Sarcode Homeopathy is a key part of Medicine

The International Journal of the Medical Science of Homeopathy, Energetic Medicine Naturopathy

Evidence Based Literature to Protect and Explore Natural Medicine since 1996

ISSN # 1417-0876, 2041-4293

http://ijmshnem4u.com/

Issue on Sarcode Homeopathy in Medicine 2017
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Medical doctors use Homeopathy everyday when they use glandular or hormone therapy.

Professor of Medicine Desire’ Dubounet for IMUNE

SARCODES (ISOPATHIC TREATMENT)

Sarcodes may be used according to the simililum or as a prophylactic. Examples of sarcode source material are:

- **plant sarcomes:** Terebitha, the oleic exudation from pine trees
- **animal sarcomes:** RNA and DNA; Cholesterinum, Folliculinum
- **bacterial sarcomes:** Penicillin derived from a culture.
A Sarcode remedy could be a tissue or secretion from an organ eg. testes, ovary or heart. Any physiological processes can be a sarcode remedy. A sarcode remedy is related to the functions of the body and can be derived from any glands, secretions, hormones, neurotransmitters, enzymes, cellular molecules such as DNA, RNA, energy releasing compounds from cellular processes in all cells of the Krebs cycle like ADP-ATP. 88 hormones have been discovered; 15 of these have been proved as remedies so far.

At this point we glimpse the sheer scope of what the sarcodes are introducing to homeopathy.

Adrenalin is a neurotransmitter and a hormone, Cholesterinum, Cortisonum, Corticotropinum, Dopamine are in many pathways; Folliculinum, Histaminum, Insulinum, Oophorinum, Orchitinum, Pancreatinum, Parathyroidinum, Pepsinum, Pituitaria glandula anterior, Pituitaria glandula posterior, Urea, Secretin in the stomach, Somatostatin in gut.

Folliculinum has to be a perfect mother, wants to take care of everyone.

Cortisone has to react quickly to keep everything damped down.

Oxytocin produces bonding and bliss, connection, addiction to the high of a sexual connection.

Glandular nutritional products, also referred to as protomorphogens, have been used for years to help balance body chemistry and rebuild health. Many people ask what glandular products are, how they are made and why they are recommended?

What are Glandulars?

Most brands of glandular products are freeze-dried tablets or capsules containing defatted organs, glands or other tissues from bovine or porcine sources. There are several other processes to produce glandulars. They can be formed with a salt extraction process or prepared in a homeopathic form. A few companies use neonatal glands - glands from very young animals. Endo-met Laboratories uses freeze-dried glandulars.

How are Glandulars Manufactured?

In the freeze-dried method, the raw material is collected from animals inspected before and after death in government-inspected facilities. Some come from the United States, but the material is often imported as well.

The material is shipped to the laboratory in a frozen form. There it is first ground in a meat grinder. It is laid on stainless steel trays and stored in a freezer until it is hard frozen. The trays are then loaded into a freeze dryer. This device creates a vacuum and applies low heat to remove most the water from the product.
In 2-3 days, the water content is reduced to less than 6%. The freeze-dried product is then defatted and ground to a fine powder. Several batches may be blended to produce the final product. This is statistically sampled for any chemical or bacterial contamination before it is released for sale.

Why are Glandulars Recommended?
Two thousand years ago, the great physician Hippocrates stated (and I paraphrase), "If a person has a weak liver, give liver. For weak kidneys, give kidney". The principle was known long ago that giving the organ or gland from another animal can strengthen and support the function of that organ in the human. Using animal glands for healing is part of many medical systems worldwide.

Homeopathy employs a similar principle that is termed "like cures like". In modern times, studies were conducted using radioactively tagged glandular products. It was found that ingesting an animal tissue, such as liver or kidney, results in the tissue's migration to the target organ. The radioactive dye concentrated in the same organ in the human as the ingested gland or organ.

Exactly how glandular products work is not absolutely clear. Perhaps they provide nucleoproteins that nourish the target organ. Or there may be a vibrational resonance or similar phenomenon that helps to rebuild and regenerate the target tissue. Perhaps other mechanisms are also at work. In practice, we know that the glandular products may be very helpful to assist the functioning and regeneration of the body.

In homoeopathy we have the following sarcode remedies:

Adrenalinum, Cholesterinum, Cortisonum, Corticotropinum, DNA, Folliculinum, Histaminum, Insulinum, Oophorinum, Orchitinum, Pancreatinum, Parathyroidinum, Pepsinum, Pituitaria glandula anterior, Pituitaria glandula posterior, Pituitaria glandula, RNA, Thyroidinum and Urea pura...
Natural Thyroid is Better than SYNthetic

Why Natural Thyroid is Better than Synthetic
This article is part one of a series.
For part Two, Click Here
For Part Three Click Here.

We use exclusively natural thyroid in our office, and a few times every day, I find myself explaining why natural thyroid is superior to Synthroid. In this article, we will explain why natural thyroid tablets are better than synthetic T4 only tablets, also called Synthroid.

Left Image: Thyroid Gland on Radionuclide Scan Courtesy of Wikimedia Commons.

What is Synthroid? What is in it?
Synthroid contains Thyroxine also called T4, which is identical hormone produced by the thyroid gland. Levothyroxine is the generic form of Synthroid. Common brand names include Thyrax, Euthyrox, Levaxin, L-thyroxine, Eltroxin and Thyrax Duotab in Europe; Thyrox in South Asia; Eutirox, Levoxyl and Synthroid in North America. Strictly speaking, Synthroid is bio-identical, even though it is synthetic.
What is in Natural Thyroid?
Natural Thyroid pills are made from desiccated porcine (pig) thyroid glands which contain Thyroxine (T4), T3, T2, T1 and Calcitonin.
Left Image: courtesy of wikimedia: Natural Thyroid tablets come from this animal, the pig.

Economics of Synthroid
As of 2005, 10 million people in the U.S. take thyroxine. When one considered that Abbott’s Synthroid is the most popular form of thyroxine, and the second-most prescribed drug in the U.S., one starts to understand the financial rivalry between Synthroid and natural thyroid competitors.

Left image: chemical structure of Tri-Iodothyronine (T3) notice three Iodine molecules. Add a fourth iodine molecule at the far left ring to make thyroxine, T4. Image courtesy of wikimedia commons.

What Does Mainstream Medicine Say?
Here is a typical statement by Mainstream Medicine found on a popular medical information web site called medicine.net. Armour is a natural desiccated porcine thyroid preparation containing T1, T2, T3, T4 and calcitonin. Synthroid contains only T4.

From Medicine.Net : Answering a Viewer Question
What is your feeling regarding natural vs. synthetic replacement therapy in hypothyroid situations? Armour, for example vs. Synthroid? from L.H.
**Doctor’s Answer:** While it is reasonable to assume that synthetic medications are less desirable than natural counterparts, in this case- natural thyroid hormone replacement is **definitely not an ideal solution** for the vast majority of people.

