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World Self-Medication Industry (WSMI) 3rd Asia Pacific Regional Conference
"Responsible Self-Medication: Recognising Its Role in Total Healthcare"
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SESSION 3

Regulation of Traditional Medicines: European Experience

Dr. Hubertus Cranz
Director
European Proprietary Medicines Manufacturers' Association (AESGP)

Current situation concerning traditional medicines

On the worldwide level, the situation for traditional medicines is characterised by a certain dilemma. On the one hand, there is a growing demand for these products and maybe also a growing recognition of the value of traditional medicines. On the other hand, there are regulatory and legal uncertainties which result in quite different regulations of traditional medicines around the world. This becomes particularly evident in the quite different classification of these products. In some countries they are mainly classified as food, in others, they are mainly classified as medicines. In those countries where traditional products are recognised as medicines, they are sometimes reimbursed by social security systems.

It has to be recognised that different efforts have been made to reach some kind of consensus with regard to the assessment of traditional medicines. However, due to the traditional use and philosophies behind these medicines, this is often difficult to achieve. As there is a worldwide trend to facilitate the free movement of all goods including medicines, the question has become increasingly relevant as to how an international transfer may also be achieved for this sector. Manufacturers of traditional medicines obviously have a particular interest in these developments, at least in Europe. Harmonisation has therefore become an important element in the regulatory debates in Europe.

Although it will hardly be possible to agree on a definition of traditional medicines, from a European perspective the major categories are:

— herbal medicinal products

— homeopathic medicines

— other more specific categories such as anthroposophic medicines which are of more regional importance.

Developments in Europe

The process of reaching more harmonisation in Europe has been particularly pursued since the establishment of the European Economic Community in 1957. Of particular importance was the goal to achieve a common market by 31 December 1992 within the then 12 Member States of the European Union. This aim also stimulated many discussions about the haromisation of regulatory and legal requirements of medicinal products.

The harmonisation efforts were related to all kinds of legislative requirements for pharmaceuticals. Of particular importance for non-prescription medicines in general and also for most traditional medicines was a package of four directives related to classification, package information, advertising and wholesale distribution. These directives came into force by 1 January 1993 and provided a clear differentiation between prescription and non-prescription medicines, the latter category allowed to be advertised to the public. Quite specific requirements for the labels and leaflets are in line with the need to provide comprehensive information to the users of medicines, in particular in the sector of self-medication.

Generally speaking, all these requirements have to be applied to those herbal products in the European Union which are classified as medicines. For other categories, such as homeopathic medicines, there are different kind of rules in light of their particularities.

Although recent efforts in the European Union have concentrated on the further development of a European marketing authorisation system to cover herbal medicinal products, first a short explanation of the situation of homeopathic medicines, the only category of medicines which has been placed in a specific legal framework in the European Union.

Homeopathic Medicines

After quite extensive and often controversial debates, the Member States of the European Union agreed on 22 September 1992 on a Council Directive 92/73/EEC widening the scope of directive 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products and laying down additional provisions on homeopathic medicinal products. This directive defines "homeopathic medicinal product" as any medicinal product prepared from products, substances or compositions called homeopathic stocks in accordance with the homeopathic manufacturing procedure established by the *European Pharmacopoeia* or, in absence thereof, by the pharmacopoeias currently used officially in the Member States. It is explicitly stated that the homeopathic medicinal product may also contain a number of principles, so that not only monocompound products are covered.

Most of the provisions of the general pharmaceutical legislation and in particular with regard to manufacture, control, import and export have to be applied also to homeopathic medicinal products. However, the proof of therapeutic efficacy should not be required from those homeopathic medicinal products registered in accordance with the so-called simplified procedure. This simplified registration is only possible:

- if the product is administered orally or externally (no injections),
- if there are no specific therapeutic indications on the labelling of the medicinal product or in any information related to the product,
- if there is a sufficient degree of dilution to guarantee the safety of the medicinal product, in particular the medicinal products may not contain either more than one part per 10,000 of the mother tincture or more than 1/100th of the smallest dose used in allopathy with regard to active principles whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription.

In addition to the clear mention of the words "homeopathic medicinal product", the label and, where appropriate, the package insert for the homeopathic medicinal products which went through a simplified procedure has to mention (and is not allowed to mention more):

- the scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia used,
- name and address of the person responsible for placing the product on the market and, where appropriate, of the manufacturer,
- method of administration and, if necessary, route,
- expiry date, in clear terms (month, year),
- pharmaceutical form,
- contents of the sales presentation,
- special storage conditions, if any,
- a special warning if necessary for the medicinal product,
- manufacturer's batch number,
- registration number,
- "homeopathic medicinal product without approved therapeutic indications",
- a warning advising the user to consult a doctor if the symptoms persist during the use of the medicinal product.

Not withstanding these requirements, Member States may demand the use of certain types of label in order to show the price of the medicine and the conditions of refunds by social security bodies.

The directive also foresees the marketing authorisation of homeopathic medicinal products which can go through a normal marketing authorisation procedure and are allowed to carry claims in the same way as any other medicinal product.

Generally speaking, this directive has clarified the role of homeopathic medicines in the European Union and is widely appreciated by the parties concerned. Specific problems such as the prohibition of the tradename for homeopathic combination products, the ban on parenteral forms coming out of the simplified procedure or the restrictions on dilution are currently being discussed and may lead to an initiative of the European Commission to amend this directive.

It is worth mentioning in this context that the directive which has to be implemented in the legislation of the European Union Member States also had a considerate impact on so-called Central and Eastern European countries when they were reconsidering their pharmaceutical legislation at the beginning of this decade after the general political changes.

Herbal Medicinal Products

When talking about traditional medicines in the context of Europe and European harmonisation, the focus has to be on herbal medicinal products. In principle, herbal medicinal products are integrated in the quite sophisticated regulatory system which has been established in the area of marketing authorisation since the first directive in this sector in 1965. Generally speaking, the European Union directives set down two principle ways of proving a product's safety and efficacy. The first is through scientific evidence, including in particular clinical trials. The second way, which is particular-

ly relevant for herbal medicinal products, is to cite published bibliographical references as evidence of well-established use of the product.

In addition to this, many years ago guidelines were established with regard to the proof of quality in respect of Good Manufacturing Practice of herbal medicinal products. All these efforts however have not been sufficient to guarantee a free circulation of herbal medicinal products in the European Union and therefore the last two years have seen a considerable increase in the activities to define ways how at least some herbal medicinal products may enter into all European Union Member States. Let me briefly refer to some milestones in this respect.

Growing recognition of herbal medicinal products in the European Union

Influenced by a resolution of the Member States of the European Union in December 1995, quite a few debates took place on the role of herbal medicinal products in the context of the development of an industrial policy for the pharmaceutical sector. The resolution of the European Parliament adopted in April 1996 was particularly outspoken on herbal medicinal products. This resolution was an important basis for concrete initiatives to establish an ad hoc working group on herbal medicinal products at the European Medicines Evaluation Agency and it also influenced the decision of the European Commission to carry out a study on herbal medicinal products in order to gain more transparency in the whole sector. All these elements together demonstrate an unprecedented level of activity concerning herbal medicinal products on the European level.

