspect of the workings of the new statute. Consumers and practitioners are encouraged to read the actual statute which is now Minnesota Statute 146A. Classes and seminars will be available for those interested in a more comprehensive discussion. Please call 612-721-3305 for more information.

Final Version Meets Freedom Goals!

What does the final version of the Complementary and Alternative Health Care Freedom of Access Act look like? Our end product legislation meets our goals and is still our "baby!" We found out that the process of passing successful legislation is akin to a parent's adventure of raising a newborn. You wouldn't think a parent's pride could get any bigger than the day their little bundle was born. But then hearts swell and buttons burst at graduation when their 18-year-old walks down the aisle grinning from ear to ear. Let's not talk about when they backed in to the neighbors' Porsche while practicing driving! Yes, we had a few of those challenges with our bill too. But growing pains or not, our bill is still as beautiful as the day it was introduced into the Minnesota legislature, February 1999. It has been shaped by the climate, expectations and the culture of the state.

For example: The first draft of legislation was one page and requested an exemption from the "practice of medicine" criminal charge for healers that were not harmful or fraudulent. This was done in 1995 during the State v. Saunders trials. Seems simple enough. But before it could be introduced, the next drafts were started and came in response to the Board of Medical Practice v. Helen Healy hearings in 1996. These drafts expanded the language requesting that a government entity not be able to take criminal or civil injunctive action against any licensed or unlicensed practitioner without showing harm or fraud. This was consumer driven and the word started to get out about just how outdated the current laws were. The third set of drafts in 1997-98 were drafted specifically so that consumers would not lose access to natural therapies due to restrictive or unnecessary licensure laws. These drafts created a new model of legislation for all the complementary and alternative health care community and was 6-7 pages long. It included "right to practice" language for practitioners and proper "disclosures and informed consent" for consumers. The fourth drafts in 1998 were direct responses to preliminary discussions with legislators who recommended that there be a special office that could direct consumer complaints to proper legal avenues. **The most common concern of legislators was how to protect the public when no licensure, registration or certification was required.** A designated government client contact phone would help refer consumers to the already existing legal avenues available. The Department of Health agreed to be such a referral office. And finally the fifth set of drafts came in early 1999 and included all of our preferred language which we were courageously ready to defend at all costs. The bill was entitled the Complementary and Alternative health Care Freedom of Access Act and was introduced February 8, 1999. This stage was like eighth grade graduation!

Our bill was considered by some to be very raw. We, on the other hand, perceived it as a fine pearl, "all growd up" – typical freshmen! Some legislators saw the bill as very progressive, allowing the maximum number of consumer options and providing a referral service to teach consumers about their existing legal recourse when they had a concern. Other legislators opposed the bill, wanting a licensure model to mandate particular types of education and give exclusive title to various groups. Our task became one of educating legislators about the wide variety of healing trades and arts, about the lack of number of complaints against natural health practitioner and the potential arbitrariness of legal actions taken against them, and about the 1998 Department of Health Study on Complementary Medicine which did not recommend licensure but rather recommended a new



Celebrating after the Senate victory. L-R: Irene Jensen, Jeanne Hollingsworth, Martin Bulgerin, Eleanor Schultz, John Schotzbarger, Jan Forsberg, Leo Cashman, Jerri Johnson, Greg Schmidt, Sen. Twyla Ring, Nancy Hone, Diane Miller, Marillyn Beyer.

Continued on next page

Final Version continued from previous page

approach addressing the ethical relationship the consumer has with a practitioner.

AMENDMENTS became the name of the game! It was a full-time job keeping up with them. Our first shocking experience was when that portion of our bill that allowed licensed practitioners to practice alternatives was taken out in one fell swoop after a three minute conversation with no testimony. Wow! What a lesson in politics! We decided to continue and work with the unlicensed practitioner portion of the bill. As the bill went forward the most significant opposing amendment came from the House of Representatives presented in the Civil Law Committee by Representative Carruthers. **This amendment required us to abandon our original language and adopt language similar to an already existing Minnesota Statute for unlicensed mental health care practitioners.** It required us to shift the jurisdiction of the natural health community from the Board of Medical Practice to the Department of Health. It also required the government to set up a new office for enforcement of practitioner ethical violations and mandated distribution of Client Bill of Rights, which in turn required us to ask the legislature for money. But it did not jeopardize our freedom goals to assure consumer access to as many healing modalities as possible. We carefully considered our options and finally decided to introduce a reformed version of the amendment. This enabled our bill to pass out of the Civil Law Committee on February 26, 2000, after being heard in a precedent number of hearings over a course of almost a year by a strong advocate and remarkable Committee Chairman, Representative Steve Smith.

The ramifications of this decision were politically very huge. Not only were our former supporters on board but many of those who had been opponents now were excited about the bill. Consumer calls, letters and e-mails were flooding the capitol, and we had a bill that was gaining momentum. In the Senate the bill moved with less resistance after the Department of Health model language was adopted. The most significant amendment in the Senate came when negotiations took place with a number of licensure Boards. The end result was that the new office in the Department of Health would not have jurisdiction over a person licensed under the Board of Medical Practice, Board of Chiropractic, Board of Dentistry, and Board of Podiatric Medicine. **Other licensed professionals could practice as "unlicensed complementary and alternative health care practitioners" under the Department of Health as long as they were not holding themselves out as licensed professionals while practicing alternatives. All licensed individuals who would hold themselves out as licensed practitioners would continue to be under their licensing Boards when practicing complementary and alternative practices. It was at this point in the process that the Board of Medical Practice voted not to oppose our legislation.** These were extremely important amendments and contributed to the mutual respect of all participating interest groups.

The last big hurdle for amendments was the financing of the Health Department office for the taking of and following up on ethical complaints. All along the way there had been many heroes helping us. This included getting the funding for this office. The hard-working authors of this bill, Representative Lynda Boudreau and Senator Twyla Ring, were fearless under the attacks of our opponents! Towards the final days, Senator Sheila Kiscaden took the language of our bill and amended it onto her health occupations bill. This was done so that our bill would not get stuck in the huge omnibus bill where it could have gotten stalemated. This allowed it to continue to move ahead through the process. Senator Kiscaden has our deepest gratitude. The bill sailed through the last week while we held our breaths. MNHLRP, the Senate, and the House had worked together to find common ground, and we had found it. The bill even got the signature of the Governor! Hurray!

And now, like the teenager graduating and meeting the world head on, we expect a time of transition for our "freedom statute." We plan to participate in this transition, and continue vigorously advocating for natural health care freedom.

WHY DO WE STILL NEED MONEY?

- There is still much to do to insure that consumers have access to ALL practitioners of complementary and alternative therapies both in Minnesota and on a national basis. Consumers want access to practitioners both inside and outside of the medical system.
- We must educate consumers and practitioners on how this first of a kind legislation works.
- We must watch over this new bill probably forever to protect it from unwanted changes.

Please be generous with your donation – help is needed now!
Together we can change the face of the nation!

____Whatever you can give ____$35 ____$55 ____$100 ____$500 ____$1000+

Send contributions to: MN NATURAL HEALTH LEGAL REFORM PROJECT, 3236 17th Ave. S., #1, Mpls., MN 55407

Because the Legal Reform Project is for lobbying purposes, your contribution is not tax deductible. If you prefer a tax-deductible contribution, please contact us as we do have a nonprofit coalition for educational purposes that welcomes funding also.

Minnesota Natural Health Legal Reform Project
3236 17th Ave. S, #1
Minneapolis, MN 55407
612 721-3305

MINNESOTA'S HEALTH CARE FREEDOM BILL SIGNED INTO LAW

May 26, 2000

In a world looking for freedom to access to alternative health care, Minnesota has found an answer. On May 11th, Governor Jesse Ventura signed the Complementary and Alternative Health Care Freedom of Access bill into law. With that signing, Minnesota protected freedom of access to health care as a basic freedom that people enjoy, along with freedom of speech and freedom of the press. Few choices are so fundamental and important as is the choice of how we shall recover from illness or improve health.

Freedom of Access The successful reform caps a grassroots campaign, waged over several years, to better assure consumer access to the kind of health care that is wanted. The bill's enactment marks a step forward for protecting consumer access not only in Minnesota, but also throughout the land. The bill has also been hailed as a bellweather signaling a long overdue recognition of freedom to practice for alternative health care practitioners. A consumer's freedom of access is dependent on the practitioner's freedom to practice, of course, much as the public's freedom of access to information rests on the writer's freedom to write freely and without suppression by state laws or actions. For many, the unfair suppression of health care practices is just as troubling and unacceptable as would be the state's censorship of books or of free speech.

How the Movement Started The health freedom movement in Minnesota was galvanized in the mid-90s by high profile legal actions taken against several of the state's most prominent alternative health care practitioners, both licensed and unlicensed. One case involved St. Paul naturopathic doctor Helen Healy, who was charged with "practice of medicine" without a license. Despite the absence of consumer complaints and even despite the absence of any allegations of patient harm, the state's Medical Board sought to shut down Healy's practice immediately and permanently. The public outcry helped save Healy from being shut down; she settled out of court before her trial. But it also helped spur a new thirst for greater protection of consumer freedom of access and a desire to affirm the practitioner's right to practice with fairer treatment under the law. A citizen 'legal committee" that researched the legal obstacles to health freedom eventually became the nonprofit Minnesota Natural Health Legal Reform Project, which spearheaded the legal reform effort.

The Overly Broad Definition The crux of the problem for all unlicensed practitioners, including Helen Healy, is the overly broad definition of the "practice of medicine." The sweeping definition includes anyone who undertakes to diagnose, correct, treat or even prevent any disease, illness, pain or infirmity by any manner or means; such people are practicing medicine, according to existing law, and must be licensed medical doctors. Nurses, dentists, chiropractors and other licensed health professionals escape charges of practicing medicine without a license because they have an exemption to the overly broad statute. But there is no such protection for the unlicensed alternative health care practitioner; they can be charged with practice of medicine whenever a complaint gets the medical board's attention. The fallout of this legal vulnerability is far-ranging: it includes a fear of becoming too prominent, a fear of being too commercially successful, a fear of being the innovator and a fear of being seen as outspoken in criticizing the more commonly used methods of treatment. As a result of the fear and intimidation, consumers can tend to be deprived of the benefits of the most honest discussions that they could have with their practitioners, and of the most innovative treatment methods. The practitioners themselves may be forced into early retirement or they and their treatment option could be difficult to find.

Licensure and Turf Battles If the state of Minnesota deems it desirable to regulate an occupation, it is state policy to only regulate the occupation with the least restrictive manner and only when an occupation would pose an imminent risk of harm to the public. In view of that, legislative health committees have declined to allow licensure for currently unlicensed modalities such as naturopathy to go forward. A registration bill for massage therapists has also been tabled. Licensure and registration approaches have other drawbacks; they seem to set up battle lines among practitioners, between those that would be allowed to practice under the proposed licensure and those that would be excluded. Minnesota's new approach to affirming health freedom avoids stirring up those kind of turf battles.

Minnesota's Freedom Solution. To assure consumer access to as many practitioners as possible, the state of Minnesota has set up a new office to provide government oversight to unlicensed practitioners. In turn, the practitioners practicing under the new statute will be exempt from criminal charges of practice of medicine without a license. The office will oversee those who are practicing "the broad domain of complementary and alternative healing methods and treatments." Naturopathy, homeopathy, herbalism, and massage, are just a few of the therapies listed in the statute as examples of practices that the new chapter of law deals with. A set of 24 rules of ethical conduct is given for the new office to oversee. The office will receive consumer complaints, investigate them, and enforce the ethical rules. The ethical rules include prohibitions against fraud, false or misleading advertising, sexual contact with a client, and inability to practice "with reasonable safety ... to the client." The rules of conduct are clearly not intended to allow suppression of therapies on the grounds that they are new or different from conventional practice. "The fact that a ...practice may be a less customary approach to health care shall not constitute the basis of a disciplinary action per se," the new law states.

The new law takes effect July 1, 2001.

How They Did It A statewide grassroots lobbying effort by the reform project helped move the health freedom bill through the tougher committee battles. A core of about eight leaders met one night a week for three years to drive the effort forward. Serving as the reform project's legal consultant was Diane Miller who, supported by a volunteer legal team, formulated the freedom approach behind the bill. Miller along with citizen-turned-lobbyist Jerri Johnson, a local homeopath, led the lobbying work at the capitol and helped to navigate the bill through 15 committees.

Consumers in all parts of the state – outstate as well as metro – played a role in reaching their elected officials. They gathered with their legislators in their districts to share their stories of the personal importance of alternative care options and to demand active reform. After a while, it was obvious that, for the people of Minnesota, this reform bill had very broad support.

The chief author in the house was state Representative Lynda Boudreau, a republican. Her leadership in moving the bill through key house policy committees was crucial. She was able to work with supportive colleagues to survive intense amendment discussions and formulate a bill that would meet new-found broad support.

Then it was largely the senate's turn, with the committee deadline clock ticking. State Senator Twyla Ring, a democrat and a rookie in the senate, was the senate author who piloted the senate version through three major dramatic hearings in one week. Senator Ring agreed to take up the senate authorship after the death of a previous senate author, Senator Janet Johnson, last August. Elected in a special election to fill the vacancy left by Johnson's death, Sen. Ring, had been a personal friend of Johnson's. Sen. Ring became strongly committed to helping finish the senate journey for health freedom that her friend Janet had begun. She did, with the help of many of her senate colleagues.

After going through a conference committee, final passage in both houses was by strong margins. On May 1st, the House approved the bill by 110 to 23, following a final, lively debate. The final senate approval for the bill on May 4th was by a 58 to 1. The freedom train had arrived.