**Here’s why:** Armour thyroid is derived from desiccated pig (porcine) thyroid gland. A number of years ago, these natural preparations were our only alternative. Replacement with desiccated thyroid creates dosing problems because there is **no way to standardize the exact amount of the dose for each batch.** As a matter of fact, **these preparations do not report their dosage strength in milligrams, but rather, in grains of thyroid.** This is because, they don’t really know the milligram equivalent in each dose. Dosing is also based on the assumptions that each gland has equal amounts of hormones as the next gland, and that the ratio of T4 and T3 (the more active hormone) are similar and constant in each gland from the pigs. There is no way to be certain of this, and patients on these preparations often **have fluctuating hormone levels,** which may or may not result in symptoms. Regardless of symptoms, the goal of replacement therapy is to keep the **hormone levels as stable as possible. This is much easier to achieve with synthetic preparations such as Levoxyl and Synthroid.** These preparations come in a vast number of standardized doses, allowing for **minute adjustments** in hormone dosing. There is another comment that should be made. With all the issues surrounding “mad cow disease” and other ailments, I personally am reluctant to offer animal based therapy to patients when a safe effective well studied synthetic preparation is widely available. I hope this helps answer any questions you may have. Thank you for your question.

**Medical Author: RM, M.D.**

“Natural Thyroid is Not an Ideal Solution” ? !!!!

This nonsense really makes my blood boil and my eyes pop out of head. Let’s start by doing a little research. If the above statement is true, we should expect to find that the FDA **HAS NEVER** recalled Synthroid because of problems with stability or potency, and we would expect that the FDA **HAS** recalled natural thyroid pills because they are unstable, and vary in potency. So let’s ask the FDA about this. What do we find? In reality, the FDA says Synthroid is unstable and varies in potency, while natural thyroid from RLC labs **HAS NEVER** been recalled for instability or variation in potency.

Is Synthroid a Reliable and Stable Drug?

No, Says the FDA.
Synthroid was marketed in 1955, but not FDA approved until July 24, 2002 because of a “history of potency failures…indicates that Synthroid has not been reliably potent and stable.” – United States Food and Drug Administration Letter to Synthroid Manufacturer, Knoll Pharmaceuticals, April 26, 2001 (link)

**Unstable, not of Consistent Potency from Lot to lot**

Here is an FDA document August 14, 1997, Docket No. 97N-0314, which says:

“The drug substance levothyroxine sodium (also called Synthroid) is **unstable** in the presence of light, temperature, air, and humidity. Unless the manufacturing process can be carefully and consistently controlled, orally administered levothyroxine sodium products **may not be fully potent through the labeled expiration date, or be of consistent potency from lot to lot.**

There is evidence from recalls, adverse drug experience reports, and inspection reports that even when a physician consistently prescribes the same brand of orally administered levothyroxine sodium, patients may receive products of variable potency at a given dose. Such variations in product potency present actual safety and effectiveness concerns.

However, no currently marketed orally administered levothyroxine sodium product has been shown to demonstrate consistent potency and stability and, thus, **no currently marketed orally administered levothyroxine sodium product is generally recognized as safe and effective.**”


**Armour Thyroid Pill Recall 2005**

To be completely fair, there was a recall of Armour thyroid in 2005. Lots manufactured in 2003 were found to have lost potency 2 years later in 2005, so Forest Labs recalled all tablets made in 2003. Since it was 2 years later, very little product from these lots was still in distribution, so it was actually a small recall.

*Left Image courtesy of wikimedia commons*
Change in Armour Formulation

Armour changed their thyroid tablet formulation in 2009, after which our patients reported they were not happy with the new formulation. To avoid any questions, we use exclusively Naturethroid from RLC labs. After five years of clinical experience with Naturethroid from RLC labs, I can fully endorse the product as an excellent form of thyroid medication.

Naturethroid Manufacturer Speaks Out: Natural vs Synthetic

From John Lowe’s article: Stability Effectiveness Desiccated Thyroid VS Levothyroxine John C Lowe Thyroid 2009 (14)

“In contrast to Naturally Desiccated Thyroid (NDT) containing T3 and T4, most synthetic medications contain T4 (or T3) only. In reality, many patients don’t start to feel normal again until they switch from synthetic to NDT (Thyroid USP). Natural Desiccated Thyroid hormone replacement has been used since the late 1800s, and it is one of the safest drugs available. It contains a full spectrum of thyroid hormones, T4 and T3 and also T2 and T1 as well.

The typical indication by the proponents of synthetic T4 is that NDT is unstable and inconsistent in its dosage. However, under the full USP monograph of both Thyroid USP as an ingredient and Thyroid USP Tablet as a finished product establishing full prescription status, this conventional argument could not be further from the truth. Unlike Nature-Throid™ and Westhroid™, synthetic medications have often been recalled due to batch inconsistencies. Yet most doctors are led to believe that desiccated thyroid is unstable.

To ensure that Nature-Throid™ and Westhroid™ Thyroid USP tablets are consistently potent from tablet to tablet and lot to lot, analytical tests are performed on the raw material (Thyroid USP powder) and on the actual tablets (finished product) to measure actual T4 and T3 activity.” (14)

By the way, contrary to the Medicine.net comment above, natural thyroid tablets are labeled in milligrams. For example, Naturethroid (RLC Labs) One Grain tablets contain 65 mg of natural desiccated thyroid.

Conversion of T4 to T3

Left Image courtesy of wikimedia: Conversion of T4 to T3 with IDI Deiodinase enzyme.
Sarcode Homeopathy is a key part of Medicine

A common problem for many patients who don’t feel well on Synthroid is the inability to convert T4 to T3. (15-18)

Synthroid contains T4 which must be converted to T3 by the body for it to work. This conversion is done by the De-Iodinase Enzyme (see image above). Sometimes this enzyme is deficient or not working, and many patients have an inability to convert T4 to T3. (15-18) They feel much better on a natural thyroid medication which contains T3 and T4. In my experience, most patients feel much better, with more energy, and relief symptoms when switching from synthroid (levothyroxine) to a natural thyroid such as Nature-thyroid.

Bio-identical hormone (Natural not SINthetic) as real Homeopathic Medicine

Bio-identical hormone replacement therapy (BHRT), also known as bioidentical hormone therapy or natural hormone therapy, is a term referring to the use of hormones that are identical on a molecular level with endogenous hormones in hormone replacement therapy. It may also be combined with blood and saliva testing of hormone levels, and the use of pharmacy compounding to obtain hormones in an effort to reach a targeted level of hormones in the body. A number of claims by some proponents of bio-identical hormone replacement therapy have not been definitively established through scientific testing. Specific hormones used in BHRT include estrone, estradiol, progesterone (which are available both in FDA-approved manufactured products and as pharmacy-compounded products), testosterone, dehydroepiandrosterone (both testosterone and dehydroepiandrosterone have some stringent limits placed on their availability and approval in Canada and the United States), and estriol (which is available in Europe but is not approved in Canada and the United States).