The strong support from the European Parliament has been a key element in the development of the support for herbal medicinal products in the European Union. Two quotes from the above-mentioned resolution may particularly demonstrate this:

The European Parliament

"Points out to the Commission that citizens' attitudes towards health have changed and demand has consequently shifted because there is greater awareness of 'gentle' forms of healing (e.g physiotherapy) and 'alternative' medicines (herbal and homeopathic) among doctors and patients, and even today alternative treatments provide significant employment opportunities in small and medium-sized enterprises."

"Calls on the Commission to prepare additional proposals on how also to facilitate the European marketing of herbal and homeopathic medicines...
Requests the Commission to adjust the authorisation procedure to allow such medicines to be generally available throughout the Community and in pursuit of such, calls for the setting up of a Traditional Medicines Evaluation Agency, comprising experts in this field, to assess the worth of phytomedicines".

EMEA ad hoc working group on herbal medicinal products

Although the requests were maybe somewhat extreme, for example with regard to the establishment of a specific agency, the resolution was most helpful in setting up the ad hoc working group on herbal medicinal products of the European Medicines Evaluation Agency (EMEA). This European agency became operational in January 1995 and is today recognised as an important element for the marketing authorisation process in Europe, particularly for innovative medicines which benefit from a so-called centralised procedure allowing access to all European Union Member States. The key objectives of the new working group of the EMEA on herbal medicinal products were the provision of guidance for applicants and competent authorities concerning the marketing authorisation for herbal medicinal products. The work of this group is therefore very much related to the so-called de-centralised procedure which should allow an easy access to all European Member States as soon as one country in the European Union has granted a Marketing Authorisation. It has been evident that, due to the considerable differences with regard to the regulatory requirements for herbal medicinal products, such transferral or mutual recognition of national marketing authorisations is not as simple as it may appear in theory.

The ad hoc group met three times in 1997 and three further meetings are scheduled for this year. Already in the first year, considerable progress has been made. This is particularly true in the area of quality, where the existing Note for Guidance on Quality has been reviewed and updated together with the existing guideline on Good Manufacturing Practice. Both guidelines have now been released for a three month consultation and will hopefully be finalised during the course of this year. The working party also issued a draft guideline on "non-clinical testing of herbal drug preparations with long-term marketing experience". This guideline is based on a similar draft for old substances in general. This guideline points out that where there is sufficient experience in humans available, quite a few safety studies are not necessary, provided that an expert report gives the ground why the documented medical experience justifies a safe use of the herbal drug preparation. Non-clinical testing of well-established herbal drug preparations should however be directed towards the study of those effects which are difficult or even impossible to detect clinically. These effects would include toxicity to reproduction, genotoxicity and carcinogenicity.

Of particular importance was the debate in the working party on the role of so-called monographs summarising the scientific knowledge of certain plants. Such monographs have been developed by the World Health Organization (WHO) as well as by the European Scientific Co-operative on Phytotherapy (ESCOP). A proposal for revision of the so-called Notice to Applicants suggests that:

"Scientific monographs on certain substances, (e.g. those drafted by the European Scientific Co-operative on Phytotherapy (ESCOP) and the World Health Organization (WHO) for herbal drugs) offer a valuable and updated overview on published scientific literature, which together may be used in support of the documentation on the safety and efficacy of the medicinal product in the bibliographic application.

These monographs may help to avoid duplication of work

and bring about gradual harmonisation in the evaluation of medicinal products, e.g. herbal medicinal products. Therefore, the Commission and the Member States recommend that the applicants and competent authorities should make use of these monographs".

Besides the general recognition of monographs, the ad hoc working group started to look at the establishment of so-called core SPCs, which means an agreement on key elements of the summaries of product characteristics, the summarising document at the end of a marketing authorisation procedure. First a core SPC was drafted for Valerianae Radix and the development of further core SPCs is planned for this year.

The work of the ad hoc working group on herbal medicinal products is an important basis to provide more guidance to those manufacturers of herbal medicinal products who would like to bring their products into more than one European Member State by using the mutual recognition procedure. At a meeting at the end of November 1997, all interested parties appreciated the work done so far by the ad hoc working group, and strongly suggested continuing its work. Through the three meetings in 1998 it is hoped to get final adoption of the different papers drafted. Together with the establishment of further core SPCs, a free circulation, at least of well-documented plant-based preparations, should be possible in the European Union.

WHO and Traditional Medicines

As stated before, the European efforts benefited from the work of the WHO Traditional Medicines Programme, in particularly in respect of monographs for widely used medicinal plants. These monographs are the final point of the important work of the World Health Organization clarifying the regulatory requirements for traditional medicines and in particularly for herbal medicinal products. Without covering the different guidelines in any detail, it seems worth remembering particularly the resolution of the World Health Assembly in 1991, which requested the Director General of the World Health Organization

- to continue to recognise the high importance of this programme and to mobilise increased financial and technical support as required;
- to ensure that the contribution of scientifically proven traditional medicines is fully exploited within all of the WHO programmes where plant-derived and other natural products may lead to the discovery of new therapeutic substances;
- to seek appropriate partnerships with governmental bodies and non-governmental organisations as well as with industry in implementing this resolution.

A most important basis were the WHO guidelines for the assessment of herbal medicinal products developed in 1990/91, which laid down the principle rules in the areas of pharmaceutical assessment, safety assessment, assessment of efficacy and intended use. These guidelines were complemented by different documents, primarily from Regional Offices of the WHO such as, for example:

- Research Guidelines for Evaluating the Safety and Efficacy of Herbal Medicines - Regional Office for the Western Pacific (1993)
- Guidelines on the Conservation of Medicinal Plants (1993)
- Quality Control Methods for Medicinal Plant Materials (1994)
- Selection of Essential Medicinal Plants - Regional Office for the Eastern Mediterranean (1995)

The above-mentioned monographs for certain medicinal plants were agreed as one of the priorities at the International Conference of Drug Regulatory Authorities (ICDRA) in the Netherlands in 1994 and led to the endorsement of a first series at a subsequent meeting in November 1996 in Bahrain. The information contained in these monographs can be separated into a first part linked to quality issues and a second part relevant to efficacy and safety as it defines the medical applications, pharmacology, posology and possible contra-indications and precautions. The final publication of the first series is expected during the course of this year. The following plants will be covered:

Allii Cepae, Bulbus
Allii Sativi, Bulbus
Aloe
Aloe Vera Gel
Astragali, Radix
Bruceae, Fructus
Bupleuri, Radix
Centellae, Herba
Chamomillae, Flos
Cinnamomi, Cortex
Coptidis, Rhizoma
Curcumae Longae, Rhizoma
Echinaceae, Radix
Echinaceae Purpureae, Herba
Ephedrae, Herba
Gingko, Folium
Ginseng, Radix
Glycyrrhizae, Radix
Paeoniea, Radix
Plantaginis, Semen
Platycodi, Radix
Rauwolfiae, Radix
Rhei, Rhizoma
Sennae, Folium
Sennae, Fructus
Thymi, Herba
Valerianae, Radix
Zingiberis, Rhizoma

The strong interest in these monographs encouraged the World Health Organization to commission the development of a second series which should be drafted during the course of this year. It is intended to cover the following plants:

01. Aesculus hippocastanum
02. Althaea officinalis
03. Angelica sinensis
04. Arctostaphylos uva ursi

05. Calendula officinalis
06. Capsicum annuum
07. Chrysanthemum parthenium
08. Cimicifuga racemosa
09. Crataegus monogyna C. laevigata
10. Eleutherococcus senticosus
11. Eucalyptus globulus
12. Hamanelis virginiana
13. Harpagophtum procumbens
14. Andrographidis paniculata
15. Hypericum perforatum
16. Melaleuca alternifolia
17. Melissa officinalis
18. Mentha piperita
19. Ocimum sanctumy
20. Oenothera biennis
21. Piper methysticum
22. Polygala senega
23. Prunus (Pygaum) africana
24. Angelica sinensis
25. Rhamnus purshiana
26. Rhamnus frangula
27. Salvia miltiorrhiza
28. Sambucus nigra
29. Serenoa repens
30. Silybum marianum
31. Syzygium aromaticum
32. Urtica dioica, U. urens

It is intended to discuss the second series at a consultation in February next year and an endorsement by the International Conference of Drug Regulatory Authorities is aimed for the time of their next meeting in April 1999 in Berlin.

Conclusion

As the phrase "traditional medicines" indicates, the assessment is strongly influenced by historic developments in a national context. For those traditional medicines with a clear concept on which international agreement can be found, commerce outside the national boundaries should be possible. In Europe, a legislative framework has been established for homeopathic medicines. Herbal medicinal products fall under the scope of the definition of medicines in general and should therefore be able to benefit from an easy access to other countries, at least in the European Union.

The intensive debate on the future of herbal medicinal products over the last years has however shown that it might not be possible to gain a European or international standard for all kinds of herbal medicines. Only products which meet the requirements on safety and efficacy by either specific bibliographic reference and/or coverage through monographs or core SPCs and/or clinical trials according to an appropriate model will be able to gain European-wide access. There is a general political agreement that other herbal medicines should not disappear from the market, but due to the strong national influence in the assessment, international commerce seem to be difficult primarily due to insufficient proof of efficacy.

What has therefore been shaping up on the European level over the last years is an approach which differentiates between products falling in areas where agreement can be reached between Member States and those which seem to be only justified in a national context. In the European Union, it will be interesting to see if this separation is a long-term solution, or whether additional legislative initiatives may clarify the whole sector.

Session Chairman, Dr Mark Seidscheck

Thank you very much Dr Cranz for that thorough review of how a market in which traditional herbal medicines are very important has managed, and are still managing, to regulate them successfully to the benefit of the people of Europe.

And now Mr Yoshihiro Kusai, President of Wakunaga Pharmaceuticals, Japan is with us to discuss the Japanese experience in regulating traditional medicines. Japan, as many other countries in the region, has been influenced by Chinese traditional medicines in addition to its own traditional medicine, and has a particular way in regulating these medicines, which I believe is of special interest to this audience. Mr Kusai, please.

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Resolving the Question of a Medically-Active Biofield:

Evidence of Existence and Partial Characterization

– An Experiment in Physics –

Richard R. Pavek,

The Biofield Research Institute

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Resolving the Question of a Medically-Active Biofield:
Evidence of Existence and Partial Characterization
– An Experiment in Physics –

Richard R. Pavek, The Biofield Research Institute

Context — The untested but prevailing belief that a medically-active Biofield* is nothing but a fiction is being challenged by a growing number of medical and medically-allied professionals who have become convinced by the consistent beneficial results of its therapeutic application. Recent estimates indicate that over one million people in the Western nations alone practice at least one form of biofield therapeutics; approximately ten percent are in the medical and allied professions. The lack of accepted detecting devices and measuring instruments has hampered investigation of the biofield's characteristics, restricted clinical trials and supported the skeptics' position that it is nothing but a major placebo, or worse – a complete fraud.

The controversy received worldwide attention in April 1998 when JAMA published the results of a study intended to resolve whether the biofield exists, *A Close Look at Therapeutic Touch. JAMA, 1998;279:1005-1010.* According to the authors, the biofield is not detectable and does not exist. However, a closer look at the data disclosed several factors that had negatively biased the trials. A new experiment designed to eliminate these factors, one by one, uncovered a previously unrecognized problem that had made it impossible for the participants in the original trials to succeed. When the original apparatus was modified to eliminate this problem and the study repeated, twenty-one experienced practitioners and practitioners-in-training of one biofield therapeutic modality were consistently able to detect the biofield with a high degree of confidence. In addition to the primary finding, several characteristics of the external portion of the biofield (the aura) were established that indicate it is likely to be a low-energy capacitive field coupled with an electromagnetic field that circulates within the physical body.

Conclusions — The results of the new trials substantiate the existence of the biofield as a field in physics and warrant further characterization of its properties towards development of improved clinical techniques for the betterment of human and animal health.

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* The terms **"Energy," "Energy Body," "Energy Field," "Human Energy Field," "Subtle Energy Field,"** and other derivations that are commonly used to identify the biofield are, or incorporate, an improper and unclear usage of previously and precisely defined scientific terms. This misuse of terms has long caused confusion and brought derision from the other scientific disciplines that originally defined energy as *"the capacity of a system to do work"* and field as *"a region of space characterized by a physical property, such as gravitational or electromagnetic force or fluid pressure."* Since all fields in physics have energy, the concept of an energy field is ambiguous, confusing and has no meaning in science. To rectify this, the editors of *Alternative Medicine: Expanding Medical Horizons, the Report to the NIH on Alternative Medicine,* (1992) unanimously adopted the unambiguous definition "Biofield."
The term has since been adopted by the National Center for Complementary and Alternative Medicine, NIH.
Biofield: 1) a *fluxive, massless medium* with the distinctive property of being *bioeffective, or having an effect on biological material.* The biofield penetrates and extends outward from the physical body a finite distance. The term **Aura** is commonly used to denote the portion of the biofield that is external to the physical body.
2) The primary operative mechanism in healing modalities using proximate touch and related hands-on techniques.