Governor Ventura's policy advisors supported the health freedom bill and the governor's office was deluged with calls from citizens urging that he sign the bill. Without fanfare, Ventura signed with bill May 11th in the privacy of his office.

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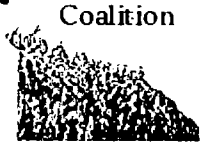
Minnesota Natural Health Coalition



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A SLICE OF LAW AND MEDICINE, *Ann Richtman*

You can make your own decisions about what is right for you. The United States Supreme Court has ruled that no one can force you to undergo certain treatment. However, it has not said that unconventional treatments will be available to you.

The mix of law and medicine has many interests and players, some more obvious than others, some more influential than others: You/your family, health care providers, the government, and the medical and healthcare industry. The University of Minnesota-Duluth Bureau of Business and Economic Research reports in an article printed in the Duluth Budgeteer July 7, 1999, that the combined dollars generated by doctors and dentists, hospitals, and other medical and health services in St. Louis County, MN, and Douglas County, WI, is $310 million annually and second only to the export value of the iron ore industry in the area. The local economy and a lot of jobs - maybe yours or your neighbor's - are dependent on the status quo. If we embrace a preventive and holistic health care model and if alternative modalities reduce health care costs, then we expect the tension that comes with shifting values and different choices.

What if you are a person who says to government: Thanks but no thanks; I am capable of determining for myself the kind of health care practices that are best for me. If the Supreme court interprets your liberty interest and your right to privacy under the Constitution to include the refusal of medical care, then you certainly ought to be able to choose options that you think, rightly or wrongly, will promote your health. But not so fast. Your interests are "balanced" by the State's interest in protecting the safety of its citizens. This is referred to as "the police power" of the States. We will examine the fit and tension among these interests.

Citizens have certain constitutional rights. The First Amendment should guarantee you the right to receive and exchange medical information. A person should have a right

under the Commerce Clause of the Constitution to practice a trade, but the government can regulate how you do that. You may have a liberty interest under the Fourteenth Amendment to access informed, safe and beneficial medical treatment, but the government can make certain health practitioners or health practices unavailable to you by laws. Some courts have ruled that a health care practitioner, whether licensed or unlicensed, cannot assert the interests or benefits to their clients as a justification for services.

There is not a universal truth or agreement about the standards for licensing or regulation from state to state. For instance, every state has some form of Medical Practice Act which defines the scope of practice for those professionals with the title of medical doctor. This means that a person cannot use the title or do those things defined within the act defined as the practice of medicine unless they meet the licensure standards of the state. There is further regulation done by a state governing board which determines professional competence and fitness, i.e. Minnesota Medical Practice Board or Wisconsin Board of Medicine.

Unless exempted by statute, current state law permits only medical doctors and osteopaths to "prevent or diagnose, correct or treat in any manner or by any means, methods, devices, or instrumentalities, any disease, illness, pain, wound, fracture, infirmity, deformity, or defect of any person" except by authority of the state board. The breadth of this authority is staggering. Occupations are regulated under the police power of the states to protect and preserve the public health. The remaining question is whether the regulation is reasonable. Does the patient have a right to choose the type of medical care preferred?

Here is where we run into some curious twists and turns of logic. The present reality is that more and more Americans are turning to practices that are considered "complementary and alternative" to the dominant conventional allopathic medical system. Studies show that 70% of all Americans and 47% of all physicians are using at least one form of complementary or alternative methods for their personal health care. The Federal government funds the National Center for Complementary and Alternative Care as a separate department of the National Institute of Health to the tune of $50 million annually.

Educational institutions want to keep abreast of the changes in consumer health choices. The University of Minnesota has added alternative therapies to its medical school curriculum and created the first graduate level minor in CAM in the

country. The College of St. Catherine offers a 10-month course to bring health professionals up to speed on various complementary models. In the Duluth area, the College of St. Scholastica, the University of Minnesota, and Lake Superior College incorporate information for undergraduates, medical students, and allied health professionals into several courses.

If an unlicensed health practitioner offers you a homeopathic remedy, herbal medicine, or applies any of a number of other healing practices, he or she can be prosecuted for "practicing medicine without license." By the same token if your physician offers you herbal medicine or a homeopathic remedy, he or she can be accused by the Medical Practice Board of practicing outside "acceptable and prevailing" conventional standards of care and be sanctioned. Doctors are in a difficult position individually if they do not know with certainty whether they can be sued for malpractice if they make a referral to an alternative practitioner, or if they co-manage a patient who sees one and experiences a bad outcome from that experience. David Eisenberg, M.D., makes specific recommendations for physicians with patients wanting alternative care in Annals of Internal Medicine 1997; 127(1):61-69.

Can consumers distinguish between competent practitioners and quacks or must they rely on the government to do so for them?

How do you minimize inherent conflicts of interest when the health practitioner's livelihood depends on marketplace demand? Will regulation of the occupation guarantee that the health of the client or patient is the primary goal?

Reasons often given for regulation of health care professionals are to prevent non-diagnosis, misdiagnosis, non-treatment, and mistreatment by unlicensed medical providers. Can we assume that a licensed medical practitioner will not fail to diagnose, misdiagnose, fail to treat or mistreat? Likewise must we assume that a unlicensed health practitioner would undoubtedly cause harm or that there arena existing civil or criminal remedies to protect the public?

I am not suggesting that an untrained or unlicensed person perform surgery or prescribe drugs. But we do need to look more closely at the many health and wellness therapies, traditions, and practices available on the health continuum and sort out the least restrictive manner of regulation, if any is necessary.

How Effective Is Occupational Regulation?

In Minnesota, the stated purpose of regulating any occupation is to protect the public: "The legislature declares that no regulation shall be imposed upon any occupation unless required to the safety and well-being of the citizens of the state." Minnesota Statutes §214.001,subd. 2.

In January of 1999, the Office of the Legislative Auditor published a program evaluation report on Occupational Regulation in Minnesota which addresses the following questions: What is the history of occupational regulation in Minnesota and other states? What are the problems and suggested solutions? What constitutes Minnesota's system of occupational regulation? How effective is regulation? (Full text version of the report is available at Web site http://www.auditor.leg.state.mn.us or from the Legislative Auditors 651-296-4708.)

While the main purpose of occupational regulation is the protection of the public it can also limit access to regulated occupations and raise prices. Most requests for regulation come from occupational associations, not consumer groups; raising the criticism that it can be controlled by the political strength of professional organizations. This is referred to as occupational "fencing." As many state legislatures were faced with increasing demand to regulate more and more occupations (Minnesota regulates nearly 200) in the past thirty years, they began to look for ways to screen such requests of validity and true public purpose.

Sunrise Legislation

One solution was "sunrise" legislation. Sunrise provisions place into statute the idea that "credentialing should be enacted only when it is clearly in the public's best interest. Moreover, the level of regulation should be no more restrictive than necessary to protect the public.

In 1976, Minnesota became one of the first states to enact sunrise legislation as a means of screening proposals for occupational regulation to ensure that they meet criteria for public protection, rather than occupational member protection. Wisconsin has adopted a sunrise policy through department rules, Department of Regulation and Licensing, rather than statute. In recent years Wisconsin has shifted towards using less restrictive forms of regulation, notwithstanding the recent certification requirement for massage therapists and body workers championed by the profession.

In Minnesota criteria were established to determine whether to regulate:

- Whether the unregulated practice of an occupation may cause a recognizable, and not remote, harm or danger to citizens of the state;
- Whether the practice of an occupation requires specific skill or training;
- Whether citizens could be protected by another means.

In addition, the law mandates that occupations should be regulated in the least restrictive manner and directed the legislature to consider in a particular order a range of options for regulation in the least intrusive manner and for which licensing is the last to be considered in the regulation scheme.

What if you know that you are skilled and well-intentioned in your healing practice but not regulated by state licensure? For instance, perhaps you have trained at the Minnesota Center for Shiatsu Study (MCSS), a professional Shiatsu massage training program. MCSS offers services to underserved communities at an Elder Center, AIDS day care facility, and a YWCA neighborhood wellness initiative for those without medical insurance, as well as corporate preventive health care programs. Should these practitioners be prosecuted for the unlicensed practice of medicine because they provide treatment for a wide range of internal, musculoskeltal, and emotional conditions?

What if you graduate from the Northwestern School of Homeopathy and successfully treat a variety of illnesses? Should you be criminally prosecuted? What if you are a naturopath, an herbalist, or practice therapeutic touch?.

In 1997 and 1998 bills were introduced in Minnesota to regulate Massage and Oriental Body Work Therapists, but they failed to pass. An attempt to license naturopathic doctors also failed. However, it did provide impetus for a 104-page report on Complementary and Alternative Medicine by the Minnesota Department of Health, which concluded in January of 1998 that there is not presently enough information to justify governmental regulation of naturopaths or other alternative medical providers.

If unlicensed healers are in the marketplace, in fact sought out by patients, and the courts are not filled with cases brought by the Medical Practice Board or attorney general to stop them or criminally prosecute them, then why worry about regulation or be anxious about access to their care? The problem is that enforcement of the law becomes arbitrary and unpredictable, a potential weapon in the hands of professional organizations or government groups that dismiss what may

work for you or me because science has not yet discovered the truth of common experience. It also has a chilling effect on the exchange of health information.

In 1999, the Minnesota Natural Health Coalition ACTION NETWORK, relying on several years of study and evaluation by the Minnesota Natural Health Coalition, proposed legislation for Freedom of Consumer Access to Complementary and Alternative Health Care (House File 537/Senate File 689). The bill is based on the principle consumers can make informed choices about the health care practices they want available to them. It moved out of the House Health and Human Services Policy Committee on March 15, 1999, after an amendment deleted all language protecting consumer access to already licensed health practitioners who wish to use complementary or alternative therapies in their practice. The Minnesota Medical Association and Medical Practice opposed the bill because they don't want consumers telling them what to do. The remainder of the bill pertaining to unlicensed providers passed and was sent to the Civil Law Committee. Hearings will continue in the next legislative session. (More information is available at Web site www.minnesotanaturalhealth.org)

The Freedom of Access bill is not a licensing bill. It's purpose is: "To protect the freedom of the individual to choose and receive the healing treatment that the individual desires and deems to correspond with his/her own view of health and disease, and which the individual deems to be effective in securing his/her own wellness; and to encourage and promote the practice of all healing methods; and to protect the right of health practitioners to practice complementary and alternative health care."

The proposed legislation adds an exemption to the Medical Practice Act for unlicensed complementary and alternative health care practitioners who practice in accordance with the full disclosure provisions. It would establish a statutory duty of care and standards of practice for the practitioner.

Healthcare in the United States is in a crisis not because of issues of managed care, insurance coverage, lengths of hospital stays, etc. but because too many people are ill or in pain. The Public Health issue is one of prevention, identifying the real causes of illness, and restoring individual and collective balance and integrity.

Ann Richtman, J.D., has practiced law and taught in Minnesota and Wisconsin for many years. She also helped

draft the proposed legislation in Minnesota on Freedom of Access to Complementary and Alternative Health Care. © 1999 Northland Natural Health Resources, Inc. Used with permission.

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Integration of Complementary and Alternative Therapies Into Care Delivery Systems

(abbreviated 3 mn version)

Respectfully submitted by Kathy A. Schurdevin, President, MN Natural Health Legal Reform Project

The main issue we are facing is how do integrate complementary and alternative therapies to provide the citizens fully with the care they need. Ideally, in the best interest of the clients, integrative care should be predicated on "clinical parity." A number of so called integrative partnerships have been tried, but these have fallen short of expectations due to the intense interest of the parties involved in maximization of revenues. A structured delivery system, consisting of "clinical parity," void of competing financial interests, and free of the dominance of the traditional JCAHO delivery model needs to be developed. Under this "integrity model", an upfront multidisciplinary patient assessment would drive patient care.

I do not feel that integration is the best option, but believe that collaboration would be a much stronger model to pursue. This would require good collaborative networking between the medical doctor and hospital systems and the alternative healers throughout the community; an intricate system that supports the client both during and after hospital care. The citizens want options and time available to them that has been eliminated from current mainstream medicine. They want their alternative healers brought into the hospital setting without interference on a consultation basis upon request of the attending physician, the client or the client's family.

Interventions must be designed to help the client progress toward personally valued health goals with comprehensive focus on multiple areas of function, such as mental, emotional, spiritual, social and work related, and taking a long term perspective toward improving the course of their health. An emerging body of evidence demonstrates that community interventions can improve the long term outcome of wellness and illness. If clinicians are to be effective in serving their clients, they must be knowledgeable about nonpharmacological interventions designed to decrease symptom severity or distress, avoid hospitalization, improve psychosocial functioning and improve satisfaction with life.

Examples of such interventions include:

A) Collaborative alternative and allopathic treatment with direct provision of services provided, rather than brokered services;

B) Assertive community treatment models of case management. This management involves clear traditional medicine and alternative therapy treatment goals and treatment options;

C) Family involvement and intervention in care. This has been found to reduce hospitalization and decrease relapse rates;

D) Illness and wellness self management training. This provides a shift from passive recipient of treatment to active involvement in management of his or her wellness and illness, with education about illness and alternative and allopathic treatment options; teaching how to recognize and respond to early warning signs of illness or relapse and teaching coping strategies to deal with stress or persistent symptoms;

E) And supportive employment incentives, such as, paid wellness days off, use of sick time accumulated revenues for alternative wellness and illness care, etc.

I respectfully request that the Commission consider this for policy recommendations. As a parting thought: " A single choice can build destinies or destroy them."