Custom-compounded BHRT is a practice almost wholly restricted to the United States. BHRT is a form of alternative medicine, and has been promoted as a panacea for many diseases in addition to being a means of relieving the symptoms of menopause and/or reducing the risk of osteoporosis (historically, the goals of hormone replacement therapy in allopathic medicine). There is little evidence to support many of these claims; the hormones are expected to have the same risks and benefits of comparable approved drugs for which there is an evidence base and extensive research and regulation. The exception is progesterone, which may have an improved safety profile than artificial progestogens, though direct comparisons with progestins have not been made. Risks associated with the process of compounding bio-identical hormones are not clearly understood. In addition, the accuracy and efficacy of saliva testing has not been definitively proven, and the long-term effects of using blood testing to reach target levels of hormones have not been researched.
The International Menopause Society, American Congress of Obstetricians and Gynecologists, Society of Obstetricians and Gynaecologists of Canada, The Endocrine Society, the North American Menopause Society (NAMS), United States Food and Drug Administration, American Association of Clinical Endocrinologists, American Medical Association, American Cancer Society and the Mayo Clinic have released statements that there is a lack of evidence that the benefits and risks of bioidentical hormones are different from well-studied non-bioidentical counterparts; until such evidence is produced the risks should be treated as if they are similar; and that compounded hormone products may have additional risks related to compounding. A major safety concern in bioidential hormone replacement therapy is that there is no requirement to include package inserts, despite the potential for serious adverse effects (including life-threatening adverse effects) associated with HRT. This can lead to consumers being deceived (and harmed), as they are misled into believing that any hormone-related problems and dangers are exclusively related to non-bioidentical hormones, and that BHRT is therefore safe and has no side effects. In reality, the risks of bioidentical hormones have not been studied to the extent of non-bioidentical hormones, so the risks are not well understood. Regulatory bodies require pharmacies to include important safety information with conventional hormone replacement therapy (CHRT) via package inserts.

History

Bioidentical hormones were first used for menopausal symptom relief in the 1930s, after Canadian researcher James Collip developed a method to extract an orally active estrogen from the urine of pregnant women and marketed it as the active agent in a product called Emmenin. It was supplanted on the market when its manufacturer, Ayerst (later Wyeth Pharmaceuticals), began producing the more easily manufactured conjugated equine estrogens in 1941 under the brand name Premarin; by 1992, Premarin was the most widely prescribed drug in the United States.

Diethylstilbestrol (DES) (INN, USAN, BAN), also known formerly and inappropriately as stilboestrol (BAN), is a synthetic, non-steroidal estrogen of the stilbestrol group that was first synthesized in 1938. It is also classified as an endocrine disruptor. Human exposure to DES occurred through diverse sources, such as dietary ingestion from supplemented cattle feed and medical treatment for certain conditions, including breast and prostate cancers. From about 1940 to 1971, DES was given to pregnant women in the mistaken belief it would reduce the risk of pregnancy complications and losses. In 1971, DES was shown to cause clear cell carcinoma, a rare vaginal tumor in girls and women who had been exposed to this drug in utero. The United States Food and Drug Administration subsequently withdrew DES from use. Follow-up studies indicated that DES also has the potential to cause a variety of significant adverse medical complications during the lifetimes of those exposed. The United States National Cancer Institute recommends all women born to mothers who took DES undergo special medical exams on a regular basis to screen for complications as a result of the drug. BECAUSE ALL FEMALE CHILDREN OF WOMEN TAKING DIETHYLSTILBESTROL GET NEOPLASTIC GROWTHS ON THE FEMALE SYSTEMS --- ALL-- Individuals who were exposed to DES during their mothers' pregnancies are commonly referred to as "DES daughters" and "DES sons". SYNTHETIC IS SYNTHETIC

Premarin: by 1992, Premarin was the most widely prescribed drug in the United States.
In the 1970s, research and reports indicating risks from synthetic conjugated estrogens began to appear. Investigation determined that the addition of a progestogen to estrogen treatment reduced the risks. As early as 1980, the British Medical Journal (now BMJ) recommended oral bioidentical progesterone as an option when side effects from synthetic progestogens otherwise mandated discontinuing treatment. Starting in 1980, side effects caused by synthetic progestin use prompted more research into bioidentical progesterone. In May 1998 the FDA approved Prometrium, an oral bioidentical progesterone product produced by Solvay Pharmaceutical.

Physicians John R. Lee and Jonathan Wright were pioneers in the area of BHRT. Lee authored several popular books on BHRT and promoted custom-compounded BHRT, with the goal of achieving what he called a "natural hormone balance". He based this goal on the clinical testing of saliva to establish where "deficiencies" existed, though agencies such as the FDA and the American Congress of Obstetricians and Gynecologists state that blood and saliva testing is unreliable and biologically meaningless. Lee also believed that progesterone acted as a panacea and general health tonic for many health conditions; he based his claims on anecdotal data rather than peer-reviewed research, and there have been no clinical trials demonstrating this to be true. Wright also authored a popular book on BHRT; he promoted a triple-estrogen formula he called "Triest", which combined the most common three estrogens (of over 25 types) found in human females: estriol, estradiol and estrone. Previous bioidential formulas had used only estradiol. This triple formula was based on a single unpublished study whose conclusions did not take into account how estrogens are processed and excreted in the body—particularly how the liver processes oral estrogens, converting most of them to estrone. No followup was performed by Wright to replicate these observations. Wright may have been the first proponent of BHRT to use the term...
"bioidentical"—the word he coined to describe unpatentable, plant-derived molecules he believed were identical to human hormones. However, no structural crystallographic evidence has been used to support the idea that these molecules are actually identical to endogenous human hormones.

When the Women's Health Initiative's reports on the unappreciated risks of equine estrogens were released, many prescribers of BHRT used Wright's assertions (and his terminology) to proclaim the superiority of bioidentical molecules despite a lack of scientifically supported evidence. Following the publication of a popular book written by actress Suzanne Somers in 2006, the term "bioidentical" gained more prominence in popular consciousness as a "poorly understood new adjective" regarding hormone replacement therapy.

**Terminology**

There is no single definition for the term "bioidentical hormone replacement therapy" (BHRT); it is generally used to refer to 17β-estradiol, but other uses include plant-based or compounded estrogen products that blend estradiol with estriol and sometimes with estrone. A "bioidentical hormone" is defined as a molecule identical to a hormone produced by the human body (though not all allegedly bioidentical hormones sold by custom-compounding pharmacies are necessarily molecularly identical to endogenous humans). Despite the term "bioidentical" being used in FDA packaging inserts since before 1998, the FDA considers "BHRT" as currently used by BHRT advocates to be a marketing term, not a scientific term, and does not recognize its use. The meaning of "plant-derived" has also been attached to the term "bioidentical", and it may also mean that the hormones are "natural"; throughout the 1990s plant-derived, compounded hormones were referred to as "natural hormone therapy". However, the term "natural" can be applied to all products where the principal ingredient originates from an animal, plant, or mineral source, and both bioidentical and nonbioidentical hormones can be produced from the same plant sources.

"BHRT" is often used to refer to a set of diagnostic, prescribing, preparation and marketing practices including compounding (the preparation of custom-mixed hormones by a pharmacist, according to a prescription), saliva testing, and an emphasis on countering the effects of aging rather than relieving the symptoms of menopause. This compounded BHRT package has been promoted by Suzanne Sommers, Oprah Winfrey and other proponents as safer and more effective than CHRT, though there is no evidence to support these claims. Compounded BHRT has been marketed on the internet by pharmacies which make unfounded claims for its safety and its effectiveness for a variety of conditions.

The lack of distinction between FDA-approved bioidentical hormones and compounded bioidentical hormones as part of a package that includes saliva testing and compounding has resulted in considerable confusion regarding exactly what BHRT is.

There are a variety of FDA-approved products, made using bioidentical estrogens and micronized progesterone, used to treat the symptoms of menopause.