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Antecedents of Current Western Biofield Modalities

The earliest known Western term for the biofield, "Life Force," represented by the hieroglyph ☥, (pronounced *ankh*), dates back to at least 2900 BC. Although the opinion is not universal, there is extensive pictorial evidence showing that medical application of the biofield through proximate touch was the essential activity in both the Asclepian incubation chambers and the Per Ankhs (Houses of Life) that were attached to certain ancient Egyptian temples. Prior to the 17th century, little attempt was made to understand the phenomena as a natural process; until then all such healing had been attributed to magic, pagan influences, or to God acting in concert with or through the healer. In August of 1665, Dr. Thomas Sydenham and other physicians investigated and confirmed the ability of Valentine Greatrakes, the Irish "Stroaker," to eliminate pain, reduce swellings and alleviate other disorders by lightly stroking his hands either on or proximate to the body. The following year, Sir Robert Boyle investigated Greatrakes' healings on several occasions, postulating that perhaps "some salubrious streams or spirits" were induced from Greatrakes' hands into the patient's body. Boyle's own experimental strokings (aided by Greatrakes' glove turned inside out) were also successful in eliminating pain.

The first to place the biofield in physics and associate it with electromagnetism was Franz Anton Mesmer. In 1766, Mesmer postulated that a "fluidium" (field) – which he termed "animal magnetism" to differentiate it from "metal magnetism" – existed as a force of nature subject to laws of physics. His attempts at further characterization now seen ludicrous; however, he did unambiguously demonstrate that the phenomenon was not a special gift from God when he and others began teaching large groups in the therapeutic procedures he devised. His work and his flamboyant manner threatened and infuriated much of the French medical establishment who prevailed upon the King's Minister to investigate Mesmer's medical claims. The majority of an appointed commission reported they saw no evidence of animal magnetism and, repelled by the "convulsions" (cathartic emotional releases) that frequently ensued during Mesmer's process, declined comment on the medical worth of his work, opining that these events could easily be produced "by the imagination."

Despite the considerable skepticism, Mesmer's work spread rapidly throughout Europe and later in America. Further evidence of the biofield's electromagnetic characteristics has been slow to emerge; too often serious attempts to investigate the biofield by reputable physicians have been met with derision, dismissal from academic office, and loss of colleagues. The hostility to medical mesmerism or "magnetic healing" was so great that from 1900 to 1974 Dorland's Medical Dictionary included the term: "Mesmeromania *Insane devotion to mesmerism."*

Despite this, during 1850-52, John Kearsley Mitchell, Professor Emeritus at Jefferson Medical College, conducted a series of blinded experiments that, among other effects, demonstrated that the field strength of the biofield decreased exponentially as the practitioner's hands moved farther from the patient's body, just as do separation of components in electrostatic or capacitive fields. Recently, the editors of the Journal of the American Medical Association validated a novel method of determining the biofield's existence when they published *A Close Look at Therapeutic Touch* (JAMA, 1998;279:1005-1010). The authors, Emily Rosa, Linda Rosa, BSN, RN, Larry Sarner and Stephen Barratt, MD, reporting the results of the detection method devised by Linda Rosa (who was eleven years old at the time of the study), claimed "unrefuted evidence" that Therapeutic Touch (TT) practitioners could not perceive the field and asserted that any professional use of TT – and presumably all therapeutic use of the biofield – was unjustified. In the following issue, George Lundberg, then JAMA's editor, declared *"This statistically valid study ... found that such a field does not exist* (and) *patients should save their money and refuse to pay for this procedure."* (JAMA 1989;279:1064).

Description of the Rosa study: *"During each test the practitioners rested their hands, palms up, on a flat surface, approximately 25 to 30 cm apart. To prevent the experimenter's hands from being seen, a tall, opaque screen with cutouts at its base was placed over the subject's arms, and a cloth towel was attached to the screen and draped over them.* (Figure 1.) *Each subject underwent a set of 10 trials. Before each set, the subject was permitted to "center" or make any other mental preparations deemed necessary. The experimenter* (Linda Rosa, who was eleven at the time of the trials) *flipped a coin to determine which of the subject's hands would be the target. The experimenter then hovered her hand, palm down, 8 to 10 cm above the target and said, "Okay." The subject then stated which of his or her hands was nearer to the experimenter's hand. Each subject was permitted to take as much or as little time as necessary to make each determination. The time spent ranged from 7 to 19 minutes per set of trials."* (JAMA, 1998;279:1005-1010.)

Interpreting the Results of the Study

The participants correctly identified which hand was closest to the practitioner's in 123 of 280 trials (44%). From this the authors concluded that the participants "were unable to detect the investigator's "energy field." This conclusion was incorrect; according to the text of the article the practitioners actually detected the biofield in nearly all trials but were able to determine the exact location of the investigator's hand only 44% of the time – which was quite another thing entirely than failing to detect.

The error was in treating the study as if it were a completed clinical trial. It was not; this was an experiment in physics and the discovery process in physics experiments is different from that used in clinical trials. In physics, the study would have been considered incomplete at the point it was halted. In physics, there are three possible results that might be obtained from an experiment of this type and three possible inferences:

1. If no one accurately and consistently detected the placement of the experimenter's hand, the biofield probably does not exist.
2. If nearly everyone accurately and consistently detected the placement of the experimenter's hand, the biofield probably does exist.
3. If nearly everyone detected the biofield but the answers were imprecise, inaccurate or confused as to location of the experimenter's hand – which was the case – it can only be concluded that:

   (A) those being tested were charlatans or delusional, or

   (B) there are problems either with the method or the apparatus and the process needs to be re-examined to discover the cause or causes of the inaccuracies.

Since the practitioners were, for the most part, reputable health professionals who offered TT without charge on humanitarian grounds, and none were known to be delusional, we are obliged (in physics) to assume (B) and attempt to ascertain the problem(s) in order to develop ways to correct them.

A brief review of the test's design against known or suspected qualities of the biofield exposed several factors any one of which could account for the confused detection.

First, it is extremely difficult to detect an undisturbed biofield; this is analogous to holding up a hand in still air to detect whether air is present. The literature referenced in the Rosa paper clearly states that when sensing the biofield, practitioners of TT (and comparable therapies) are detecting disturbances and anomalies in the biofield such as *"... tingling, pulling, throbbing, hot, cold, spongy ...,"* that are associated with injury or disease states (JAMA, 1998;279:1007). By not providing these disturbances the authors negatively predisposed the experiment.

Second, there are significant differences in the strength of individual biofields. At the high end of the spectrum are those known as "sensitives," "gifted" or "natural healers" because of their exceptionally strong fields(JAMA, 1998;279:1005-1006); at the low end are children who generally exhibit low field strength. By choosing a child as the source of the biofield, the authors further negatively biased the experiment.

Third, the participants' hands were not checked for individual sensitivity prior to the trials. In any one trial, if the farther hand were more sensitive than the one the investigator's hand was above, it might mistake the experimenter's hand as being closer than it actually was.
Fourth, a basic premise of the test was the unstated but obvious assumption that the biofield from the experimenter's hand would not (if it existed at all) extend far enough to affect both of the participant's hands.