Integration of Complementary and Alternative Therapies Into Care Delivery Systems

(Complete statement; Please read in its entirety.)

The main issue we are facing is how do integrate complementary and alternative therapies to provide the citizens fully with the care they need. Ideally, in the best interest of the clients, integrative care should be predicated on "clinical parity." A number of so called integrative partnerships have been tried, but these have fallen short of expectations due to the intense interest of the parties involved in maximization of revenues. If the Commission is sincere in assessing the effectiveness of integrating complementary and alternative therapies into mainstream medicine, it should encourage federal funding of a credible research and development project based upon a structure consisting of "clinical parity," void of competing financial interests, and free of the dominance of the traditional JCAHO delivery model. Under this "integrity model", an upfront multidisciplinary patient assessment would drive patient care, rather than the "power of the allopathic pen."

I do not feel that integration is the best option, but believe that collaboration would be a much stronger model to pursue. This would require good collaborative networking between the medical doctor and hospital systems and the alternative healers throughout the community; an intricate system that supports the client both during and after hospital care. We must look at who all the healers are. Our biggest allies are the healers in the community that keep the people well and we must strive for a permeation of healers throughout each community. Our focus should be on getting as many healers as possible to have time to be with the people. The citizens want options and time available to them that has been eliminated from current mainstream medicine. The issue is about the consumer: how to get people well in their community.

The present system has only been looking at integration in the hospital/ clinic setting. There needs to be a de-integration that looks at how the traditional medical community can know community resources, so they do not have to bring healers into the hospital as staff. Rather, alternative healers would be openly brought into the hospital setting without interference on a consultation basis upon request of the attending physician, the client or the client's family. There needs to be genuine curiosity by mainstream medical providers. A major problem has been the long history of hostility by mainstream providers toward alternative providers, as well as, ignorance of alternative therapies. Many medical doctors are interested, but are not taught about alternative therapies and the clients that use alternative therapies often do not come to them routinely. The quickest way to remedy this would be to provide coverage for alternative modalities and more research funded by the federal government and research organizations. An open flow of discussion needs to happen that will make the way for referrals.

The hospital setting is necessary to take care of acute illness and trauma and collaboration with the healers in the community will keep the people well. The result will be that the hospital and clinic systems may lose revenues, but that is not the issue. Whose money is it? It's the people's money. The issue is not money. It is the wellness of the people.

Interventions must be designed to help the client progress toward personally valued health goals with comprehensive focus on multiple areas of function, such as mental, emotional, spiritual, social, and work related, and taking a long term perspective toward

improving the course of their health. An emerging body of evidence* demonstrates that community interventions can improve the long term outcome of wellness and illness. If clinicians are to be effective in serving their clients, they must be knowledgeable about nonpharmacological interventions designed to decrease symptom severity or distress, avoid hospitalization, improve psychosocial functioning and improve satisfaction with life.

Examples of such interventions include:

A) Collaborative alternative and allopathic treatment with direct provision of services provided, rather than brokered services;

B) Assertive community treatment models of case management. This management involves clear traditional medicine and alternative therapy treatment goals and treatment options;

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I respectfully request that the Commission consider this for policy recommendations. As a parting thought: " A single choice can build destinies or destroy them."

Respectfully,
Kathy Schurdevin
President, MN Natural Health Legal Reform Project

* Medscape Mental Health 6(1),2001. Article by Kim Meuser PhD, Gary Bond PhD, Robert Drake, MD, PhD "Community –Based Treatment of Schizophrenia and Other Severe Mental Disorders: Treatment Outcomes."

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Ken

White House Commission, Testimony by Matthew Wood

Thank-you for the opportunity to speak before you today. I am a member of the Minnesota Natural Health Coalition and the American Herbalists Guild. I have been a practicing herbalist for twenty years, have seen thousands of clients and earn my income solely from my calling. I believe herbalism is one of the more difficult issues the Commission will face. Both safety and freedom issues are involved so I offer the following suggestions.

First, safety issues can be met by establishing an official herbal pharmacopoeia, like that for allopathy and homeopathy. Plants, genera and families with toxic compounds should be noted and controlled. A broad base of traditional non-toxic herbs (similar to those currently on the GRAS list of the FDA) can be established which will be in the public domain and available for professional and folk usage. Suspected side-effects and drug interactions should also be noted. Appropriate manufacturing methods for standardized extracts would be included, as well as simple standards for traditional preparations. Herbal products should be described in both scientific and traditional terms. For the latter, I would avoid terms implying specific uses such as diuretic, adaptogen, alterative, etc., in favor of a few wide, general categories based on obvious physical characteristics like bitter, astringent, stimulant, mucilage, etc. These are in fact scientifically valid.

Second, I believe there should be a two tier system of regulation for practitioners.

Tier 1. Medical and naturopathic physicians who desire licensure should be allowed it, but it should be based on their use of medical procedures, not alternative therapies – these should remain in the public domain.

Tier 2. CAM practitioners such as herbalists and homeopaths, who do not practice medical diagnosis or treatment, should be allowed to practice under guidelines similar to those we have developed here in Minnesota. However, if groups within these movements desire licensure in the future they should be allowed to have it, based on their education in and use of medical procedures. Thus there would be room for evolution within a profession. A third tier may have to be instituted for folk healers who do not keep records and practice completely without regulation. They should not be subjoined from practice but should be held responsible for injury.

Payment. Federal reimbursement of medical expenses should only extend to diagnosis and treatment of serious medical conditions. Competition for other services will improve care and control prices. The poor are protected by the protection of folk healers; this I know from working at an inner city herb store for eight years.

support the Medtronic model

Most importantly, these guidelines should be established by people within the professions themselves, working in conjunction with the government, not by outside experts with no practical experience in the field.

STATEMENT FOR THE WHITE HOUSE COMMISSION ON COMPLEMENTARY AND ALTERNATIVE MEDICINE POLICY, MARCH 16, 2001, MINNEAPOLIS, MN

Dear Commissioners,

Thank you for this opportunity to express the needs of 5000 Minnesota pharmacists, and more than 1000 physicians and nurses of HealthPartners, a non-profit HMO.

People, who are choosing to self medicate with herbal dietary supplements, are calling upon us for information in order to avoid adverse reactions and/or interactions with these products.
We are called upon because herbal dietary supplements lack appropriate labeling for self-medicating.
The labels do not provide the information that would enable a person to avoid adverse reactions and/or interactions. In many cases, the information *itself* is not available.

Cases in point: ginkgo biloba, do the case reports of bleeding episodes imply a trend? Does ginkgo biloba really interact with warfarin? Kava, do the recent liver toxicity reports reflect a reaction that will be expected to show up in 0.01% of people using or in 10%? St.John's wort, the recently documented interactions between St.John's wort and pharmaceuticals makes us question our current sources for adverse reaction/interaction information, including traditional use and Germany.

The first article to systematically summarize the published literature on potential adverse reaction/ interactions was published last year.[1] The data suggests adverse reactions/interactions exist. We need to know which ones are relevant. We must be able to distinguish between significant adverse reaction/interactions and minor ones.

We need reliable data. Numerous authoritative references today have direct contradictions about adverse reactions/interactions. We do not have the data people need to safely self-medicate.

With no pre-marketing review for dietary supplements, we need a post-marketing program to increase the detection of adverse reactions/interactions.

We need a program that will:
1) Be publicized to healthcare providers, hospitals, pharmacies, clinics, and others.
2) Make it easy to report adverse reactions/interactions, such as a telephone hotline, one that involves no paperwork for the person reporting.[2]
3) Utilize a critical review process to distinguish between significant adverse reactions/interactions and minor ones.
4) Provide the information to manufacturers that will in turn provide the information to consumers via labeling.
5) Provide the information to healthcare providers so that they can: 1) assist their patients when labels state "seek advice from your doctor or pharmacist before using" and 2) eventually develop enough confidence in these products to recommend them.

The collection and distribution of adverse reaction/interaction information needs to be a priority so that people can safely reap the benefits of dietary supplements.

Sincerely,

Jodi A.Chaffin RPh
Herbal Resource Pharmacist for HealthPartners,
Chair of the Herbal Committee of MN Pharmacists Association.

[1] Ernst, E. Possible interactions between synthetic and herbal medicinal products. Part 1: a systematic review of the indirect evidence. Perfusion, 2000; Vol. 13 pp. 4-15.
[2] Vitillo, J. Adverse Drug Reaction Surveillance: Practical Methods for Developing a Successful Monitoring Program. Medscape Pharmacists, 2000.

Rick Kingston PharmD
University of Minnesota, College of Pharmacy
PROSAR International Poison Center
Statement to the Presidents Commission on Complementary and Alternative Medicine Policy

Dear members of the Commission. As a University of Minnesota professor in the College of Pharmacy serving as course director for one of the only CAM courses in the Academic Health Center that specifically focuses on the clinical application of herbal and other dietary supplements, I personally believe in the incredible potential of CAM practices as they pertain to improving and maintaining the health of Americans. Unfortunately, my views are not shared by many of my colleagues. CAM certainly includes a variety of approaches and practices, but often times the most visible link with patients and their healthcare provider regards patient use of commercially available Dietary Supplements, more broadly defined as Nutraceuticals. Although these substances are regulated by the FDA through DSHEA, Pharmacists and other mainstream medical practitioners continually cite inadequate regulation as a barrier to full acceptance.

In a study to assess the attitudes of pharmacists regarding dietary supplements, Mitzi Welna, a Colleague of mine in the College of Pharmacy randomly sampled practitioners throughout the State. Almost ninety six percent (95.9%) of the 533 survey respondents indicated that they felt "government oversight/regulation of herbal/natural products" is only "somewhat" or "less than adequate". It's apparent that GMP's which are in large part supported by Industry are on the way. What will remain an issue with many is how we can monitor both for the successful implementation of these GMPs as well as the overall patient experience regarding safety including interactions with pharmaceuticals and, adverse incidents.

Along with many of my colleagues and others interested in the safe and efficacious use of these valuable healthcare related products, I believe there are a few specific things that can be done to address this area.

1) The Commission needs to embrace strategies that encourage and support the development of product stewardship programs that address these concerns on the part of product manufacturers and/or their professional trade associations. Effective post market surveillance cannot be accomplished solely by regulatory bodies. It will only be accomplished with effective partnerships with responsible manufacturers. As regards dietary supplements the partnership is even more important as consumer routinely turns to the manufacturer as the product expert. Thus the manufacturer is in the best position to monitor the patient experience and share necessary information that they learn with regulators, the patient, and the practitioners that recommend/advise on product use. Changes in DSHEA which could require manufacturers to report adverse effects involving their products may be one way to move the process forward. Another option would be for the Commission to encourage conscientious manufacturers to implement voluntary systems of their own that collect, analyze and report information related to the patient experience. } yes!

2) The Commission should also support the development of multidisciplinary education programs that teach clinical application of dietary supplements in a broader sense across the multiple healthcare disciplines that typically recommend or advise on their use.

3) The Commission should also support the development of recognized certification programs by professional bodies that assess the competency of those professionals that request the public trust when recommending or advising on the use of these products for a variety of medical or health related needs.

Focus on responsibility of manufacturers
methods & systems in place to identify sentinel events

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COLLECTION:
Federal Records
White House Commission on Complementary and Alternative Medicine Policy [WHCCAMP]

OA/Box Number: 43231

FOLDER TITLE:
WHCCAM Town Hall Meeting Testimony, Minneapolis, Minnesota, March 16, 2001
[Folder 2] [2]

2011-0568-S
kc804

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
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b(6) Release would constitute a clearly unwarranted invasion of personal privacy [(b)(6) of the FOIA]
b(7) Release would disclose information compiled for law enforcement purposes [(b)(7) of the FOIA]
b(8) Release would disclose information concerning the regulation of financial institutions [(b)(8) of the FOIA]
b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

[005] 15

DIETARY SUPPLEMENTS – PANEL
JOHN MASTEL – RETAILER 33 YEARS
(b)(6)
ST. PAUL, MN 55105
(b)(6)

The AMA, FDA, and pharmaceutical companies seem to be involved in a silent conspiracy to prevent the average consumer from getting proper access to nutritional supplements and information regarding supplements' role in bettering our health. Though it may not be a full-fledged conspiracy, the results are certainly the same.

One example is the B vitamin, folic acid; until 1974, regulations for a non-prescription supplement only allowed one fourth of the daily adult requirement. Studies on folic acid showed a decrease in instances of spina bifida with increased consumption of folic acid. Folic acid has also been shown to help lower homocysteine levels. Excess levels of homocysteine have been implicated in heart, stroke and other diseases. However, we cannot make claims for folic acid's benefits as a supplement. Meanwhile, the food industry is now fortifying foods, for example white flour, with folic acid to prevent health problems. Similarly, scientific studies on food-source vitamin C show many health benefits yet we cannot claim these same benefits for vitamin C *supplements.* Also the critical mineral, iodine, is required in table salt but a large number of people no longer use it.

The AMA and the dairy industry are telling people to get their vitamin D from fortified milk rather than supplements. Regardless of the fact that a large percent of the population are lactose intolerant or have milk allergies.

Guidelines and laws seem to be made more to please the legal regulators and large industries than to benefit the average citizen. In fact the FDA, through their Federal Register, tried to make the law that any vitamin supplementation beyond the Recommended Daily Allowance could be dispensed only by prescription.

Medical doctors in the United States seldom recognize nutritional problems but our health system depends on them for it.

A research and regulatory body needs to be established to provide adequate and *unbiased* information on dietary supplements. The German Commision E Monograph is a fine example of what needs to be done in this country to create standards and guidelines for dietary supplements.