<table>
<thead>
<tr>
<th>Hormone class</th>
<th>Type</th>
<th>Brand names</th>
<th>Preparations</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estrogens</td>
<td>Micronized estradiol</td>
<td>Estrace and others</td>
<td>Pill and vaginal cream</td>
<td>Vaginal cream for vaginal symptoms only; sourced from plants; estradiol is bioidentical until ingested and</td>
</tr>
</tbody>
</table>
### Estradiol and Progesterone Preparations

<table>
<thead>
<tr>
<th>Micronized progesterone</th>
<th>\textbf{Micronized progesterone}</th>
<th>Prometrium</th>
<th>Pill</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prochieve 4%</td>
<td>Vaginal gel</td>
<td></td>
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<tr>
<th>Combined preparations</th>
<th>\textbf{Estradiol and norethindrone acetate}</th>
<th>CombiPatch</th>
<th>Patch</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>\textbf{Estradiol and norgestimate}</td>
<td>Prefest</td>
<td>Pill</td>
</tr>
</tbody>
</table>

* Estradiol is bioidentical, but the progestin is not*
The term "synthetic" is also used incorrectly by lay "experts" in two different ways - to refer to the process used to manufacture all estrogens, including bioidentical estrogens, and to compounds that interact with estrogen receptors similarly to estrogen molecules, but that are not found in nature. Examples of the latter two included diethylstilbestrol and ethinylestradiol.

Uses

Main articles: Menopause and Hormone replacement therapy (menopause)

BHRT is used to reduce the symptoms of menopause. It is also promoted by some practitioners for anti-aging purposes and as providing benefits beyond menopausal symptom relief—improving the quality of life, though there is little evidence to support these claims.

Components and compounding

Typically, compounded preparations of bioidentical hormones include estriol, estrone, estradiol, testosterone, progesterone and sometimes dehydroepiandrosterone (DHEA), either individually or in some combination. They are promoted as natural, safer and (in some cases) more efficacious than CHT; however, there are no scientific studies to support claims of superiority of BHs over CHRT. Estimates from sales of bulk hormones for compounding suggest that more than one million women may be using compounded BHRT in the U.S.

Estrogens

In premenopausal women the majority of estrogen produced by the body is estradiol (produced primarily in the ovaries), while in postmenopausal women estrone (produced in fat cells) is the type of estrogen present in the greatest amount; however, the body is able to convert one type of estrogen into another to a certain extent. Because of the limited research into potency, delivery methods and conversion of the various estrogens, a valid scientific understanding of compounded estrogen products has not been achieved. Synthetic estradiol, taken orally, splits when absorbed in the gastrointestinal tract and delivers bioidentical estradiol to the bloodstream.

The hormone estriol, produced during pregnancy, is frequently compounded into bioidentical preparations in the United States. While some think it to be a weaker estrogen, with a more limited period of effectiveness than estradiol, it has been demonstrated to be a stronger estrogen in certain ways. Though initial research in the 1970s suggested possible use, follow-up studies have failed to confirm this potential. Estriol is not found in any FDA-approved drug, and its safety and effectiveness as a hormone supplement is unknown.

Estriol was part of the United States Pharmacopeia before FDA approval was needed for its use. Its approval was grandfathered in by the FDA until 2008 when the agency banned its use, stating that manufacturers of estriol would have to create a new application and estriol would be treated as a new drug. Its use is not approved by Health Canada; estriol is not available as a pharmaceutical preparation in Canada or the United States, but is a commonly prescribed conventional treatment in other countries and is available as a cream or vaginal suppository in the United Kingdom and the European Union. Estradiol is available as brand-name products in both oral and transdermal forms.
Progesterone

Progesterone is used both orally and transdermally. Oral progesterone is micronized (ground) to increase availability, and is approved by the FDA to treat endometrial hyperplasia when used in opposition to estrogen. It has also been approved to relieve menopausal symptoms, either alone or in combination with estrogen. It is more reliable in treating menopausal sleep disorders than synthetic progestins. Transdermal progesterone is often used as a component of compounded BHRT but has not been clinically proven to prevent endometrial hyperplasia, as oral progesterone has. The editors-in-chief of the scientific journal Climacteric state that the greatest difference in function between bioidentical and synthetic hormones may be found in progesterone's behavior compared with progestin. Laboratory studies have suggested that bioidentical progesterone binds primarily to progesterone receptors, while synthetic progestins activate other receptors with a variety of effects. The editors suggested that progesterone may have neutral-to-positive effects on the cardiovascular system, and induce apoptosis in breast epithelial cells. They also called for more research to examine and confirm the effects of progesterone on health, and for continued use of regulated (rather than unregulated) individually compounded products provided by pharmacies. These compounds have not been directly compared with each other in appropriate scientific tests, though as of 2010 trials had begun. Progesterone is approved for use by both the FDA and Health Canada as a brand-name oral preparation. The French epidemiological study Etude Epidemiologique auprès de femmes de l'Education Nationale suggested micronized progesterone may offer a reduced risk of breast cancer compared to other progestins, though large-scale clinical trials have not yet been conducted. A 2012 practice advisory published by the journal Canadian Family Physician concluded "...there is no convincing evidence that bioidentical hormones are safer or more effective than synthetic HRT."

Other hormones

Testosterone supplementation can improve libido in postmenopausal women, but can also reduce levels of high-density lipoprotein (good cholesterol). Commercial sources for testosterone for women in the U.S. are limited, and include the commercially prepared estrogen-testosterone mixture Estratest; compounding pharmacies are the main source of testosterone-only preparations for women. There is little published data to indicate dosing, duration and method of administration, although there is increasing popular awareness of testosterone's use for increasing postmenopausal libido. A testosterone patch has been approved for use in the United Kingdom and European Union, but in Canada and the United States it awaits long-term safety data.

DHEA is an androgen precursor that lacks FDA and Health Canada approval for use in women, and is not available in Canada as a pharmaceutical preparation; it is sold as an over-the-counter drug or incorporated into compounded preparations in the United States. In the body, it can be converted to testosterone and then to estrogen; there are no consistent scientific findings or safety information supporting its use. High levels of DHEA have been linked to breast cancer.

Compounding

Compounding pharmacies use commercially available bulk drugs to create new formulations which differ (in form or dosage) from those manufactured on a large scale by pharmaceutical companies. Custom-compounded BHRT is almost wholly restricted to the United States, where pharmacy compounding is governed at the state level while the FDA has regulatory authority over the compounded product. Some internet-based compounding pharmacies understate harm and claim benefits of compounded BHRT beyond what can be proven by evidence-based medicine, and many of their claims exceed those made by other, more mainstream, BHRT practitioners.
Adverse effects

The benefits—as well as adverse effects—are expected to be the same for bioidentical and synthetic hormones.[29] Dosages used in BHRT can be as high as ten times the oral dose provided by comparable HRT regimens; the hormones used are known to adversely impact biological markers of cardiovascular disease and may produce a substantially higher risk of heart attack or stroke because of this.[30] There are potentially serious adverse effects and important safety information which is required to be given with FDA approved HRT in the form of package inserts; however, package inserts are typically not given (or required) with compounded bioidentical preparations.[31][32][33] This has led consumers into the erroneous assumption that bioidenticals are safer than FDA-approved hormones or lack any adverse effects—one of the concerns expressed about the hormones.[34] BHRT has also been associated with endometrial cancer.[35]