Basic Considerations for this Experiment

Since this study was only meant to resolve a question in physics and not whether the biofield is medically effective, providing an injury or illness to be detected was automatically ruled out. Attempting to resolve the four factors in one trial would have been problematic at best and probably unworkable. Therefore it was decided that factors two, three and four above would be investigated one at a time. The factor chosen for investigation in the first stage of the experiment was whether a more robust biofield would be more readily detected. Since the biofield around his hands is known to be more robust than usual, the author elected to be the source of the biofield.

Three minor changes were made to improve the soundness of the test method and one to gather additional information:
(1) On the advice of the Marin General Hospital's Institutional Review Board, a buzzer replaced the audible "OK" to preclude audible cueing of the location when announcing that the experimenter's hand was in place.
(2) Since there were objections to the towel placed across the arms in the original study it was replaced with two layers of opaque cloth draped from the top of the screen; one was split with the split placed close under the chin and the tails draped across the participant's shoulders; the other was placed across the first, in the area between the chin and the screen. This eliminated any possibility of seeing movement through the cutouts around the participant's hands.
(3) Since some of the original participants had mentioned a desensitizing "memory build-up" in their hands after several trials (See JAMA, 1998;279:1008) the participants in this experiment were asked to flex their fingers slightly after every few trials to offset possible desensitization.
(4) The subject base was expanded to include practitioners from therapeutic modalities that espouse different concepts about, and approaches to, healing with the biofield. Subjects were gathered from Healing Touch™ (HT) and SHEN® Therapy (ST). Healing Touch is an international association of nurses who trained in TT as the foundation of their practice. HT practitioners scan diagnostically and believe that a concurrent mental process – willfully intending to heal – is necessary for the process to be effective. HT is used for the relief of pain, the reduction of anxiety and a range of adjunctive and palliative uses. ST derived from the observation that placing the

hands in specific polarized pairings on bodily regions associated with an emotion evoked the emotion, while reversing the hand pairings suppressed the emotion. ST is used primarily to assist in releasing painful emotions and in promoting emotional growth. ST practitioners are not trained in TT, do not scan diagnostically and do not believe that an willful intention to heal is necessary for the process to be effective. *(See Table 1 for additional conceptual and operational differences.)*

First Stage Trials

36 HT practitioners and 17 ST practitioners were recruited to participate in the first stage of the experiment. Testing was done at conferences or organizational sites where the necessary apparatus could be set up and numbers of participants tested in orderly fashion. It became clear during the Lakewood section that pressing the buzzer while simultaneously placing the other hand over the participant's hand was awkward and problematic. Subsequently an assistant was brought in to flip the coin, press the buzzer when the experimenter was in position, and chart the results.

First Stage Results

HT, Lakewood, CO	06/23/1999	5 subjects, aggregate score of 54% correct
HT, Kauai, HI	01/22-24/2000	32 subjects, aggregate score of 50% correct
ST, San Diego, CA	01/29/1999	11 subjects, aggregate score of 60% correct
ST, Sausalito, CA	02/06/2000	6 subjects, aggregate score of 60% correct

Analysis of the First Stage Results

(1) The increase in both HT and ST scores over the 44% correct in the Rosa study confirmed that increasing the strength of the biofield made the biofield easier to detect.

(2) All trials were completed in less than 6 minutes. This compares to the 7 to 19 minutes for the Rosa test and is consistent with an increase in field strength.

(3) The greater score of the ST practitioners over HT practitioners indicates that developing the flows through the arms results in increased sensitivity.

(4) There appeared to be no significant difference between those who had been practicing for several years and those who had been practicing for only a short period of time.

(5) Several participants mentioned either during their trials or afterwards that they had difficulty determining which was the closer hand because they felt the biofield with both hands.

Second Stage of the Experiment

To establish consistency, a few practitioners were tested with a larger number of trials. Three ST practitioners were chosen for this stage; all had scored 50% or higher in the initial trials. Each was tested a total of 120 times during this stage. The tests were conducted on three separate occasions at approximately one-week intervals. At each of the three sessions the participants were rotated through 4 sets of 10 trials at approximately fifteen-minute intervals. Scores were tabulated

both for totals and to evaluate for differences in accuracy between the transmitting hand and the receiving hand. *(See Table 3.)*

Analysis of the Second Stage Results.

(1) All participants maintained scores well above chance; the aggregate score was 63.3%.
(2) All of the participants increased their previous scores slightly during the course of their trials.
(3) The results did not support the earlier assumption that the transmitting hand (with the greater field) would always be the more sensitive, as it was true with two but not the third.
(4) All three reported that they always felt the effects with both hands; it was always a question of discerning which hand was feeling the effect more strongly. It became obvious that the envelope of the biofield at the experimenter's hands extended far enough to affect both hands, not just one as had been unwittingly assumed in the original Rosa study.

Considerations for Stage Three

Given that the field effect from the experimenter's hand was reaching both of the participant's hands, it was doubtful that merely increasing the strength of the biofield again would increase the scoring any considerable amount; the increased field strength would affect the participant's further hand proportional to the effect on the nearer hand. A shield was needed to prevent the field from the experimenter's hand from reaching the participant's farther hand.

Isolating the participant's hands and arms. On the chance that the biofield may be an aspect of the electromagnetic field, Faraday screens or sleeves of brass screening were constructed to enclose and isolate the participant's forearms and hands from each other. (Faraday screens block any electromagnetic effects on one side of the shield from affecting whatever is on the other side of the shield.) To confirm the ability of the sleeves to block the effects of the biofield, several test subjects placed their hands and forearms inside 5" diameter Faraday sleeves. None of the participants were able to sense the biofield from the experimenter's hand when it was outside the screen above the participants' hands.

Concentrating the biofield to increase its strength. It was mentioned earlier that a polarity between the hands has been identified. In the Rosa article this was referred to as "transmitting" and "receiving" hands; it is also commonly identified as the "positive hand" and the "negative hand." Since polarities do not exist separately in nature and are always internally connected; having a "transmitting hand" and a "receiving hand" means that the internal portion of the biofield must circulate internally though the arms and externally between the hands similarly to the way fields circulate through and around magnets. *(See Figure 4.)*

A well-known method of increasing a magnet's field intensity is to bend the magnet into a horseshoe shape; this concentrates the flux and increases the field strength between the poles. Likewise, bringing the experimenter's hands into close proximity increases the intensity of the biofield. *(See Figure 5).* To increase the intensity of the biofield one of the experimenter's hands could be placed above and the other below the participant's hand.

Third Stage of the Experiment

Both the above modifications were made for the third stage of the experiment. 12" x 14" oval Faraday sleeves were constructed large enough to accommodate one of the participant's hands and both of the experimenter's hands. The participant's hands and forearms were elevated on a block of folded cotton towels inside the sleeves and the experimenter's hands approximately 4 cm above and 4 cm below whichever of the participant's hands the experimenter was attempting to affect. As in the previous trials, each participant was allowed to feel the experimenter's hands in place at each hand inside the sleeves prior to the trials. *(The apparatus is shown in Figure 6.)*

Results of the Third Stage

Twenty-two ST practitioners or practitioner trainees were tested for a total of 220 trials. Individual scores ranged from 6 correct to 10 correct for a total of 208 out of a possible 210 (95%). Completion times for the sets of 10 had again shortened, now ranging from 40 seconds to 3 minutes. Compared to the earlier tests, their responses were quick and firm, often spoken as the buzzer was still sounding.