- toll-free # for consumers to call vs. ~~listing~~
  ~~&~~ labelling (too much to put on the bottle)

Send transcript
to FDA / Levitt
for comment

IOM also?
- provided definition
clarity of "self-medication"

IOM study funded
by CFSAN on select cast
of ass - still being ~~def~~ identified

update 3/20 Ken AND
Look at ~~testimo~~
transcript

CHPA
FOUNDED 1881

Producers of Quality Nonprescription Medicines and Dietary Supplements for Self-Care

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION®

Oral Testimony of the Consumer Healthcare Products Association to the White House Commission on Complementary and Alternative Medicine Policy

Minnesota Town Hall Meeting
Hubert H. Humphrey Institute
301 19th Avenue South
Minneapolis, MN
on
March 16, 2001

R. William Soller, Ph.D.
Senior Vice President and
Director of Science & Technology

The Consumer Healthcare Products Association is a 120-year-old trade organization representing the manufacturers and distributors of dietary supplements and nonprescription medicines. CHPA has over 200 members across the manufacturing, distribution, supply, research, and advertising sectors of the self care industry.

We have been intimately involved in the regulatory development of the industry, commenting and facilitating dialogue and activities relating to safety, labeling, quality and other matters affecting the production and distribution of dietary supplements. Just last week our Association adopted eight voluntary programs on dietary supplements relating to manufacturing, labeling, and formulation of safe and high quality products, adding to our programs already in place on St. John's wort, ephedra, and use of dietary supplements during pregnancy.

My remarks address two aspects of the questions that were set forth in the announcement of this meeting: (a.) health professional and consumer access to safe and effective dietary supplements[1]; and (b.) educational issues relating to complementary and alternative medical practitioner use of dietary supplements.[2]

First, on safe, effective, high quality dietary supplements, our call is to the White House Commission as well as health professionals to support the Congressional

[1] WHCCAMP Registration Form Question 2.a.: How can access to safe and effective CAM practices and interventions be improved?

[2] WHCCAMP Registration Form Question 3: Training, Education, Certification, Licensure, and Accountability of Health Care Practitioners in Complementary and Alternative Medicine.

appropriations process soon to be initiated by the Center for Food Safety and Applied Nutrition (CFSAN). Consumers, health professionals and industry need an FDA that is adequately funded to appropriately and reasonably implement the spirit and intent of the Dietary Supplement Health Education Act, or DSHEA. Along these lines, let me share the following points:

- FDA and the Federal Trade Commission have the tools they need to adequately regulate dietary supplements[3] [4].
- FDA has put in place the strategic management tools to justify allocations of increased funding [5], including the development of its long range plan and annual priorities through extensive stakeholder input, as well as use of a year-end report card process to define the extent it met its priorities that year.
- This Spring, FDA will provide Congress with two important fiscal reports – one pertaining to the how much it spent on dietary supplement regulation in 2000; another pertaining to the funding needed to implement its long-range strategic plan. This is the start of the appropriations process.

Our message is, the White House Commission should report to the new Administration the clear need to push for the level of appropriations necessary for CFSAN to fairly and reasonably implement DSHEA, thereby allowing FDA to use its existing substantial enforcement tools to regulate dietary supplements, in order to ensure safe, effective, high-quality dietary supplements for consumer and health professional use [6].

Further to this point, the Commission has an opportunity to support FDA in achieving its priority "A" list in its 2001 Annual Priorities[7] (Attachment A), including especially the publication of Good Manufacturing Practices, the finalization of which is necessary before FDA can have an effective field presence through an enforcement program. Additionally, FDA proposes to develop a master research plan for dietary supplements, and the White House Commission should recommend that this be developed with full stakeholder input, including that from CAM practitioners.

Other "A" priorities should be evaluated by the Commission as possible areas for additional recommendations. A member of the Commission should be tasked with this activity, and I have appended a copy of FDA's long-range strategic plan and 2001 annual priorities for this purpose (Attachment B).

---

[3] Soller, R.W.: Regulation in the Herb Market: The Myth of the Unregulated Industry. *Herbalgram* Feb.-Mar., 2000.

[4] FDA Commissioner Jane E. Henney, M.D. before the House Committee on Government Reform, March 25, 1999: "FDA has tools at its disposal to take enforcement actions against dietary supplements found to have safety, labeling, or other violations of the FD&C Act, as amended by DSHEA."

[5] Levitt, J.: Formal address to the CHPA Annual Meeting, *Nutritionals 2001*, Anaheim, CA, 1/31/01.

[6] Soller, R. W.: Will FDA Get the Funds to Effectively Regulate Dietary Supplements? *JANA* March, 2001.

[7] See Attachment B: Program Priorities in the Center for Food Safety and Applied Nutrition; Request for Comments [65 *Federal Register* 39415-39416 (6/26/2000)].

Second, with respect to the educational aspects of CAM practitioners and dietary supplements, we recommend a strategic perspective on the use of collaborative educational partnerships between the National Institutes of Health (i.e., National Center for Complementary and Alternative Medicine and Office of Dietary Supplements) and professional groups. For example, we are aware that the University of Minnesota and the American Nutraceutical Association are developing a collaborative approach to certifying licensed healthcare practitioners in dietary supplement use. Such certification brings quality to the informational aspects of product use, and special funding vehicles should be developed to encourage such upgrading of the knowledge base of health professionals.

Thank you.

Attachments A FY 2001 CFSAN Program Priorities: www.cfsan.fda.gov.
B Center for Food Safety and Applied Nutrition: Dietary Supplement Plan: Ten-Year Strategy, www.cfsan.fda.gov.

WS/jq:DietSup:WhitehouseCommissions/Minn Mtg Mar 2001 Testimony

A

FY 2001 CFSAN Program Priorities

Center for Food Safety and Applied Nutrition
Food and Drug Administration

January 2001

Excerpts from FY 2001 CFSAN Program Priorities
Pertaining to Dietary Supplements Only
Reproduced by CHPA 3/15/01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

JAN 9 2001

Dear Colleague, FDA Foods Community:

I am pleased to share with you the FY 2001 program priorities for FDA's Center for Food Safety and Applied Nutrition (CFSAN). This is the third consecutive year we have developed a program priorities document, incorporating input we received from many stakeholders. This workplan builds on the success we have had with the last two plans (see most recent "Report Card" dated December 5, 2000 on our website, www.cfsan.fda.gov). There are three points I would like to highlight:

1. The paramount theme for the FY 2001 workplan is program continuity. We will continue to place our highest emphasis on food safety, food additives, dietary supplements, and food biotechnology. This includes completing those goals from last year's plan that were not fully completed by the end of fiscal year 2000 (see Appendix B in the December 5, 2000 "Report Card").

2. You will see a substantial list of goals in the cross-cutting program section regarding our move to College Park. As you may know, CFSAN personnel and laboratories in the downtown D.C. area have the good fortune to be moving to a new facility in College Park, Maryland, starting in the fall of 2001. We have included this new section in the 2001 workplan to highlight that preparing for the move, in and of itself, is going to be a major effort this year, and needs to be factored into our overall productivity planning.

3. As in previous years, we will again provide a mid-year "progress report" later this spring. This will also provide an opportunity to make any needed adjustments in the workplan (additions or deletions) for the balance of the fiscal year.

In keeping with the format of the last two annual priorities documents, the workplan contains two lists of activities in most major sections -- the "A" List and the "B" List. In total, there are over 120 discrete "A" list activities. (This is an increase from 83 "A" List goals in 1999 and 108 "A" List goals in 2000.) Our goal will be to fully complete at least 90% of the "A" List activities by the end of the fiscal year, September 30, 2001. I frequently describe these as the "boulders" we will strive to move up and over the mountain top. Activities on the "B" Lists are those we plan to make progress on during the year, but may not complete. A new feature of the FY 2001 workplan is "B" list items with an asterisk. These are the highest priority "B" List activities, most of which are two-year projects that we are positioning to be on the "A" List next year.

The Center has responsibility for many important ongoing activities that are not identified in the workplan. For example, the Center's base programs in data collection, research and enforcement

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

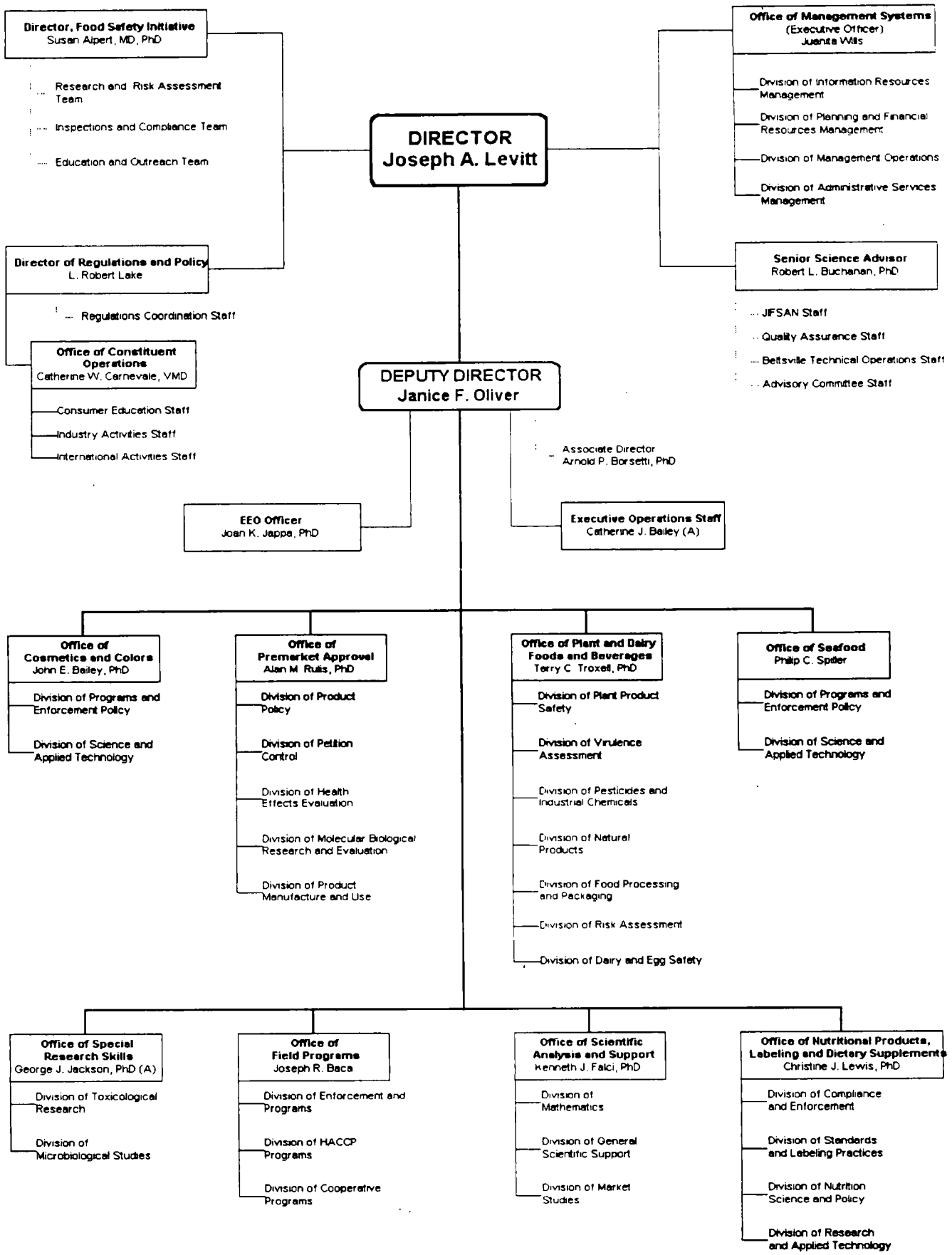

Table of Contents

Part II: Major Program Areas

Strategy 2.3
****
Dietary
Supplements

"A-List" Goals:

1. **Regulations/Guidance**

   (a) Publish dietary supplement GMP proposed rule and conduct outreach program.

   (b) Complete health claim evaluations for three diet/disease relationships begun in FY 2000: antioxidants and cancer; vitamin B and vascular disease; and vitamin E and heart disease.

   (c) Continue to review premarket (75-day) notifications for new dietary ingredients within the statutory timeframe.

2. **Enforcement/Outreach**

   (a) Continue to identify highest priority safety issues and initiate appropriate enforcement actions against unsafe, adulterated, or misbranded dietary supplement products and ingredients.

   (b) Establish a system for making adverse event reports (AERs) promptly available to manufacturers that includes the timely redaction of confidential information.

   (c) Establish strategy for dietary supplements that contain ephedrine alkaloids based on March 2000 release of AER's and related material and August 2000 public meeting/public comments.

   (d) Complete Dietary Supplement Labeling Guide.

3. **Research/Science Base**

   (a) Work with National Academy of Sciences' (NAS) Institute of Medicine (IOM) to review dietary supplement safety.

   (b) Develop mechanisms to expedite dietary supplement adverse event investigations and enhance timely clinical assessment of dietary supplement adverse event reports.

Strategy 2.3
****
Dietary Supplements
Contd.

"B" List

Regulations/Guidance (contd.)

(d) Develop final rule on 'per day' labeling for dietary supplements.

(e) Collaborate across Agency to complete guidance document on structure/function final rule. (CDER Lead)

(f) Collaborate across Agency to publish proposal for labeling dietary supplements for women who are or may become pregnant. (CDER Lead)

2. **Enforcement/Outreach**

(a) Continue to review the 30-day postmarket notifications for structure/function claims in a timely manner.