Estrogens

Less common (but serious) side effects of all post-menopausal estrogens include increased risk or severity of breast, ovarian or uterine cancer, stroke, heart attack, blood clots, dementia, gallbladder disease, high blood pressure, liver problems, high blood sugar, fluid retention, enlargement of benign tumors (fibroids) of the uterus, a spotty darkening of the skin, especially on the face (melasma), and vaginal yeast infection.[29]

Estradiol

See also: Estradiol § Adverse effects

Estradiol (a type of estrogen) is—in the case of naturally menopausal women—only recommended for use for the shortest period of time and at the lowest effective dose due to its adverse-effects profile.[29] There is the potential for a range of adverse effects in breasts, skin, eyes, cardiovascular, gastrointestinal, genitourinary or central nervous systems. These risks, however, are very low.[29]

Progesterone

See also: Progesterone § Adverse effects

Progesterone can cause the emergence (or significant worsening) of abdominal pain, constipation, yeast infections, breast cancer, cystitis, acne, conjunctivitis, thrombotic disorders resulting in pulmonary embolus, strokes or heart attacks and—due to increased fluid retention—epilepsy, migraine, asthma and cardiac or renal dysfunction. Psychiatric reactions can include emotional instability, depression, aggression, decreased libido and drowsiness. Adverse effects can also occur in the urinary, central or peripheral nervous system or bones and muscles.[35] A review of clinical trials studying bioidentical progesterone use found that it was ineffective in managing vasomotor symptoms of menopause, but had mild and self-limiting side effects.[36]

Administration

Hormones can be administered in a variety of ways, including percutaneous skin and vaginal creams, oral pills, topical gels, vaginal rings and tablets, and transdermal patches. Though all preparations of a given type of estrogen (e.g. estradiol) may be molecularly identical before their introduction into the human body, estrogens administered orally are modified by the liver before entering the bloodstream and in this process, most is converted to estrone. However, estrogen bypassing the digestive tract and liver and entering through the skin is not converted to a new form before entering the bloodstream. Creams and gels applied to the skin also enter the blood directly and without modification but absorption of the gels, creams, and patches can vary from application to application, depending on the temperature and condition of the skin.[13] Pharmaceutical compounding is frequently used to modify the dose, form, and additives of the preparations, based on instructions from a health-care practitioner.
Criticisms

The primary difference between the popular promotions of CHRT and compounded BHRT involves BHRT advocates' use of regular testing of blood or saliva-bound hormone levels, use of individualized compounding rather than standard doses, dosing to attain certain levels in the body rather than for symptom relief, and the use of hormones for purposes other than relief of menopausal symptoms. Proponents of compounded BHRT have been criticized by many mainstream medical sources for making unsubstantiated claims about its effectiveness for a variety of purposes, and for promoting it as more safe and "natural" than CHRT.

Advocates for BHRT have claimed that commonly compounded BHRT preparations are not commercially available; this is false, as there are many FDA-approved hormone preparations containing bioidentical molecules available both as proprietary or generic brands. The exception is estriol, used in the compounded bioidentical preparations Triest and Biest—in 2008, the FDA banned estriol until a New Drug Application had been completed; these preparations are not approved by either the FDA, or Health Canada. Some advocates of compounding have also falsely claimed that customized compounding provides customized results; this is incorrect since it is aimed at producing a single hormone profile with absolute blood or saliva levels—which has not been demonstrated to be better than CHRT—and does not consider the rate at which individuals will differ in the activity, metabolism and excretion of the hormones. There have been no clinical trials directly comparing the effectiveness or efficacy of bioidentical versus nonbioidentical compounds.

A 2010 article published in The Medical Letter on Drugs and Therapeutics concluded "There is no acceptable evidence that 'bioidentical' hormones are safe or effective. Patients should be discouraged from taking them."

Salivary testing and compounding

BHRT is frequently associated with testing of saliva to establish a baseline hormone level and compounding of the substances by pharmacists (according to a doctor's advice) to produce preparations (and blood levels) of hormones that are individualized to the patients. There is no research demonstrating any benefit to either of these practices. Though promoters of BHRT claim that saliva testing can be used to "customize" the level of hormones for individuals, and tests are used to determine which hormones are supposed to be deficient and require supplementation, there is no scientific basis to support the use of saliva testing. Estrogens are secreted in pulses within and over days, resulting in varying saliva levels. Certain compounding formulations also attempt to use a single profile for all women, with no evidence that a specific profile is beneficial in all cases and no recognition that women differ in their sensitivity to hormones and metabolic rate. Testing-based customizing also does not account for much of the effects, and synthesis of hormones occurs within tissues rather than in the blood; therefore, blood or saliva levels of hormones may not necessarily reflect actual biological activity. Other concerns include lack of evidence that samples are stable during storage and transportation, poor replication of results and considerable variation among assays. There are also no studies that link symptoms with blood or saliva levels of hormones. The FDA recommends, instead, adjusting hormone therapy to the symptoms of the patient, and there is no reason to adjust the dosing or monitor patients receiving BHRT. Skeptics of BHRT have also pointed out that there is no certainty regarding hormone levels in the body. The North American Menopause Society has supported warnings about the potential harm BHRT could cause, as it unnecessarily compounds drugs that are already FDA-approved in ways that lack an evidence base of safety or harm; this warning is supported by the Society of Obstetricians and Gynaecologists of Canada.

Although promoted as a way of customizing treatment, hormone therapy does not require customization; the use of testing to determine the amount of hormones administered could result in the dose being higher than the minimum recommended level to alleviate symptoms, or the administration of unnecessary hormones to asymptomatic women may result in greater risks to the
In addition, analysis of the material used to promote BHRT suggests that rather than basing hormone doses on saliva results, practitioners are actually adjusting the dose based on symptoms. Health practitioners customize the care of their patients on an ongoing basis by choosing the medication, dose and administration route individually, using approved medications that have a demonstrated safety record and are not subject to the errors and inconsistencies of custom-prepared combinations. Different bioidentical preparations result in mixtures with different strengths, and practitioners using compounded formulations may be unaware of the total dose of hormones their patients receive. In a 2001 test of compounded bioidentical hormone products, the FDA found that 10 out of 29 products failed their quality tests; nine out of ten failed potency tests (comparable rates for drug manufacturers were less than 2% and 0.13%, respectively). A 2006 test found potency levels ranging from 67.5% to 268.4% of the potency specified on the label; some samples were mixtures of different hormones with some being above, and others below, the specified potency. The failure of potency testing could be problematic and dangerous for progesterone products, where specific levels of progesterone are required to protect the endometrium against precancerous hyperplasia.

Boothby, Doering and Kipersztok summarize the issue as being a poor effort to apply principles of pharmacokinetics to achieve individualized dosing for drugs that do not require it.

Saliva testing has not been shown to accurately measure blood-bound hormone levels. The FDA recommends the lowest dose of hormones that effectively relieve symptoms and does not recommend custom compounding, blood or saliva testing.