Fourth Stage, checking the Experiment

Persons skeptical of the biofield's existence made numerous suggestions as to what they thought might be actually sensed during scanning. The most common suggestion (apart from the arch skeptic's statement that it is all imagination anyway) was that it was merely heat or wind from the experimenter's hand. *(See Table 2 for a list of actual reported sensations.)*

Several tests were conducted to rule out the possibilities of heat and wind. A Wandel Golterman Wavetek 23XT with a K-type thermocouple with a sensitivity of 1% was used to check for heat.

(1) The same procedure used in Stage Three was repeated with the thermocouple fixed in place ½" above the participant's hand. The participants detected when the experimenter's hand was in place above one of the participant's in less than one second, but it took 5 seconds for the thermocouple to register a change of 1/10° C. This appears to rule out heat.

(2) To test for the possibility that wind from the experimenter's hand was being detected, the experiment was repeated with the participant wearing a semi-transparent, green plastic glove. The thermocouple was placed inside the glove and allowed to stabilize. The participant reported sensing the biofield in approximately one second and still reported the "magnetic-like effects" but it now took 9 seconds for the thermocouple to record a 1/10° C change.

(3) An extra experiment was conducted with an apparatus devised to block both heat and wind. Open-ended boxes were constructed of corrugated cardboard sides and front (facing the experimenter) with thin sheets of tissue forming the top and bottom. These were inserted into the Faraday screens and the participants were instructed to place their hands inside the boxes. The experimenter inserted his hands above and below the boxes during the trials. Again the participant scored ten out of ten correct; however, the response times were several seconds longer and the participant reported that the sensations were blurred. Following this, the participant hands were removed and the thermocouple was inserted into the space where the hands had been. It took 20 seconds for the temperature to rise 1/10° C when the experimenter's hands were placed above and below the box.

(4) An additional test was performed to determine which of the two added features (Faraday sleeves or bringing the experimenter's hands together to concentrate and increase the biofield being detected) was the major cause of the increase in scores. Three practitioners repeated the ten trial tests with the Faraday sleeves in place but with the experimenter hovering one hand above the participant's hand but without the other below it. All three again scored 10 out of 10 but the overall response time for the answers was somewhat longer than with both hands. This confirms that bringing the hands close together does increase the field strength.

(5) An unplanned event confirmed the capacitive characteristics of the external portion of the biofield. Several participants had gathered on a day of high humidity in preparation for a portion of the third stage experiment. None of the first six who participated in the pretest trials (where the experimenter allowed the participants to feel what it was like when his hand is in place above each of the participant's hands) could feel the experimenter's hand at all. This sensitivity to humidity is consistent with the effect of humidity lowering the dielectric constant of capacitors and with the difficulty of producing minor static charges during high humidity conditions. (The trials were postponed to allow the humidity to normalize.)

Conclusions

This experiment, using a method originally developed by skeptics as a secure way to detect whether the biofield existed, has established that the biofield can be detected by proximate touch; the fact that it is detectable demonstrates that it is a field in physics.

The success of the Faraday screens in blocking the effects of the biofield offers strong evidence that the biofield is a field within the electromagnetic continuum; this is further confirmed by the humidity sensitivity noted in the experiment. These characteristics, as well as others noticed in clinical practice indicate that the external portion of the biofield, the aura, is likely to be a low-

energy capacitive field similar in nature to low-voltage electrostatic fields (too low to produce sparks). With this evidence, these characteristics can be further investigated and quantified in low energy physics laboratories.

Although this experiment was not intended to prove clinical efficacy, the information that was obtained should aid in the construction of improved clinical trials. Divorcing the biofield from the notion that it is just a placebo, or that it is a product of mind, and establishing it as a field in physics begins the process of rational investigation that can only lead to improved therapeutic techniques for the betterment of human and animal health.

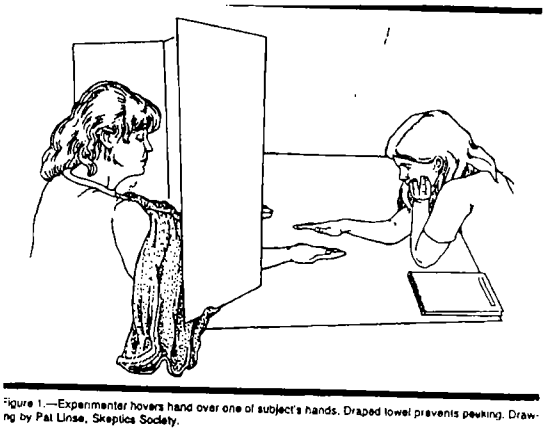


Figure 1.—Experimenter hovers hand over one of subject's hands. Draped towel prevents peeking. Drawing by Pat Linse, Skeptics Society.

Figure 1 (from JAMA, 1998;279:1007-8.

Table 1

Differences in concepts about the biofield and approaches to practice between HT and ST *Note: Not all practitioners hold to every concept.*	
Healing Touch™ & Therapeutic Touch™ Practitioners	SHEN® Therapy Practitioners
Scan the external portion (the aura) of the biofield as part of the therapeutic strategy	Do not scan for disturbances in the aura of the biofield as a part of their therapeutic strategy
Rely on metaphysical principles and concepts to explain the biofield	Explanatory model of the biofield is based on classical (mechanical) physics
Believe that active intention is a necessary part of their procedures	Do not believe that active intention is necessary for their procedures to work
No therapeutic use is made from having identified that they have a transmitting and a sending hand	Use the polarity between their hands in ways similar to the ways polarity works in electromagnetic circuitry
Do not incorporate the conventions of the physics of fields in developing their procedures	Follow the universal conventions of the physics of fields in developing their therapeutic strategies
Believe healing comes through resonance of the practitioner's field with the client's	Believe healing occurs through a describable chain of physiological/biological events
	Observe that the polar difference between their hands increases through their training and practice

Table 2

Primary sensations reported when sensing the biofield between palms of one person and another
"A pulling feeling"
"Feels like magnetism"
"There is something stretchy"
"I feel tingles"
"Outward pressure"
"A spongy feeling"
"It's like elastic strings"
"Something pushing"
"It prickles"
"A cushion"
"A static-like feeling"
"It feels like electricity"
"Rubbery feeling"
"Something sticky"
"Heat"
"Coolness"

First Stage Statistical Results

A total of 540 trials were performed; individual scores ranged from 3 to 10 of 10 correct. The HT group (N=37) had a mean of 5.08 with a standard deviation of 1.95. A 95% confidence interval around their mean is from 4.43 to 5.73. Since this interval includes the chance level of 5, the HT scores are not better than chance.