(b) Clarify policy and enforcement strategy for the definition of "represented as a conventional food" (e.g., beverages).

(c) Develop dietary supplement consumer information document on topic of product category boundaries.

(d) Enhance and improve the dietary supplement website and create a "list serve" for dietary supplement topics.

(e) Prepare regulatory guidebook for industry.

3. **Research/Science Base**

(a) In conjunction with NAS/IOM, investigate criteria and options for evaluating emerging science relative to dietary supplements.

(b) Develop analytical methods for conjugated linoleic acids (CLA).

(c) Implement a 'Dietary Supplement Analytical Methods Working Group' for safety issues.

B

U. S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
January 2000

Dietary Supplement Strategy

(Ten Year Plan)

Letter | Outline | The Plan

Letter from the Director

Dear Colleague, FDA's Food Community:

This document sets forth the Center for Food Safety and Applied Nutrition's (CFSAN's) overall dietary supplement strategy. In January, 1999, CFSAN issued its 1999 workplan. In that workplan, the Center announced that in calendar year 1999, it would "in conjunction with other involved Agency units, and providing an opportunity for stakeholder input, develop an overall strategy for achieving effective regulation of dietary supplements under the Dietary Supplement Health and Education Act of 1994." I am pleased to report that this document sets forth that strategy. There are five points I would like to highlight:

1. FDA held public meetings on June 8, 1999 in Washington, D.C. (East Coast) and on July 20, 1999, in Oakland, California (West Coast) to solicit comments on the development of its overall dietary supplement strategy. In addition, throughout the 1999 calendar year, FDA held several other public meetings on other dietary supplement issues that are part of this strategy (e.g., structure/function claims and current good manufacturing practices). All of these public meetings built upon themes that emerged from a broader stakeholder meeting sponsored by CFSAN in June, 1998.

2. Shortly after the June 8, 1999, public meeting, FDA developed five internal dietary supplement strategy teams to consider the ongoing stakeholder input, and to discuss the dietary supplement activities. The team members were drawn from several Agency units. The teams were organized as follows: Safety, Labeling, Boundaries, Enforcement, and Research. Except for the addition of a section on Outreach, and the broadening of the Research category to Science Base, these categories formed the organizational structure of this strategy.

3. This strategy is built on the "twin pillars" of law and science. Therefore, the strategy establishes a clear program goal to accomplish, by the year 2010, having a science-based regulatory program that fully implements the Dietary Supplement Health and Education Act of 1994, thereby providing consumers with a high level of confidence in the safety, composition, and labeling of dietary supplement products.

4. As with other new legislative mandates, there needs to be a long-term implementation process

to accomplish all of the dietary supplement activities the Agency and/or its stakeholders identified. Therefore, the Agency developed a strategy that sets forth a ten-year implementation plan. This strategy can be accelerated or decelerated, depending on resource availability and safety concerns. FDA will continue to seek additional resources for initiatives identified in this plan through the established budget process. The items in this strategy are not listed in priority order. Instead, FDA will develop, on an annual basis, specific items that are to be accomplished that year within the level of available resources.

5. FDA recognizes that the success of this strategy will not only depend on adequate funding levels, but also on FDA's new and continued partnerships with other governmental agencies, academia, health professionals, industry, and consumers. FDA will continue its outreach to stakeholders to enhance two-way dialogue, establish stronger working relationships, leverage resources, and communicate dietary supplement information.

I am pleased that I had the opportunity to personally chair the June 8 and July 20 public meetings. If you had the opportunity to attend either meeting, I'm sure that you'll agree that one theme prevails, and that is we all want to do what's best for the American consumer. I truly believe that this strategy reflects that goal. With the consumer's interest at the forefront, I look forward to working with you during its implementation.

Sincerely yours,

Joseph A. Levitt
Director
Center for Food Safety and Applied Nutrition

Outline

Overall Ten-Year Goal

I. Safety
   - A. Adverse Event Reporting
   - B. Good Manufacturing Practices
   - C. Health Hazard Evaluation
   - D. Dietary Supplement Safety Database
   - E. New Dietary Ingredients
   - F. Voluntary Submissions
   - G. Internet Surveillance

II. Labeling
   - A. Pearson v. Shalala
   - B. Health Claim Petitions
   - C. Database
   - D. Substantiation
   - E. Authoritative Statements
   - F. Consumer and Marketplace Labeling Surveys
   - G. Publications
   - H. Small Business Exemption

III. Boundaries
- A. Structure/Function Claims
- B. Dietary Supplement vs. Drug
- C. Dietary Supplement vs. Conventional Food
- D. Botanicals
- E. Dietary Supplement Exclusions
- F. Dual Status
- G. Combination Products
- H. Dietary Supplement vs. Cosmetic

IV. Enforcement Activities
- A. Enforcement Strategy
- B. Capacity Building
- C. Federal Trade Commission Coordination

V. Science-Base
- A. Strengthen Science-Base
- B. Strengthen Research Efforts
- C. Regulatory Oversight of Human Studies
- D. Adverse Event Report Monitoring System
- E. Claims
- F. Inter-agency Clearinghouse

VI. Outreach
- A. Advisory Committee
- B. Additional Stakeholder Outreach
- C. Communication

Ten Year Plan

PROGRAM GOAL. By the year 2010, have a science-based regulatory program that fully implements the Dietary Supplement Health and Education Act of 1994, thereby providing consumers with a high level of confidence in the safety, composition, and labeling of dietary supplement products.

I. SAFETY

A. Adverse Event Reporting.

1. **Systems Enhancement.** Improve adverse event report monitoring system capability by enhancing the data systems and integrating them into the Agency-wide adverse event report monitoring system program.

2. **Timely Release of Reports.** Eliminate freedom of information act backlog and make reports available promptly to manufacturers on an ongoing basis.

3. **Clinical Evaluation and Follow-Up.** Institute an efficient system for the monitoring, clinical evaluation, and timely regulatory follow-up of significant adverse event reports.

4. **Outreach.** Educate consumers and health care professionals on how to use the adverse event reporting system.

B. **Good Manufacturing Practices.** Publish regulations on good manufacturing practices. Once the regulations are issued, establish an outreach program to small business manufacturers and an ongoing inspection program.

C. **Health Hazard Evaluations.** Enhance mechanisms for evaluating health hazards of dietary supplement ingredients and contaminants.

D. **Dietary Supplement Safety Database.** Explore development of a database to help anticipate health hazards.

E. **New Dietary Ingredients.**

1. **Notifications.** Continue to review premarket (75-day) notifications for new dietary ingredients within the statutory timeframe.

2. **Guidance.** Develop guidance for safety substantiation for premarket (75-day) notifications for new dietary ingredients.

3. **Database.** Incorporate the premarket (75-day) notifications in the comprehensive database created for claims notifications (see strategy item in II. C.).

F. **Voluntary Submissions.** Explore mechanisms for encouraging voluntary submissions of confidential premarket safety data to FDA (e.g., similar to procedural mechanisms for food additive master files).

G. **Internet Surveillance.** Implement an Internet surveillance program to monitor whether products are marketed for safe uses.

II. LABELING

A. **Pearson v. Shalala.** Implement court decision as outlined in December 1, 1999, strategy notice.

B. **Health Claim Petitions.** Meet statutory obligations by responding to health claim petitions within statutory timeframes.

C. **Database.** Complete and activate database for 30-day label claim notifications and courtesy letters.

D. **Substantiation.** Identify criteria for substantiation of structure/function and related claims and identify conditions for sharing substantiation documents.

E. **Authoritative Statements.** Publish final rule on the applicability to dietary supplements of the FDA Modernization Act provisions on nutrient content/health claim notifications based on authoritative statements.

F. **Consumer and Marketplace Labeling Surveys.** Perform surveys and track data of consumer purchases and marketing trends to support sound labeling policies.

G. **Publications.** Resolve issues on use of third-party publications.

H. **Small Business Exemption.** Resolve small business exemption issues for dietary ingredient claims.

III. BOUNDARIES

A. **Structure/Function Claims.**

1. **Final Rule.** Publish a final rule on structure/function claims.

2. **Small Business Regulatory Enforcement and Flexibility Act (SBREFA) Guidance.** Following publication of final rule, issue SBREFA guidance.

3. **Claims Review.** Review 30-day postmarket notifications for supplement claims.

B. **Dietary Supplement vs. Drug.**

1. **Definitions.** Clarify the boundaries between dietary supplements and drugs by defining key terms and phrases (e.g., "dietary substance" and "intended to supplement the diet").

2. **Claims.** Clarify when a disease-related statement is an appropriate health claim for a dietary supplement, and when a disease claim is necessarily a drug claim.

C. **Dietary Supplement vs. Conventional Food.**

1. **Definitions.** Clarify boundaries between dietary supplements and foods by defining key terms and phrases (e.g., "intended for ingestion" and "represented for use as a conventional food") and clarifying the forms of dietary supplements.

2. **Stakeholder Discussions.** Coordinate and review stakeholder discussions addressing structure/function claims issues on conventional foods that may impact dietary supplement boundary issues (e.g., nutritive value).

D. **Botanicals.** Develop a regulatory framework for botanicals used in traditional/alternative medicine (including how they relate to over-the-counter drugs).

E. **Dietary Supplement Exclusions.** Clarify statutory provisions that exclude selling a

product as a dietary supplement if the substance was first approved as a new drug under a New Drug Application or studied as an Investigational New Drug.

F. **Dual Status.** Clarify the regulation of dual status products (i.e., one substance intended for use as a supplement and a drug).

G. **Combination Products.** Clarify regulation of combination products (i.e., a supplement and a drug combined in a single dose, unit, or package).

H. **Dietary Supplement vs. Cosmetic.** Develop criteria for defining boundaries between products intended for cosmetic effect from dietary supplements.

IV. ENFORCEMENT ACTIVITIES

In cooperation with the Office of Regulatory Affairs, and assisted, where appropriate, by other agency components:

A. **Enforcement Strategy.**

1. **Safety Issues.** Identify the highest priority safety issues and take appropriate action against unsafe products.

2. **Boundary Issues.** Take appropriate action on products excluded from being marketed as dietary supplements.

3. **Labeling and Consumer Fraud.** Take appropriate action on inaccurate and misleading labeling and consumer fraud, including trade complaints.

4. **Routine Compliance.** Maintain routine compliance activities, incorporating enforcement of final rules.

5. **Surveillance and Monitoring.** Conduct marketplace surveillance and monitoring activities.

6. **Partnerships.** Establish partnerships with federal, state and local agencies to enhance enforcement efforts by sharing data, heightening communication, and utilizing resources.

B. **Capacity Building.** Make necessary internal enhancements to effectively fulfill enforcement obligations.

1. **Agency's Compliance Procedures.** Develop standard operating procedures for improving the compliance review process.

2. **Case Tracking System.** Contract for and activate computerized dietary supplement case tracking system.

3. **Training.** Provide in-house training to field and headquarters staff to ensure

consistency with current FDA regulatory procedures and practices.

4. **CFSAN/CDER Coordination.** Evaluate, and streamline, to the extent possible, current mechanisms for resolution of cross-center compliance issues.

5. **Laboratory Capacity.** Enhance analytical lab support for regulatory decisions.

C. **Federal Trade Commission (FTC) Coordination.** Enhance coordination with FTC on enforcement cases.

V. SCIENCE-BASE

In collaboration with stakeholders (e.g., academia, health professionals, other organizations, and industry), enhance research/science capabilities, including:

A. **Strengthen Science-Base.** Ensure a sound science-based program for all dietary supplement review and develop a core of well-trained, multidisciplinary scientists in support of supplement review and research.

B. **Strengthen Research Efforts.**

1. **Research Agenda.** With the assistance of a nationally recognized organization, develop a broad research agenda and needs assessment framework to implement priority-based research for dietary supplement issues.

2. **Research Capabilities.**

a. **Inventory and Peer-Review Process.** Identify the Agency's scientific research capabilities relative to dietary supplements, and develop a mechanism for ensuring dietary supplement research is mission-relevant, of high scientific quality, and consistent with regulatory priorities.

b. **Intramural/Extramural Research.** Determine what research can or should be done by FDA (in-house) and what research should be done by extramural sources.

c. **Laboratory Based Research.** Conduct priority- based methods development and safety research for dietary supplement ingredients and contaminants.

3. **Dietary Supplement Ingredient Reviews.** Identify mechanisms for obtaining state-of-the-art science reviews on dietary ingredients in the marketplace, giving highest priority to those with potential health risks.

4. **Leveraging.** Identify leveraging opportunities with universities, JIFSAN, and other government agencies.

5. **Consumer Research.** Conduct research on consumer understanding of label

information, and compare consumer understanding of labeling of conventional foods and dietary supplements for support of regulatory decisions.

6. **Marketplace Research.**

   a. **Economics and Marketplace Research.** Perform necessary economics and marketplace research for support of regulatory decisions.

   b. **Market Analysis.** Explore innovative mechanisms to determine the nature and scope of the dietary supplement market.

C. **Regulatory Oversight of Human Studies.**

1. **Oversight Mechanism.** Clarify when an Investigational New Drug filing is necessary for a substance marketed as a dietary supplement and determine whether a separate mechanism needs to be developed for clinical studies on supplements.

2. **Science-Based Standards.** Develop science-based standards for conducting human studies of dietary supplements using human subjects.

D. **Adverse Event Report Monitoring System.** Conduct research to support enhancing and improving the quality and reporting rate of the adverse event report monitoring system and consider how the adverse event report monitoring system can be used for trend identification of adverse events.