Lack of evidence for claims

Bioidentical hormones have been advertised, marketed and promoted as a risk-free panacea that is safer than standard HRT. Literature reviews by private practitioners who sell bioidentical preparations suggest benefits and advantages in the use of BHRT over its conventional counterpart but there is significant skepticism over claims made about BHRT; there is no peer-reviewed evidence that compounded bioidentical hormones are safer or more effective than FDA-approved formulations or that they carry less risk. The hormones are expected to carry the same risks as their conventional counterparts, while the risks of including estriol—a hormone normally produced in large amounts only in pregnant women—have not been studied. The United States Food and Drug Administration (FDA) warned that claims about compounded BHRT products are unsupported by medical evidence—unlike claims about manufactured, FDA-approved products. Bioidentical hormones have been described as a form of marketing; the chief medical editor of Endocrine Today called compounded BHRT a "marketing concept" with no scientific backing and the FDA warned that pharmacies use these terms to imply that the drugs are natural and have the same effects as endogenous hormones. Other claims include compounded BHRT's ability to prevent or treat conditions such as heart disease, stroke, Alzheimer's disease, endometrial and breast cancer; fewer side effects; and custom blending to uniquely address individuals. There is no credible evidence to support these claims. Bioidentical hormones and compounded BHRT are expected to have the same risks and benefits as CHRT; the latter benefits from years of study and regulation, while compounded BHRT has no scientific data to support claims of superior safety or efficacy. The specific claims have been made for the efficacy of bioidentical hormones and compounded BHRT, with varying evidence to support or contradict them.

<table>
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<td>Bioidentical hormones fit precisely into human hormone receptors while conventional hormones fit have different binding affinities for different</td>
<td>Synthetic progestins and endogenous progesterone</td>
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"cockeyed"; this mismatch causes serious side effects receptors, depending on the model and animal used; these differing pharmacodynamics have not been associated with specific side effects

The body is unable to metabolize synthetic hormones The biological half-life for synthetic hormones is between five minutes and two days

Lack of progesterone causes irregular or painful, heavy menses Oral progesterone is no more effective than placebo at alleviating symptoms of premenstrual syndrome

Progesterone can counteract stress, increase metabolism and decrease abdominal fat There is no evidence to support weight loss due to progesterone

"Normal" levels of progesterone protect against breast cancer The claim is based on a single study of infertile patients during child-bearing years. Some evidence exists supporting a link between hormonal treatment for infertility and a reduced risk of breast cancer, but these benefits may not translate to women seeking relief from the symptoms of menopause

Progesterone therapy can prevent cardiovascular disease and atherosclerosis, and raise good cholesterol The use of micronized progesterone does not affect cardiovascular risk

The side effects reported in the Women's Health Initiative study were due to the synthetic nature of the hormones used "Cardiovascular benefit has not been proven with micronized progesterone in observational or experimental research...a multicenter, case–control study was conducted in postmenopausal women aged 45–70 years to examine potential differences in cardiovascular risk between the subtypes of synthetic progestins and micronized progesterone...Micronized progesterone and pregnane derivatives were not associated with an increased venous thromboembolism risk, whereas norpregnane derivatives...were associated with increased risk of thromboembolism...Thus, certain progestins are associated with increased cardiovascular risk, whereas pregnane derivatives
and micronized progesterone neither increase nor decrease cardiovascular risk in the doses studied."

| Proponents claim that bioidentical hormones, in addition to the demonstrated benefit of improving bone-mineral density, protecting the eyes and skin from drying out, regulating the menstrual cycle, improving mental function, improving blood cholesterol and reducing hot flashes and night sweats associated with menopause | There is no published evidence (derived from controlled research) supporting the claims of superior beneficial effects for bioidentical hormones as compared to conventional hormone therapy. Risk data have been published for conventional hormone therapy, and CHRT is not recommended to manage any chronic diseases, or for the prevention of cardiovascular disease |

| Estriol can decrease the risk of breast cancer | Estriol has been shown to cause breast cancer cell growth |

| Pharmacists use their expertise regarding bioidentical hormones to meet the needs of their clients and improve health outcomes | Compounding is a legitimate practice, but there is no evidence that clearly illustrates the benefits and risks of BHRT |

In 2006, actress Suzanne Somers released the book Ageless: The Naked Truth About Bioidentical Hormones endorsing the use of bioidentical hormones. The book was criticized by a group of doctors who (though generally supportive of BHRT) state that more research is required, and object to protocols mentioned in the book—because of their potential danger and the promoters' lack of qualifications. Somers' book may have increased awareness of the existence of BHRT for a growing number of menopausal women, but also may have caused confusion by making unsubstantiated claims for BHRT and referring to bioidentical hormones as non-drug products with fewer risks. Bioidentical hormones have also been discussed on The Oprah Winfrey Show, with Somers as a guest.

Bioidentical-hormone proponents Erika Schwartz and Kent Holtorf criticized a 2008 literature review on bioidentical hormones for addressing only compounded bioidentical hormones and not reviewing FDA-approved bioidentical products, which they believed added to the existing confusion. Michael Cirigliano and Judi Chervenak have stated in reviews of literature on BHRT that large-scale, peer-reviewed studies should be used to establish the safety, efficacy and beliefs about the use of bioidentical hormones. Two 2008 studies conducted in France found that estradiol plus micronized progesterone did not increase the incidence of breast cancer, while a comparison of estradiol plus different types of progestins found a reduced risk of invasive breast cancer with micronized progesterone. Christine Derzko stated that the evidence supported the use of bioidentical estrogen plus progesterone, but since the trial was an observational cohort study rather than a randomized controlled trial that compared different types of hormones head-to-head, more data was required before concluding bioidentical hormones were safer and preferred. Derzko concluded that there was weak (but promising) preliminary evidence that bioidentical hormones may present equal (or possibly lower) risks than conventional HRT; however, there was no data supporting the use of compounding. Derzko recommended following evidence-based medicine and cited concerns over BHRT by numerous medical organizations—requirements for oversight over
compounding, black box warnings for all bioidentical products, and the establishment of a mandatory adverse-events registry.[6] M. Sarah Rosenthal, Director of the University of Kentucky Program for Bioethics and Patients’ Rights, has stated that she believes BHRT is an experimental therapy that is often prescribed by practitioners who sell the products, and are thus in an unethical position of conflict of interest. Rosenthal has also described problematic issues with BHRT including patients receiving information from popular books while lacking the scientific literacy to separate rhetoric from evidence about hormone replacement, illegitimate claims of a "big pharma" conspiracy to suppress bioidentical prescribing, the extra and unnecessary cost of the products that are often not covered by insurance plans, and the inaccurate depiction of bioidentical prescribing as "cutting edge science" rather than unproven alternative medicine.[6]

"Natural" claims

Bioidentical hormones are frequently marketed as being "natural", or more natural than conventional HRT. The term "natural" can be used to suggest or emphasize a variety of different ideas—similarity with endogenous hormones, extraction from a plant-based source, and that the hormones are not manufactured or synthesized.[44]

- **Endogeny** - this meaning of "natural" implies that the hormones are molecularly identical to those found within the body. However, BHRT (like all types of HRT used in naturally menopausal women) is unnatural in that it opposes the biologically determined declining levels of fertility hormones in aging women and medicalizes a stage of human life that is probably normal.[48] In addition, most of the conjugated equine estrogens (CEE) extracted from pregnant horse urine (such as Premarin) are converted to human estrogens once they enter the body. However, not all are converted, and BHRT advocates allege that the small amount that is not converted may have some harmful effects. This is still being studied.[49]