The ST group (N=17) had a mean of 6.00 with a standard deviation of 1.70. Their 95% confidence interval runs from 5.13 to 6.87. The ST group is significantly above chance.

Table 3 Second Stage Individual Results

JD 1" 4 SETS 04/08/00 2" 4 SETS 04/14/00 3" 4 SETS 04/25/00
SCORES: 6-8-8-5 (T27:40) 8-7-6-6 (T27:40) 5-6-10-7 (T28:40)
AGGREGATE: 82 OF 120 OR 68.3%

COMPARISON OF HAND SENSITIVITY

RH	LH	RH	LH	RH	LH
0*V*	0 V	0 V	0 V	0 V	0 V
8-5	2-4	5-5	5-3	4-1	6-4
4-4	6-4	4-3	6-4	4-3	6-3
3-3	7-5	7-4	3-2	3-3	7-7
3-2	7-3	6-3	4-3	5-3	5-4
18-14	22-13	22-15	18-12	16-10	24-18
.780	.590	.682	.666	.625	.750

CM 1" 4 SETS 04/08/00 2" 4 SETS 04/14/00 3" 4 SETS 04/25/00
SCORES: 6 6 3 6 (21:40) 6 6 6 5 (T23:40) 7 6 6 5 (T24:40)
AGGREGATE: 68 OF 120 OR 56.6%

COMPARISON OF HAND SENSITIVITY

RH	LH	RH	LH	RH	LH
0 V	0 V	0 V	0 V	0 V	0 V
8-4	2-2	4-2	6-4	5-3	5-4
6-4	4-2	6-3	4-3	6-4	4-2
3-0	7-3	3-2	7-4	5-3	7-3
7-4	3-2	7-4	3-1	9-4	1-1
24-12	16-9	20-11	20-12	25-14	15-10
.500	.562	.550	.600	.560	.600

HN 1" 4 SETS 04/08/00 2" 4 SETS 04/14/00 3" 4 SETS 04/25/00
SCORES: 4 5 5 7 (T21:40) 7-6-6-6 (T25:40) 9 9 8 7 (T33:40)
AGGREGATE: 79 OF 120 OR 65.8%

COMPARISON OF HAND SENSITIVITY

RH	LH	RH	LH	RH	LH
0 V	0 V	0 V	0 V	0 V	0 V
6-3	4-1	7-5	3-2	3-3	7-6
3-2	7-3	5-4	5-2	6-5	4-4
6-3	4-2	5-4	5-2	4-4	6-4
3-3	7-4	5-3	5-3	6-4	4-3
18-11	22-10	22-16	18-9	19-15	21-17
.611	.500	.727	.500	.790	.784

Figure 4

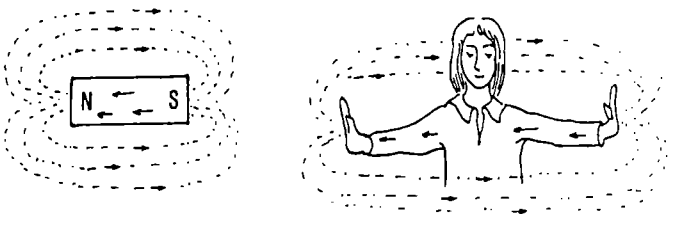


Figure 5

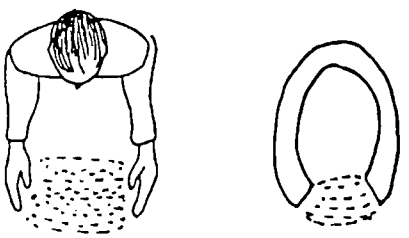
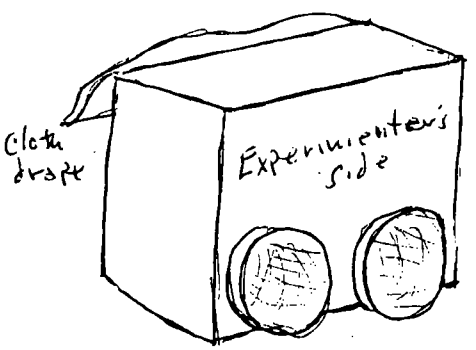


Figure 6



14 x 18 mesh brass screen used in the sleeves

****

TRAVEL PRINT/REVIEW - APPROVED

08/17/00 16:18:47

****

ORDER#: WYW00133 ENTRY DATE: 08/17/00 FY CAN: 08338443
BID: NCCAM CLERK ID: CB AO: MDA AO APPROV DATE: 08/17/00
UPDATE: 08/17/00

SSN: ----------
TRAVELER: STEPHEN C GROFT STATUS: REQUEST APPROVED
TITLE: EXEC. DIR., WHITE HOUSE COMM.
MAIL ADDRESS: TRIP START: 09/07/00 07:30 AM
2 HARVARD COURT END: 09/10/00 06:30 AM
ROCKVILLE, MD 20850

DUTY STATION: BETHESDA, MD BLDG: RKLG RM: 1010 TEL: 435-6198
CONTACT: CAROLYN BELLAMY BLDG: 31 RM: 5B37 TEL: 496-8004
RECOMMENDED BY: CAMILLE HOOVER TITLE: EXEC. OFF., NCCAM
EMPLOYEE: CIVILIAN EXEMPT FROM CREDIT CARD REGS: NO
PURPOSE: TO ATTEND MEETING IN SAN FRANCISCO, CA ON BEHALF OF THE WHITE HOUSE COMMISSION FOR NCCAM

ITINERARY: SAN FRANCISCO/BETHESDA
PRIMARY TRANSPORTATION: AIR CLASS TRAVEL: COACH
JUSTIFICATION NON-CONTRACT CARRIER: HOURS
AEA AUTHORIZED IN ONE OR MORE ITINERARY LINES!

			SPONSOR NO/RC
FARE: BLANKET GTA	CAN: 08338443 OC: 2113	EST.COST:	610.00
POV-EST. MILES: 120	MILEAGE RATE: .325	EST.COST:	39.00
EXCESS TAXI (OTHER THAN TO AND FROM TERMINAL)		EST.COST:	
CAR RENTAL, IF AUTHORIZED:		EST.COST:	
OTHER TRANSP. (PARKING, TOLLS, TAXI, SUBWAY, BUS)		EST.COST:	100.00

MIXED MODE AUTHORIZED? NO
GSA VEHICLE AUTHORIZED? NO
EXCESS BAGGAGE AUTHORIZED? NO ESTIMATED WEIGHT?