E. **Claims.** Evaluate systems used in other organizations (e.g., health care reimbursement) to distinguish "valid substantiation" for claims (structure/function) from "invalid substantiation" for such claims.

F. **Inter-agency Clearinghouse.** Explore the establishment of an inter-agency dietary supplement research clearinghouse and develop an integrated list of information to be included.

VI. OUTREACH

Enhance outreach efforts to stakeholders to assure effective communication, including:

A. **Advisory Committee.** Establish a standing group to provide a routine public forum to obtain and integrate stakeholder input related to various dietary supplement issues. The group will be comprised of members having expertise relevant to the review of dietary supplement issues (e.g., subcommittee of the Food Advisory Committee).

B. **Additional Stakeholder Outreach.**

1. **Public Forums.** Sponsor and participate in public forums for enhancing dialogue with stakeholders.

2. **Partnerships.** Establish a stronger working relationship with organizations interested in promoting two-way communication and cooperation.

C. **Communication.**

1. **Mechanisms.** Develop mechanisms to communicate dietary supplement information to the general public, FDA field offices, health care professionals, and industry, including:

   a. **Website.** Expand use of FDA website to communicate dietary supplement information to the general public and health care professionals, and guidance to the industry.

   b. **Information Kits.** Develop information kits for FDA field staff.

2. **Information Dissemination.** Communicate dietary supplement information to the general public, FDA field offices, health care professionals, and industry, including:

   a. **Safety Data.**

   b. **Enforcement Policies and Procedures.**

This document was issued in January 2000.
For more recent information on Dietary Supplements
See http://www.cfsan.fda.gov/~dms/supplmnt.html

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To : White House Commission on Complementary and Alternative Medicine March 16, 2001

My name is Margery Wells. I am here representing the American Association of Oriental Medicine, (AAOM), the largest and oldest national association of oriental medicine professionals. I am licensed by the Minnesota Board of Medical Practice and a Diplomate of Traditional Oriental Medicine by the National Certification Commission of Acupuncture and Oriental Medicine. I have been practicing and integrating medicine since 1982.

In our paper, "Integrative Medicine: Merging Traditional Oriental and Western Medical Practices", Dr Gonzalez-Campoy, M.D., Ph.D. and I define oriental medicine , compare it to western medical practices, and address the potential for creating collaborative research and clinical work.

Traditional Oriental Medicine (TOM) is a system much different than Western Medical (WM) practice, with its own views of pathogenesis, its own methods of diagnosis, and its own methods of treatment. There are numerous modalities of treatment within this system as a whole, which in general, are meant to be used together to provide the best possible benefit to the patient.

Just as individuals have the right to responsibly choose how they care for themselves and the right to choose their health care practitioners, people also have the right to expect that the licensed acupuncturist they select is fully trained in TOM. Nationally, graduates from colleges of TOM, have on average, between 2700 and 3300 classroom and clinical hours over a two to three year period. These hours are over and above the health science prerequisites of a two to four year undergraduate degree. Then the focus of training is on pathogenesis, methods of diagnosis , and methods of treatment in TOM, which includes acupuncture, herbal pharmacopoeia, nutritional therapies, and various exercise recommendations. The health care consumer has the right to know if a practitioner has abbreviated or partial system training of anything less than the above mentioned educational hours. And since there are new immigrants who wish to practice acupuncture, people also have the right to expect that their licensed practitioners speak fluent and articulate English, and that they are capable of communicating with patients and their physicians. It is the recommendation of the AAOM and myself that only those with full TOM training be allowed to advertise and practice the treatment modalities of TOM.

Also, utilizing any of the TOM modalities without proper TOM diagnosis training, as in a "cookbook" approach has resulted in a great deal of variability in the type and quality of care among current practitioners. For the future development of our profession, for the benefit of our patients, and for the opportunities to collaborate on research projects with the WM community, which ultimately benefits all, I respectfully submit these recommendations.

March 12, 2001

To: White House Commission on Alternative and Complementary Medicine

The Minnesota Homeopathic Association was founded as a state-wide professional organization for homeopathic practitioners with the following mission:

to promote homeopathy as a safe and effective health care choice for Minnesotans;
to protect the public interest by upholding high standards of care by its member practitioners;
to serve and support the community of Minnesota's professional homeopaths.

We would like to share with you our dedication to the idea that health care consumers should have access to the modalities they feel are most appropriate to their individual needs. While government should protect citizens from harm, we believe it is also the government's important role to protect the citizen's right to individual choice and autonomy as regards the way in which they decide to protect and enhance their own health and well-being.

We enthusiastically support the Minnesota Model as it has supported maximum access by health care consumers to the many modalities and types of healers available while at the same time protecting the individual through a Health Department consumer hot-line for complaints and the enforcement of 24 paragraphs of practitioner prohibited conduct.

We believe that the Minnesota Model was carefully crafted after much thought and deliberation as well as the legislative give-and-take of all interested parties. We want you to know that the Minnesota Complementary and Alternative Health Care Freedom of Access Act has the full support and confidence of our professional organization. In sum, the Minnesota Model provides the opportunity for the citizens of Minnesota to maintain their health and well-being across a broad spectrum of choices while at the same time protecting Minnesota health care consumers from harm.

Best regards.

Valerie Ohanian, R.S. Hom., C.C. Hom.
President

Written Statement: Education of CAM Providers Panel Discussion

Jackson Petersburg, CenterPoint Co-Director
Formerly Northern Lights School of Massage Therapy and the Minnesota Center for Shiatsu Study

"The Evolution of Massage Therapy Education in the United States"

Let me begin by saying what a privilege it is for me to be participating in a process that I am convinced will impact on the very nature of the health care delivery system in this country. I would especially like to thank Mary Jo Kreitzer and the Center for Spirituality and Healing for organizing this event and allowing me the time to share my thoughts concerning the education of complementary and alternative health care providers.

I originally intended to start by giving a brief history of my own profession, citing some of the major factors that may have influenced how massage therapists were and are educated in this country. Unfortunately, that took up all of my allotted time. I will instead give you a very condensed version of the salient points of this history. In a nutshell, war, drugs, sex and a defining moment in time.

After WWII, the development of analgesic drugs started to replace manual methods of pain control. There also seemed to be a proliferation of massage parlor activity, which slowly eroded the reputation of legitimate therapists. This tainted reputation lasted well into the end of the twentieth century and heavily influenced the development of municipal massage parlor ordinances, that are still in effect in many cities and towns across the country that do not have some form of statewide regulation that supersedes municipal jurisdiction. In fact, the city of Minneapolis still has such an antiquated ordinance. If it were strictly enforced, most self-employed massage therapists would be required to work in a five square block, red

light section of downtown. To my knowledge, we are the only emerging health care profession regulated by municipal law.

In addition to drugs and sex, the other primary factor that influenced massage therapy education after WWII, was the conscious decision by massage therapy organizations not to align themselves too closely with the conventional medical model. In hindsight, this proved to be a defining moment for the profession. I think that it severely slowed down the development of educational standards for the profession, while at the same time, allowing the profession to develop in a much more organic way. It moved out of the medical model of the first half of the century, to the experiential model of the 1970's. This model was tremendous for fostering experimentation, and disastrous for establishing well defined professional boundaries and a strict ethical code of conduct. Eventually, this dichotomy created dissonance in the souls of the new wave of massage therapy educators. The most balanced of these educators managed to create a system that established boundaries and ethics, while at the same time, retaining this experimental energy and heart.

In my experience, I don't think that this history is decidedly different than many of the other complementary and alternative health care professions. In my opinion, the development of educational standards goes hand in hand with the development of other nationally recognized standards or benchmarks, that assist the consuming public in defining a professional. My professional association, the American Massage Therapy Association (AMTA), and more specifically, the AMTA Council of Schools, planted the seeds to create the National Certification Board for Therapeutic Massage & Bodywork (NCBTMB) and the Commission on Massage

Therapy Accreditation (COMTA). COMTA was then and still is primarily comprised of professionals in the field who volunteer their time and energy to create a realistic, programmatically-based, accreditation model. These oversight agencies may not be perfect, but their mission is driven by people currently working in the field. This is critical!

Finally, what national trends do I see in massage therapy education that may also apply to other CAM professions? The first trend that is especially evident across the country is that cutting edge education will never be contained by either state or municipal laws. This is evidenced by the fact that training institutions across the country are developing degree granting programs (AA, BS, MS, Ph.D.), that far exceed the requirements of existing laws. Another trend that is closely related to this is that freestanding training programs are establishing some form of articulation agreement with colleges and universities to streamline this process and also allow them to participate in research that otherwise would too complicated and costly for them to do on their own. A third trend is the rapid growth of programs across the country being developed by trade and technical schools who are scrambling to create curriculum and find qualified faculty to teach their program.

In conclusion, there will always be individuals and institutions that are pushing the envelope in educational standards and experimentation and there will always be individuals and groups that will resist these changes. The key is to not become complacent. Or as my father used to say, "If you can keep your head in all this confusion, then you don't understand the situation." Thank you.

Professional Biography

Jackson Petersburg founded and directed Northern Lights School of Massage Therapy from 1985-2000. This year, Northern Lights School combined with the Minnesota Center for Shiatsu Study to become CenterPoint. CenterPoint offers training programs in both massage therapy and Shiatsu therapy, Advanced Certification programs and a public clinic. Jackson received his training in massage therapy from the Boulder School of Massage Therapy. He has a Bachelors Degree in Recreation Education, from the State University of New York, College at Cortland. Jackson has served on the National Board of the American Massage Therapy Association (AMTA), the Executive Committee of the AMTA Council of Schools and as President of the Minnesota Chapter of the AMTA. He has been in private practice since 1979, focusing primarily on soft tissue injuries and conditions. Jackson has presented workshops throughout the U.S. for the past fifteen years.

White House Commission
On Complementary and Alternative Medicine Policy
Hubert H. Humphrey Institute, Cowles Auditorium
Minneapolis, Minnesota
March 16, 2001

Education of CAM Providers Panel

Barbara York

President, MTMN—Minnesota Touch Movement Network

Board Member, MN Natural Health Legal Reform Project

Chair, IMA Network of Minnesota

Jin Shin Jyutsu® Practitioner

Massage Practitioner

Member NCBTMB

Member UMC

I believe that the best practitioners of complementary and alternative medicine are those who realize that this work is best met with experience, personal study and the time to know their client. Because of the variety of practices, I do not believe that uniform standards can be applied in this field. It has been said that you cannot put your foot into the same river twice. By the same token, every session with a client is a new experience for both parties no matter how exacting the technique may be.

Though I personally chose to pursue a thousand hour accreditation course and passed the national certification exam for massage therapists, I still believe the best lessons come in hands-on experience, whether as an apprentice or a seasoned practitioner of 18 to 30 years. Essentially learning is never finished, regardless of certificates and testings. The true lesson is with the client. Without respect for that, any education is worthless.

As a Jin Shin Jyutsu® practitioner, I participate in an ancient art that was passed down from generation to generation by word of mouth. Jin Shin Jyutsu is a Japanese phrase which means the "art of the Creator through compassionate man". The study of Jin Shin Jyutsu is a way to expand awareness and understanding. The practice is considered a demonstration of the art. The responsibility for usage of knowledge received, is within each practitioner. I believe each person in this room is equally wonderful at Jin Shin Jyutsu, the only difference between us is in awareness. The Art of Jin Shin Jyutsu is a simple and powerful tool, equally available to all.

In similar fashion, I have a book called Primitive Remedies which was collected by John Wesley the founder of the Methodist church. It was a record of

parishioners remedies which he collected and shared as he traveled his church circuit. He did not present himself as a trained healer. Many of these remedies are practical and based on principles recognized by contemporary healers.

I would like to quote from the introduction to Primitive Remedies— "Wesley's concern was for the common people and it was his purpose to give them 'a plain and easy way of curing most diseases'; 'to set down cheap, safe, and easy medicines; easy to be known, easy to be procured, and easy to be applied by plain, unlettered men.'

The field of Complementary and Alternative Medicine remains this simple. It is safe, it is accessible to the consumer. It is uncomplicated, despite the sometimes confusing emphasis on technique. The Minnesota Complementary and Alternative Health Care Freedom of Access Act of 2000 provides a legal environment in which practitioners of alternative health can practice regardless of their education and training as long as they practice within reasonable conduct guidelines. ??

I encourage the commission to consider this simple, profound approach of honoring both the consumer and the practitioner.

Respectfully,
Barbara York

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Further Points:

• Safe and easy remedies become packaged and sold as privately held techniques.

One of the simple and common ideas of John Wesley's, is recommended in his "Plain Easy Rules" "(9) The flesh brush is a most useful exercise, especially to strengthen any part that is weak." [1], which now in our time is rediscovered and trademarked as a technique called "Vital Chi Skin-Brushing System™" which is being sold by a Bruce Berkowsky, N.M.D. [2]

• Even children are capable of providing CAM.

The founder of shiatsu, Tokujir Namikoshi, who recently died at the age of 94, developed his approach starting at seven years of age massaging his own mother

who suffered from rheumatoid arthritis. [6]

•Educational standards can become an obstruction for the consumer to find their appropriate provider.

Jin Shin Jyutsu® is considered modality training. Many CAM providers take specialized, extensive and expensive training in fields such as; Ortho-Bionomy™, the Rosen Method of Bodywork and Movement™, Reflexology, and NeuroMuscular Therapy. [5] Dawn Nelson, though a nurse, found her most profound connection and effectiveness with patients was in simple holding. [3] Many providers have created simple ways of being with people. They have found that the CAM client is a very subjective healing relationship. It is not based on outcome but support and understanding of the patients belief system. Though many long time providers are also teachers, they would not qualify for many regulation requirements. [4]

•Lack of harm in CAM providers.