- Plant-derived - Women who purchase compounded BHRT are more likely to associate the term "natural" with the idea that the hormones are derived from plant sources.[1] However, both bioidentical and nonbioidentical hormones are sourced from the same plants, generally soy beans or yams.[13]

- Manufacturing - both bioidentical and nonbioidentical hormones are synthesized using the same chemical precursors; diosgenin is extracted from soy or yam plants, converted into progesterone and used as a hormone chemical precursor to create the final product.[13] "Natural" is also used to promote the idea of being unmodified, and containing the "goodness" of a pure substance. However, this argument simultaneously draws upon a scientific discourse and methodology; even hormones called "bioidentical" have been heavily processed and converted in a pharmaceutical lab.[44] Premarin (conjugated estrogens extracted from the urine of pregnant horses) contains the only truly "natural" hormones—natural in the sense of being completely unmodified beyond blending the estrogens to achieve a specific ratio.[6]

The monthly newsletter Harvard Women’s Health Watch, published by Harvard Medical School, states that "natural" does not automatically mean "safe", and that "natural" can be used to indicate any product with an animal, plant, or mineral source—including hormones that are not bioidentical (such as Premarin), as well as the molecules extracted from soybean and yam sources used in many bioidentical and nonbioidentical commercial preparations.[13]

**Cost**

Compounded BHRT may be more expensive than conventional, FDA-approved HRT, and is often not covered by health insurance.[8][50]
Safety

Bioidentical hormones are expected to carry the same risks and benefits as their non-bioidentical counterparts, but there have been no studies that directly compare compounded bioidentical hormones with their non-bioidentical counterparts.\[1\][2] Hormones—as used in CHRT—have been studied for years and their risk, benefit, and effectiveness profiles are known and demonstrated through considerable research.\[12\]

In 2002, the Women's Health Initiative study (WHI), which was designed to demonstrate additional benefits for conventional hormone therapy (study participants were given Prempro or a placebo), was terminated prematurely after preliminary data indicated small increases in the risks of breast cancer, heart attack and stroke in older women using Prempro.\[51\] The early termination of the WHI study (which used conjugated equine estrogens) and the subsequent publicity about these previously unappreciated risks led to a decline in prescriptions for CHRT.\[52\] The results of the WHI were used by BHRT prescribers to promote bioidentical hormones as safer than the FDA-regulated preparations despite a lack of evidence;\[6\] according to the FDA, the results found by the study apply to all estrogens.\[12\] BHRT has since been strongly promoted as a natural alternative with fewer risks than CHRT, though there is no evidence to support this claim. BHRT practitioners recommend compounded hormones due to their claim that they more closely mimic the composition and ratio of circulating hormones in a woman's body than do commercially manufactured products.\[12\]

The Endocrine Society issued a position statement that bioidentical hormones carry essentially the same risks and benefits as non-bioidentical molecules.\[14\] In February 2009 the American Congress of Obstetricians and Gynecologists re-iterated its position (of November 2005) that there are no proven benefits in regard to the safety or efficacy of compounded bioidentical hormones, nor are there any benefits in salivary testing of hormone levels or customized dosing of hormones.\[53\] The Mayo Clinic states that there is no evidence that pharmacy-compounded BHRT is safer or more effective than conventional hormone replacement, and that some bioidentical hormones are already available in certain FDA-approved products.\[27\] The American Cancer Society also stated that “natural” and "bioidentical" hormones present the same risks as synthetic hormone replacement therapy such as heart disease, blood clots, strokes and an increased risk of breast cancer with long-term use.\[53\]

The U.S. Food and Drug Administration has warned several pharmacies about making unsubstantiated claims about the safety and effectiveness of compounded hormone products.\[38\] The North American Menopause Society has stated that compounded bioidentical hormones have not been approved by the FDA; there is no guarantee of purity, potency, efficacy or safety, and they may contain unknown contaminants.\[57\] The Australian Menopause Society has similarly stated that there is no evidence that bioidentical hormones administered using lozenges are any safer than their approved counterparts.\[38][59] The International Menopause Society has stated "There are no medical or scientific reasons to recommend unregistered 'bioidentical hormones'. The measurement of hormone levels in the saliva is not clinically useful. These ‘customized’ hormonal preparations have not been tested in studies and their purity and risks are unknown."\[38\]

In November 2006, the American Medical Association adopted a policy requesting that the FDA better monitor and regulate bioidentical hormones,\[67\] releasing an editorial stating that compounded bioidentical molecules were expected to have the same risks as conventional hormones until proven otherwise.\[67\]

Erika Schwartz and Kent Holtorf published papers stating that there is evidence to support a superior safety profile for bioidentical hormones when compared with non-bioidentical hormones, as well as improved relief of postmenopausal symptoms and better bone density and serum lipoprotein levels.\[4][59] Deborah Moskowitz also published an article stating that bioidentical hormones are superior to non-bioidentical hormones in safety and effectiveness,\[43\] though this review was criticized for “[attemtping] to demonstrate that BHRT has a good safety profile, but the data presented only serve to demonstrate similar risks to conventional HRT.”\[43\]
Quackwatch recommends against the use of bioidentical hormones due to lack of quality control over compounding, posing the same risks as conventional hormones, the use of unnecessary saliva testing, and for including the non-FDA-approved hormone estriol. Stephen Barrett, the site’s owner, concludes his review with the statement "The bottom line for consumers is very simple: Steer clear of anyone who prescribes "bioidentical" hormones or recommends saliva testing as the basis for evaluating hormone status."

**Regulatory status in the United States**

Compounded BHRT is used almost exclusively in the United States, and many FDA-approved formulations that are wholly or partially made of bioidentical hormones are available. Topical hormone preparations such as progesterone, estrogen and DHEA creams can be purchased in stores or over the internet and are not regulated by the FDA, as they are generally considered cosmetic.

When prescribed by a licensed practitioner, the compounding of bioidentical hormones is controlled by the state pharmacy boards rather than the FDA, and pharmacists are permitted to adjust dose and delivery method according to the prescription. However, the FDA does have authority over the compounded product. In 2001 the FDA surveyed a limited number of compounded preparations, including eight hormone compounds. All three estradiol products passed every test; however, two out of five progesterone products failed at least one test of potency, content or uniformity.

In October 2005 Wyeth Pharmaceuticals, a manufacturer of both FDA-approved bioidentical and nonbioidentical HRT preparations, filed a Citizen Petition with the FDA asking for enforcement action against compounding pharmacies which dispensed BHRT, and to investigate labeling and advertising guidelines. Soon after, the FDA took a number of enforcement actions against several (primarily Internet-based) pharmacies that were producing compounded BHRT and in 2008, banned the use of estriol in the US. The FDA stated that they did not take these regulatory actions against compounded bioidentical hormones in response to Wyeth’s request, since that is not the purpose of a citizen petition. They said that they had an ongoing investigation when they received the petition. The FDA has acknowledged that they are unaware of any adverse events connected to the use of estriol, but ordered pharmacies to discontinue its use. The agency’s Assistant Director of the Office of Compliance stated that use of estriol would require a permit for research and a new drug application. The FDA also stated that it has not approved any drug containing estriol and that no information had been submitted to the FDA regarding its safety and effectiveness. The FDA’s concerns over the marketing and use of bioidentical hormones were supported by the American Association of Clinical Endocrinologists. In response to the FDA’s actions, the International Academy of Compounding Pharmacists began a letter-writing campaign to the FDA to reverse this action, citing Wyeth’s attempt as a "self-serving, and at times duplicitous, campaign to restrict patients’ access to alternatives to its own products."