********** SUMMARY **********

	OC	EST. COST
MAXIMUM ESTIMATED PER DIEM:	2113	1,179.00
TRANSPORTATION (EXCLUDING GTA/GTR):	2113	139.00
ADDITIONAL EXPENSES:	2113	.00
SUBTOTAL:		1,318.00
REGISTRATION: DUE DATE:	252W	.00
GTR#: APPROP#: 0896 GTA/GTR COST:		610.00
TOTAL ESTIMATED COST:		1,928.00

ADVANCE TO BE PAID BY (ATM MACHINE) SPONSORED AMOUNT: .00
ADVANCE RELEASE DATE: 08/28/00 AUTHORIZED TRAVEL ADVANCE: 484.00

8/17/00 _____

DATE SIGNATURE (STEPHANIE FURIN - AUTH OFFICIAL)

RECEIPT ENVELOPE

WYW00133
ACCOUNT

DATE ENDING
09/09/00

NO.	DATE	ITEM	TAX	CASH	CHK	CARD	AMOUNT
1							
2							
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4							
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MILEAGE:	ENDING		SUBTOTAL	
	BEGINNING			
	TOTAL MILEAGE		OTHER	
	PERSONAL		LESS REIMBURSEMENT	
	BUSINESS		**TOTAL**	

NOTES WITH WHOM, DISCUSSED WHAT, WHERE

USE FOR REIMBURSEMENTS, TAX PURPOSES, ETC. FOR EASY RETRIEVAL, WRITE CORRESPONDING NUMBER ON RECEIPT.

ORDER No. 011-217

Withdrawal/Redaction Marker
Clinton Library

DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. agreement	contract between Betia Bentley and WHCCAMP (partial) (1 page)	nd	b(6)

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

OA/Box Number: 43233

FOLDER TITLE:
Town Hall, San Francisco, September 8, 2000 [2]

2011-0568-S
kc842

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]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
P6 Release would constitute a clearly unwarranted invasion of personal privacy [(a)(6) of the PRA]

C. Closed in accordance with restrictions contained in donor's deed of gift.
PRM. Personal record misfile defined in accordance with 44 U.S.C. 2201(3).
RR. Document will be reviewed upon request.

Freedom of Information Act - [5 U.S.C. 552(b)]

b(1) National security classified information [(b)(1) of the FOIA]
b(2) Release would disclose internal personnel rules and practices of an agency [(b)(2) of the FOIA]
b(3) Release would violate a Federal statute [(b)(3) of the FOIA]
b(4) Release would disclose trade secrets or confidential or financial information [(b)(4) of the FOIA]
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]

INDEPENDENT CONTRACTOR SERVICES AGREEMENT

This independent contractor agreement is entered into by and between Betia K. Bentley, an individual who resides at (b)(6) Waycross, Georgia (hereinafter referred to as "Contractor"), and the White House Commission on Complementary and Alternative Medicine Policy with its principal place of business at Rockledge Center, 6701 Rockledge Drive, Building 2, Bethesda, Maryland (hereinafter referred to as "Client").

SECTION 1: ENGAGEMENT

It is understood and agreed that Contractor is an independent contractor and not an employee, agent, joint venturer, or partner of Client. Contractor has been retained to assist in administrative support, research assistance, and analysis preparation of the Client's projects, including but not limited to, town hall meetings and regular meetings of the Commission .

SECTION 2: COMPENSATION

A. In full consideration for the performance of the Services hereunder, and for any rights granted or relinquished by the Independent Contractor under this Agreement, the Client shall pay the Independent Contractor an annual fixed fee (the "Fee") in the amount of $73,000.00 payable in monthly installments of $6083.33, due on the 1st day of each month. No employment taxes of any kind (including, but not limited to, FICA, federal or state personal income taxes, state disability insurance taxes, and state unemployment insurance taxes) shall be withheld or paid with respect to any payments to Contractor.

B. In the event that the project terminates prior to termination date, Client agrees to pay entire remainder due in one payment or continue payment of fixed fee for duration of the contract.

C. Client agrees to pay a one time recruitment/relocation bonus of $5,000.00, which will be due immediately upon commencement of this contract.

D. Payments shall be preceded by an invoice from Contractor (to be submitted monthly), which Client shall then pay in the ordinary course.

E. Client will reimburse Contractor for reasonable and necessary expenses, within 15 days of submitted expense report, incurred in the performance of the Services; provided, however, that all such expenses shall be subject to Client's prior approval.

F. Client will reimburse Contractor for all reasonable and necessary travel expenses, including, but not limited to, air fare, ground transportation, and lodging, incurred in the performance of the Services, within 15 days of submitted expense report.

G. Contractor shall be responsible for all necessary travel expenses, of a single trip, within a 30 mile radius.

SECTION 3: INDEPENDENT CONTRACTOR RELATIONSHIP

A. Contractor agrees to perform the services hereunder solely as an Independent Contractor. The parties to this Agreement recognize that this Agreement does not create any actual or apparent agency, partnership, franchise, or relationship of employer and employee between the parties.

B. Further, Contractor shall not be entitled to participate in any of the Client's benefits, including, but not limited to, any health or retirement plans.

C. Client shall not be liable for taxes, medicare, social security, or other withholdings for or on behalf of Contractor under this Agreement. All such costs shall be Contractor's responsibility.

SECTION 4: TERM

A. The term of this Agreement shall commence on the date hereof and shall continue until March 8, 2002, unless extended by both parties.

B. Upon the completion of this project, Client and Contractor may agree to renegotiate this contract for further services.

IN WITNESS WHEREOF, the parties have caused this Independent Contractor Services Agreement to be executed by their duly authorized representative.

Contractor:

_____ _____

(Printed Name) (Signature/Date)

_____

(Title)

Client:

_____ _____

(Printed Name) (Signature/Date)

_____

(Title)

Witness:

_____ _____

(Printed Name) (Signature/Date)

CALCULATED ANNUAL FEE

Base Annual Fee: $45,000.00

Withholdings	**Percentages**	**Total Amount Applicable** (Multiply Percentage with Base Annual Fee for this total)
Federal Taxes	28% of everything over $26,000 + $3937.00	$9257.00
State Taxes	3.01% (Maryland taxes)	1354.50
Self-Employment Tax	15.3%: Medicare (12.4%) Social Security (2.9%)	6885.00
Health Benefits	25%	11250.00
Retirement	6%	2700.00
Disability Insurance	$50.00 per month	600.00
Life Insurance	$40.00 per month	480.00
TOTAL:		**$77,526.50**

Steve,
Above is the original calculation with the advised percentages. Keeping our budget concerns in mind, I recalculated some of my benefit percentages and amounts, which I could legally adjust.

Base Annual Fee: $45,000.00

Withholdings	**Percentages**	**Total Amount Applicable** (Multiply Percentage with Base Annual Fee for this total)
Federal Taxes	28% of everything over $26,000 + $3937.00	$9257.00
State Taxes	3.01% (Maryland taxes)	1354.50
Self-Employment Tax	15.3%: Medicare (12.4%) Social Security (2.9%)	6885.00
Health Benefits	**20%**	**9000.00**
Retirement	**3%**	**1350.00**
Disability Insurance	$50.00 per month	600.00
Life Insurance	$40.00 per month	480.00
TOTAL:		**$73,926.50**

(*I decreased the asking fee to **$73,000.00**)