With the number of practitioners, modalities and contact hours incidents of harm would be headlines. Yet professional liability insurance providers know that the true issues of concerns are standard "trip and fall" hazards. One company allows membership with full benefits based upon experience. [7]

•Delayed care concerns

John Wesley [1] recommended "In uncommon or persistent cases, he advised 'every man without delay to apply to a Physician that fears God.' " Many consumers come to CAM providers **after** they have exhausted traditional medicine or while they **wait** to see their primary care provider or specialist who may not be able to see them for weeks.

RESOURCES:

1—Primitive Remedies, John Wesley, Woodbridge Press Publishing Company, Santa Barbara, California, 1973.

2—Massage & Bodywork, Associated Bodywork & Massage Professionals, Inc., Evergreen, CO, Vol.#XV, Issue #5, October/November 2000, pg.13-20.

3—Compassionate Touch, Dawn Nelson. Station Hill Press, Inc., Barrytown, NY, 1984

4—Healers On Healing, Richard Carlson and Benjamin Shield, Jeremy P. Tharcher, Inc., Los Angeles, CA, 1989.

5— The Encyclopedia Of Bodywork, Elaine Stillerman, Facts On File, Inc., NY, NY, 1996.

6— Massage Magazine, Massage Magazine Inc.,Spokane, WA, Issue 90, March/April, 2001, pg. 31

7—The IMA—International Massage Association, P.O. Drawer 421, Warrenton, VA 20188-0421• (540) 351-0800 • Info@IMAGroup.com • www.imagroup.com/

MTMN—Minnesota Touch Movement Network

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www.geocities.com/mtmn4u/

The Minnesota Touch-Movement Network is a professional, state-wide, non-profit, inclusive organization of complimentary and alternative health care providers; including massage therapists, touch therapists, somatic educators, energy therapists, body workers and healing artists. The MTMN was founded in 1981.

The purpose of the MTMN is to support and protect the practice of massage and touch movement therapy.

The MTMN is a grassroots organization. The focus of networking, or exchange of information is vital to its existence. The MTMN places members' ethics above the amount or style of training. Because the MTMN is a statewide organization, it has more flexibility than groups which are national in scope to adapt to the individual needs of its membership.

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Mary Burmeister, President, Jin Shin Jyutsu, Inc.

David Burmeister, Director, Jin Shin Jyutsu, Inc.

OUR MISSION STATEMENT

Through the dynamic Art of Jin Shin Jyutsu (Physio-Philosophy), our mission IS to create a safe environment for reawakening the true SELF. Being the testimony of this simple, profound Art of Living, made known to us by Mary Burmeister and Jiro Murai, we educate, harmonize and inspire ourselves and others through integrity, compassion, trust and freedom to BE...NOW KNOW MYSELF.

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INTRODUCING JIN SHIN JYUTSU®
PHYSIO-PHILOSOPHY·

JIN SHIN JYUTSU literally translated is:

JYUTSU - Art
SHIN - Creator
JIN - Man of Knowing and Compassion

(Art of the Creator through man of knowing and compassion)

JIN SHIN JYUTSU is the art of releasing tensions which are the causes for various symptoms in the body. Our bodies contain several energy pathways that feed life into all of our cells. When one or more of these paths become blocked, this damming effect may lead to discomfort or even pain. This blockage or stagnation will not only disrupt the local area but will continue and eventually disharmonize the complete path or paths of the energy flow.

Through JIN SHIN JYUTSU our awareness is awakened to the simple fact that we are endowed with the ability to harmonize and balance ourselves (in rhythm with the universe) physically, mentally and spiritually.

JIN SHIN JYUTSU is an art as opposed to a technique because a technique is a mechanical application, whereas an art is a skillful creation. This beautiful, simple Art is our inheritance. According to ancient written records, which remain in the Archives of the Imperial Palace in Japan, JIN SHIN JYUTSU was widely known before the birth of Gautama (Buddha, India), before the birth of Moses (recorded in the Bible), and before the Kojiki (Record of Ancient Things - Japan, A.D. 712). JIN SHIN JYUTSU is an innate part of man's wisdom - simplifying the complexities of existence - and is truly an ART OF LIVING.

JIN SHIN JYUTSU was rediscovered by Master Jiro Murai early in this century. His student, Mary Burmeister, brought the Art from Japan to America in the 1950's. Classes in JIN SHIN JYUTSU are currently offered by Mary's associate instructors, Muriel Carlton, Philomena Dooley, Wayne Hackett, Susan Brooks (on sabbatical), Lynne Pflueger, Waltraud Riegger-Krause, Matthias Roth Jed Schwartz, Ian Kraut, and Birgitta Meinhardt.

Jin Shin Jyutsu® physio-philosophy is an ancient art of harmonizing the life energy in the body. Born of innate wisdom and passed down from generation to generation by word of mouth, the Art had fallen into relative obscurity when it was dramatically revived in the early 1900's by Master Jiro Murai in Japan.

After clearing himself of life-threatening illness, Master Murai devoted the rest of his life to the research and development of Jin Shin Jyutsu, gathering insight from a range of experiences and resources, including the Kojiki (Record of Ancient Things). The resulting knowledge of Jin Shin Jyutsu was then given to Mary Burmeister, who brought it to the United States in the 1950's.

Mary Burmeister began teaching the Art to others in the early 1960's, and today there are thousands of students throughout the United States and around the world.

Jin Shin Jyutsu brings balance to the body's energies, which promotes optimal health and well-being, and facilitates our own profound healing capacity. It is a valuable complement to conventional healing methods, inducing relaxation and reducing the effects of stress.

Jin Shin Jyutsu employs twenty-six "safety energy locks" along energy pathways that feed life into our bodies. When one or more of the paths becomes blocked, the resulting stagnation can disrupt the local area and eventually disharmonize the complete path of energy flow. Holding these energy locks in combination can bring balance to mind, body, and spirit.

Learning Jin Shin Jyutsu engages one in self study, self help. Through the process of "now know myself" we recognize the wisdom of the body, and we learn to interpret the messages provided and utilize them to restore balance.

Jin Shin Jyutsu can be applied as self-help and also by a trained practitioner. A Jin Shin Jyutsu session generally lasts about an hour. It does not involve massage, manipulation of muscles, or use of drugs or substances. It is a gentle art, practiced by placing the fingertips (over clothing) on designated safety energy locks, to harmonize and restore the energy flow. This facilitates the reduction of tension and stress which accumulate through normal daily living.

For those of us addressing existing stress or health disharmonies, or for those simply wishing to participate actively in maintaining health, harmony and well-being, the Art of Jin Shin Jyutsu is a simple and powerful tool, available to all!

Mary Burmeister,
by Melissa Higgins
Article published in the March/April 1988 issue of Yoga Journal
(Slightly revised to reflect today's teaching staff)

The tiny, energetic woman placed one of my hands in hers, grasping my forefinger firmly but not tightly. Her eyes sparkled as she looked into mine and said, "See? Isn't that simple?" Miraculously, the tension of months of work disappeared. It was Jin Shin Jyutsu in action, she explained.

Categorizing Jin Shin Jyutsu can be as difficult as pigeonholing its one-woman leading force, Mary Burmeister. More than a style of bodywork, it's a philosophy of life taught by a master who lives her philosophy.

Burmeister describes Jin Shin Jyutsu (which means "art of the Creator through compassionate man" in Japanese) as a "physio-philosophy" that is used by everyone unconsciously, doesn't "do" anything, yet encompasses everything. "I call it the art of life, the art of life itself. It is the whole cosmos and cannot be categorized," Burmeister explains.

The purpose of Jin Shin Jyutsu is to release the tensions that cause various physical symptoms. The body, Burmeister teaches, contains energy pathways that feed life into all cells. When one or more of these paths become blocked, the damming effect can lead to discomfort or pain. Jin Shin Jyutsu, like acupuncture and acupressure, reharmonizes and balances the energy flows.

Recently I participated in Burmeister's five-day Jin Shin Jyutsu course to learn more about this little-known "art" from the Orient. Although she has a large and loyal following, Burmeister keeps a low public profile and, until now, has never allowed an interview.

Based on ancient knowledge of the body and creation, Jin Shin Jyutsu was passed down orally from one generation to the next and had virtually disappeared in Japan when it was rediscovered in the early 1900s by Jiro Murai, a Japanese philosopher. As a young man, Murai contracted what was diagnosed as a terminal illness. He asked his family to take him to the mountains and leave him in solitude for seven days.

In a feverish state, Murai imagined sages in spiritual meditation using hand mudras, which he applied to himself as he went in and out of consciousness. By the seventh day he was completely healed, and he vowed to spend the rest of his life studying the connection between his amazing recovery and the mudras he had used.

Searching for answers, Murai studied the Bible (which he translated himself) and ancient Chinese, Greek, and Indian texts. But it was the Kojiki, the Japanese "Record of Ancient Things," that opened the door for him.

"He unraveled the mystery of a plain, old story, the Kojiki, which describes creation in allegories," says Burmeister. "He read into the words."

From his study of the Kojiki and his 50 years of personal experimentation, Murai concluded that Jin Shin Jyutsu was more than a philosophy of the body.

"Murai studied the Chinese acupressure points, then took them a step further by experimenting on himself and fasting. He compared what he experienced to the ancient acupuncture writings and compared them to what he felt. His experiences were much deeper than what he found in the writings. There is an awareness in Jin Shin Jyutsu that is deeper than technique," Burmeister says.

Theories of the body and philosophies of creation were far from Burmeister's mind when she met Murai in the late 1940s. A first-generation Japanese-American born in Seattle, she went to Japan to learn Japanese, not to study Jin Shin Jyutsu. "A young lady came to me and asked me to tutor her in English," Burmeister recalls. "It was through this casual meeting that some months later I met Jiro Murai at her home. The first words he said to me were, 'How would you like to study with me to take a gift from Japan to America?' I had no idea what he was talking about, but I went to hear him speak and knew I would stay to listen. I studied with him in Japan for five years, then in America through correspondence for seven more years."

It was 17 years, however, before Burmeister started sharing Jin Shin Jyutsu with others. "I just felt I had to know something before I could say I knew it. Then I realized you can't say you ever really know an art like this. One day I found myself timidly putting my hand out to a neighbor with a back problem and saying, 'Maybe I can help you.' After five years of working with her, I moved, and she then went back to her chiropractor, who called me soon after and requested that we meet. The chiropractor became my first student.

"After two years of sharing with the chiropractor, I started to translate and write down what I had learned from Jiro Murai. I'd stay up late at night after taking care of the children, writing and making

drawings. The chiropractor said she had a few colleagues with whom she'd like me to share Jin Shin Jyutsu. Our group grew to about six students, including a psychologist, a physician, and another chiropractor. That's how it began."

Burmeister explains that our revitalizing energy, which flows up the back and down the front of the body, can become blocked in 26 "safety energy locks," or what she terms "specialists," located throughout the body and in the organs themselves.

"As we abuse our bodies in our daily routines, mentally, emotionally, digestively, or physically, our safety energy locking system becomes activated," says Burmeister. "This is simply to let us know we are abusing our bodies."

A flow can be unblocked through a sequence of steps, or through a "quickie" step as simple as grasping a finger. The revitalizing energy then flows through the hands, or what Burmeister calls the "jumper cables," and can penetrate through clothing, even a brace or a cast.

"Light pressure goes through the skin and into the bone. If pain is present, it's because there is blockage and the pain is coming from the person, not the pressure. We don't have to dig into the very marrow of the bone. All we have to do is take away the dams."

Burmeister says that in Jin Shin Jyutsu there is no diagnosing, healing, or curing. "Some of you can go out today and look at the book and try this out. But you're not doing it, it's the light and the 'specialist' that are doing it. And the person you're working on says, 'Hey, my headache's gone.' But it's not you who's done it, it's the 'specialist' on step one, step two, step three, that's cleaning the debris for that particular complaint. We cannot do wrong because we are not doing anything. We are only jumper cables."

"Not doing anything" while at the same time doing something is one of several paradoxes in Jin Shin Jyutsu. Despite its esoteric principles, however, Burmeister maintains that Jin Shin Jyutsu is an inborn art that anyone can learn without much training.

"Plato said, 'Learning is remembering.' There's nothing we have to learn. We're always utilizing part of Jin Shin Jyutsu naturally, but as soon as we come into the world, it's 'gotta get,' 'gotta go,' 'gotta get your education,' and the skill lies dormant."

A student with a sprained ankle tells Burmeister that after her accident she has developed a habit of holding her wrist "That's helping the sprained ankle," Burmeister replies. "We carry a baby a certain way, and that's helping the little one without our knowing why. When a baby sucks its thumb, we tell it, 'No, no, that's wrong,' but the baby is telling us about its needs. It's in need of real energy, or its digestion needs help. Sucking the thumb helps the baby's nervous and muscular systems. As adults, we can hold the thumb and get the same result."

Burmeister says that Jin Shin Jyutsu not only aids the body, but changes the attitudes that underlie the physical symptoms. "Jin Shin Jyutsu helps everything from head to toe and toe to head. There are 27 trillion cells in the body, and if we smile, all 27 trillion cells smile with us. This is how we help ourselves in health.

"A five-year-old girl came in for a session with her parents. At the first session she was unhappy, all frowns. After the third session, she smiled at her mother and said, 'I love life.' Isn't that dynamic?"

During the five days of class, Burmeister shared other success stories. A woman in a wheelchair whose hands were stiff with arthritis was unable to enjoy her favorite hobby, knitting. A friend who was familiar with Jin Shin Jyutsu told her about holding the fingers. A few days later, after using Jin Shin Jyutsu on herself every night, the woman was knitting again.

A teenager working in a fast-food restaurant burned his arm in a vat of hot oil. His mother, a student of Burmeister's, placed her hands gently on his calves, the location specified in Jin Shin Jyutsu for helping skin ailments. The next morning, not only had all signs of the burn disappeared, but his complexion had cleared up as well.

Amazing as these stories are, I wondered how any kind of body therapy that didn't include direct and deep manipulation of the spine or muscles could be so effective. Although I felt tension disappear when Burmeister held my finger, I was not completely convinced.

Then I experienced a full Jin Shin Jyutsu treatment firsthand. In a class practice session, Burmeister took one look at me and said, "You're a 'doer.' You're always out in the world trying to get things done, rather than relaxing and letting things be."

From observing my body - the bend of my toes, my hands held over my stomach, my left shoulder higher than the right - Burmeister seemed to know almost everything about me. Yet she insists there is nothing unusual in what she does.

"When someone comes in for a session, I know the way they eat, I know what their needs are. And they say, 'Gee, you're psychic.' I'm not psychic. There's nothing mysterious about it. I'm just reading what the body is telling me."

At Burmeister's direction, one student placed her fingers under the back of my neck and another held my big toe and ankle. Two students on either side of my body each put a hand under my back. Then one of these students grasped my inner thigh at the knee, and the other put his free hand on top of my calf. Over the next 20 minutes I felt the tension in my back muscles melt away. Gurgles rose up from the depths of my torso. Toes and fingers twitched and moved. My breathing became deeper and more even. In general, I felt a sense of calmness, balance, and well-being. Even the puffiness in my cheeks disappeared.

Other students experienced their own small successes. Obviously something was working, but would the results last?

"The physical, mental, and emotional may be cleaned up for now," Burmeister says, "but if we go out and dirty it up again, we need to clean up the dirt, dust, and grime again. That's all it is. You'll just come in for more housecleaning, or you'll do it yourself."

Although dedicated to her work, Burmeister is hesitant to promote Jin Shin Jyutsu as a business. She does no advertising for her courses or private practice in Arizona, yet her classes fill quickly with students from around the world, and new clients have to wait up to one year for treatment. Watching and talking with Burmeister, I soon understood why: By living the simplicity, calmness, patience, and self-containment that lie at the heart of Jin Shin Jyutsu, she has become its best promoter.

"In Jin Shin Jyutsu there are no teachers or masters, they are all the same. I always say, 'Be the example.' We don't have to preach to other people. When people see me and say, 'You're so calm and relaxed. How do you do it, are you on pills or something?' then I can tell them about the hands. The jumper cables are the light. I've been studying for 30 years, and I know nothing.

"I don't see a future. I'm just in the now. Whatever direction it is, so it is. Whatever direction comes up, that's what I am. We're having this interview because David [her son and business manager] said it's time to get out a little bit more. I never butt into God's plans, I just go along with what is. Life is not a struggle, life is enjoying the now. It's simple."

Resources: Jin Shin Jyutsu, Inc.

JIN SHIN JYUTSU IS.

by David Burmeister and Michou Landon

Article from Massage and Bodywork Quarterly; Fall 1992 - slightly revised to reflect our current teaching staff and accommodate this home page.

Jin Shin Jyutsu is an ancient Japanese Art of harmonizing life energy within the body. Said to predate Buddha and Moses, it was rediscovered in the early 1900's by Master Jiro Murai, who, after recovery from "terminal" illness, devoted himself to the revival of the Art for future generations. He believed that the capacity to use this Art is born to all of us, like our hands, the tools with which it is applied.

Literally defined, Jin Shin Jyutsu is the Art of the Creator expressed through knowing and compassionate man.

It is a physio-philosophy that involves the application of the hands for gently balancing the flow of life energy in the body; more generally, it is the awakening to awareness of complete harmony within the self and the universe.

There are two important distinctions between Jin Shin Jyutsu and many other massage and oriental healing modalities to which it is often compared.

First, Jin Shin Jyutsu is an art, as opposed to a technique; a technique is a mechanical application, whereas an art is a skillful creation.

Second, Jin Shin Jyutsu is not a physical manipulation of tissue and uses only minimal pressure. The hands are used as "jumper cables," contacting 26 "safety energy locks" to redirect, or unblock the flow of energy along its pathways.

A practitioner of Jin Shin Jyutsu is not the "do-er", s/he simply assists in the flow of an infinite supply of universal energy. This process does not affect the practitioner's personal supply of energy.

In a typical Jin Shin Jyutsu session, which lasts about one hour, the receiver remains clothed and lies face-up on a cushioned surface. After "listening" to the energy pulses in the wrists, a practitioner employs a harmonizing sequence, or "flow," appropriate for unblocking particular pathways and restoring the energy to the energy rhythm of the universe.

A "flow" is a series of hand placement combinations (using the "safety energy locks") that stimulates circulation of energy along a given pathway. There are many such pathways in the body, each with a distinct function or essence.

To a certain extent, the experience of Jin Shin Jyutsu is unique to each person for each session.

However, the most common effect is that of deep relaxation. Who among us doesn't welcome any opportunity to let go of stress, which so often interferes with optimum health?

Mary Burmeister, a close student of Master Murai, brought the gift of Jin Shin Jyutsu to America upon returning from Japan in the 1950's. Over the years, demand for Jin Shin Jyutsu has grown steadily, primarily by word of mouth. Mary began teaching in the early 1960's, and, although she does not currently present the basic workshops herself, she continues to see clients in her office in Scottsdale, Arizona.

Now, the five-day seminars are offered by Mary's ten associate-instructors, Muriel Carlton, Philomena Dooley, Wayne Hackett, Susan Brooks (on sabbatical), Lynne Pflueger, Waltraud Riegger-

Krause, Matthias Roth Jed Schwartz, Ian Kraut, and Birgitta Meinhardt. These workshops are held throughout America, as well as in Canada, Europe and South America. There are currently well over 5,000 students of Jin Shin Jyutsu worldwide.

Jin Shin Jyutsu, Inc., offers practitioner certification to students who complete the training; this certification does not constitute a license, however, such as that required for massage therapists. Jin Shin Jyutsu training is based upon two text books, which are only issued to workshop students and are not available to the general public. However, in addition to the text books, three self-help books are available to everyone. There is even a self-help book designed for children. For more information about these materials consult various sections of this web site: http://www.jinshinjyutsu.com/

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Dear Students and Friends of Jin Shin Jyutsu,

Thanks to your love and enthusiasm, the Blessings of the Art of Jin Shin Jyutsu continue to ripple out into ever-widening circles, reaching growing numbers of people around the world. It is inspiring to see so many of you continue to grow in your awareness and to hear your beautiful stories about the special ways Jin Shin Jyutsu has touched the lives of your friends and families.

In order to grow together as a strong community, we feel it will be helpful to clarify certain practical matters which, until now, may have seemed vague. What follows are several questions that we have consistently heard over the years. We feel that a discussion of these will be helpful to students and practitioners alike.

PRACTICING THE ART OF JIN SHIN JYUTSU:

1. Q: When am I able to practice Jin Shin Jyutsu on a professional basis and refer to myself as a Jin Shin Jyutsu practitioner?

A: First of all, we encourage you to use your jumper cables from the beginning. However, since such a volume of material is covered in the seminar, and no test is given to measure one's understanding, we feel that a certain amount of time and experience is essential to assimilate the teachings. For this reason, we encourage new students not to hurry through the process of completing three classes. A time period of about 18 months is as fast as we recommend for proper integration of understanding the Art.

Upon completing the five-day seminar three times, each student receives a certificate, which we regard as the practitioner level certificate. At this point, a student has usually gained a basic understanding with which to embark upon a lifelong study and practice of the Art of Jin Shin Jyutsu.

2. Q: Is a Jin Shin Jyutsu certificate the same as a license?

A: No. The certificate issued by Jin Shin Jyutsu, Inc. does not constitute a license like those required by state or municipal governments for massage therapists. We suggest that a practitioner consult the laws concerning bodywork* in his or her own community to determine whether (and if so, what) licensing is necessary. Some locations do not require any license.

*Although we do not label Jin Shin Jyutsu as "bodywork", it is generally laws pertaining to "bodywork" that govern the practice of Jin Shin Jyutsu.

3. Q: What should I charge for a Jin Shin Jyutsu session?

A: Fees charged for a Jin Shin Jyutsu session tend to vary according to the location and experience of the practitioner. (For instance, Mary Burmeister herself charges $80 while her associates at the Scottsdale office charge $55 per session.) Factors such as local cost of living, overhead expenses for

an office, and the extra expense of house calls will all influence a practitioner's fee.

(Also, we have found that Jin Shin Jyutsu practiced at luxury resorts and health spas is often priced much higher than fees of a private practitioner.)

Keeping all of this in mind, we encourage practitioners to keep prices affordable, because modest pricing (and even a sliding scale) makes Jin Shin Jyutsu available to all.

4. Q: What terminology is appropriate to use as a practitioner and as a self-help instructor?

A: Mary Burmeister and Jin Shin Jyutsu, Inc. tend not to use terms, concepts, and practices which are closely associated with the medical profession such as "therapy", "diagnosis", etc. We do not make claims to "cure" or to supplant appropriate medical care. Indeed, the use of such terms or the making of such claims could be illegal in certain circumstances. However, we believe Jin Shin Jyutsu profoundly supports the healing process of body, mind and spirit, and is a valuable complement to conventional healing methods.

5. Q: Can I use the name Jin Shin Jyutsu and its Kanji (Japanese characters) on my business card?

A: The name Jin Shin Jyutsu, the Kanji and finger logos are valuable assets of Jin Shin Jyutsu, Inc. and serve to identify and distinguish the Art brought to us by Master Jiro Murai and Mary Burmeister from other forms of "bodywork" which are practiced by people who neither understand nor share our values and teachings. Jin Shin Jyutsu, Inc. registered these marks with the government so they would truly identify the gift given to us. It is our policy to license and encourage practitioners trained by Jin Shin Jyutsu, Inc. to use the marks. In that respect, the certificate issued by Jin Shin Jyutsu, Inc. to persons who have completed the five day seminar three times serves as a license to use the name Jin Shin Jyutsu, the Kanji and finger logos, always identified with the trademark symbol ®, in connection with the practice of the Art of Jin Shin Jyutsu as given to us by Master Jiro Murai and Mary Burmeister. We encourage qualified practitioners to use the marks on stationery, business cards, promotional fliers, etc., together with the trademark symbol. Of course, Jin Shin Jyutsu, Inc. reserves the right to revoke a person's right to use any of the registered trademarks if the marks are not being used in a manner consistent with the Blessings of the Art of Jin Shin Jyutsu or for other reasons which are in the best interest of Jin Shin Jyutsu, Inc.

6. Q: How may I inform people about Jin Shin Jyutsu?

A: Jin Shin Jyutsu, Inc. is making available an information brochure for use in introducing Jin Shin Jyutsu to others. Further, we happily permit publication of articles in your community, provided that we are given the opportunity to review them in advance for accuracy.

7. Q: Who is authorized to teach Jin Shin Jyutsu?

A: Currently Jin Shin Jyutsu, Inc. has ten instructors - three senior and seven more recent instructors authorized to present the materials in Text I & II. The senior instructors are: Muriel Carlton, Philomena Dooley and Wayne Hackett. The more recent instructors are: Susan Brooks (who is presently on sabbatical), Lynne Pflueger, Waltraud Riegger-Krause, Matthias Roth, and Jed Schwartz, Ian Kraut and Birgitta Meinhardt. The above mentioned are the only instructors (of text materials), other than Mary Burmeister, recognized by Jin Shin Jyutsu, Inc.

PRESENTING SELF-HELP CLASSES

1. Q: At what point can I present a self-help class?

A: We believe a self-help class should be taught only by people who have completed the five day seminar at least three times. Upon completion of the basic training, Parts I & II three times, a practitioner level certificate will be issued. This qualifies you to attend the "Instructor Training in Self-Help" (IT IS) seminar. The IT IS seminar helps prepare interested students to conduct self-help classes using Mary Burmeister's self-help books. A certificate of attendance is issued upon completion of the IT IS training. Please note that the IT IS certificate does not give one the right to use the name Jin Shin Jyutsu, the Kanji or the finger logos other than in connection with self-help classes and your private practice. Our authorized instructors for this new class are Sara Harper, Janet Oliver, Phyllis Singer, Iole Lebensztajn, and Birgitta Meinhardt.

2. Q: Are there any other considerations I should know about before presenting self-help Jin Shin Jyutsu to others?

A: Please use our name and trademark properly when producing brochures or fliers about your class. We do ask that you clearly refer to yourself as a self-help instructor (preferably including the words "self-help" in the title). Please contact David Burmeister in Scottsdale, should you have any questions.

We have found it very helpful when you present a self-help class to communicate to students that, while this instruction is intended to assist them in helping themselves (and perhaps friends and family), it is not intended to prepare them to share Jin Shin Jyutsu with others in a professional capacity (such as practitioner or instructor). Making the latest seminar calendar brochure available can help students differentiate between the levels of training.

We deeply thank you for your loving participation in sharing the Art of Jin Shin Jyutsu. We know that our community will continue to flourish with your collective support and dedication.

In Unconditional Cosmic Love,

Mary Burmeister
President, Jin Shin Jyutsu, Inc.

David Burmeister
Director, Jin Shin Jyutsu, Inc.

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