In November 2006, the American Medical Association adopted a policy urging the Food and Drug Administration to survey compounded BHRT products for purity and dosage; to maintain a registry and require mandatory adverse event reporting by manufacturers and compounding pharmacies related to bioidentical hormones; to mandate the inclusion of uniform patient information, including warnings and precautions regarding bioidentical products; and to prohibit use of the term "bioidentical hormones" unless the agency has approved the preparation.

On July 18, 2008, a US Appeals Court issued a ruling stating that new drug approval processes should not be applied to compounded drugs that complied with established guidelines, and also that provisions of the regulations relevant to the use of estriol were still in effect, preventing the FDA from taking action against pharmacies using estriol in compounded products.
The Wiley Protocol is a version of compounded BHRT, endorsed by T. S. Wiley, whose goal is to produce serum levels of estradiol and progesterone that are identical to those of a young woman with a normal menstrual cycle. The Wiley Protocol has been criticized for a variety of reasons. 

See also

- European Menopause and Andropause Society
- Women’s health

References

35. Columbia Laboratories, Inc. (November 2004). "Prochieve (progesterone gel)".PDF.
Sarcodes Homeopathy is a key part of Medicine

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http://www.downloads.imune.net/medicalbooks/Myths%20of%20Homeopathy.pdf
Sarcoid Homeopathy is a key part of Medicine

SYNTHETIC IS SYNTHETIC

When you discuss this with skeptical friends, ask them 2 questions First: Do they really trust the SIINthetic Chemical companies to put people over profit, do you trust that someone does not twist statistics to make money and compromise safety?? and the Second Question is --If you went to the restaurant tonite and saw SIINthetic Wine, Cheese, Spice, Apple Juice, or Meat , Would you order it??? Most People have now learned to Not Trust SIINthetics. Would you let your children order a SIINthetic (Totally ManMade) french fry.???
Glandulars, Protomorphogens and Cytosol Extracts

What are the benefits of glandulars, protomorphogens and cytosol extracts?

Often when you take a bunch of supplements “for prevention”, you are wasting your money and putting additional stress on the body because it needs to remove and process those things that it
Sarcode Homeopathy is a key part of Medicine

is not really utilizing. I’m rather Scotch. I’ll take supplements when I need to, but I don’t like wasting my money on them if I really don’t need them. I prefer using foods to establish health whenever possible, but I understand that some people would rather just pop a few pills. I’d rather have you pop the ones you need.

As I was researching the topic of glandulars, *protomorphogens* and cytosol extracts to write up this web page, I noticed one of my books said of glandulars, “Glandulars are concentrates of the hormonal glands, and have over the past decade, been hailed as a wonder drug. Evidence does not, however support these claims and many experts now discourage their use. The premise is that failing or aging glands can be rejuvenated by supplementation.”

**Glandulars:**

By definition, glandulars (also called Whole Gland Desiccated products) do consist of glands, but not specifically “hormonal” glands. Glandulars are whole organs that are dried at low temperatures and ground up then put into capsules. They are given for general support of various organs.

**Protomorphogens:**

Protomorphogens are like homeopathics. They promote healing over time. Protomorph products are composed of nuclear proteins and used to supply a better RNA/DNA template so that the body can assemble available nutrients to repair damaged tissue in the glands being treated. What differentiates protomorphogens from glandulars from cytosol extracts is the patented extraction process.

Protomorphogen extracts were first invented by a dentist, Dr. Royal Lee, in the 1940’s. This man was a genius and pioneer in the field of nutrition. Far advanced when compared to anyone in his field during his time and even now.

**Cytosol Extracts:**

Cytosol extracts are liquid extractions of the liquid within the cell and surrounding the nucleus. This liquid, called cytoplasm, that is extracted after the glands are ground up and the cellular walls have been broken. Cytosol products work faster and are stronger than whole gland products. They are great for people over the age of 40.

Whoever wrote the little educational quip above has OBVIOUSLY has never tried these products as many disease processes respond fabulously to these products! As Wayne Dyer always says, “Never criticize anything you know absolutely nothing about.” I have found that when I do this, it comes back to bite me. Maybe life will help them reevaluate their comments.

Standard Process glandulars, protomorphogens and cytosol extracts products (when well-placed and in the proper dosage) have been extremely effective in my practice. I have used 46 different Standard Process glandulars, protomorphogens and cytosol extract products over the last 1 1/2 decades, most with exceptional results. During the beginning of my career as a then “resisting
and skeptical” natural medicine practitioner, I started out taking 85 capsules and tablets each day! That’s a lot of capsules. I will say that I had a LOT of things wrong with me and was a pretty sick girl. I’m down to around 6 capsules and tablets a day now on a regular basis. Standard Process glandulars, protomorphogens and cytosol extracts products have truly changed my life. I can honestly say I have never felt this healthy…actually never believed I could feel this way.

I am living proof of what I teach my clients…if you give the body what it needs, it will respond.

Protomorphology, the study of how protomorphogens work, has determined that protomorphogens are just bundles of enzymes and their activators. Enzymes are the key to growth and repair and to maintaining cell health.

I’ve often wondered how cells inside the embryo break off and decide to differentiate into skin cells, hair cells, liver cells, etc. Well, inside each cell, we have hundreds of different enzymes. These enzymes are influenced by and responsive to nutrition, genetics, hormones, and the vibrations around us—including our thought processes. These protomorphogens acts as one tool we can use in the healing process to provide a healthy genetic template or blueprint for cellular repair.

For example, desiccated thyroid gland was first used in the late 1800s to help people with goiter and low thyroid function. Then thyroxine (T4) was isolated and used, but many doctors still preferred the whole gland as it seemed to be better absorbed and utilized. Later, the other thyroid hormones, triiodothyronine (T3) and calcitonin were discovered, but these were always part of the whole gland. Today, both individual synthetic hormones and standardized formulas of active thyroid tissue are used to support or replace thyroid activity.

In the early 1920’s, insulin was isolated by Sir Frederick Banting and Charles H. Best, who received the Nobel Prize for their discovery. Insulin has been a lifesaver for many diabetics, but it is also a very dangerous drug because it has such a narrow range of safety. Overdoses can cause very low blood sugar and shock. Insulin is destroyed in the gut, so it must be injected, but protomorphogens seem to be protected from this digestive process. The incorporation of pancreas protomorphogens and glandulars may not take away the need for insulin, especially for brittle diabetics, but it certainly can cut down the amount necessary to stabilize insulin levels.

Glandulars, like food, supply basic nutrients, such as amino acids, oils, vitamins, other active ingredients, and “Chi” or “life force,” where drugs do not. Evidence from radioisotope studies suggests that glands, when eaten, do in fact get to their glandular counterpart within the body and influence them. One study done with Cardiotrophin PMG showed that within 15 minutes of taking the protomorphogen/glandular supplement, the patients electrocardiogram detected it and shifted the electrical fields accordingly.

In modern medicine, glandular therapy with the use of whole glands began in the late nineteenth century when doctors suggested that their patients eat the animal parts, usually from cows, that corresponded to the weak areas of their own bodies. So people began eating brains, hearts, kidneys, and so on as part of their medical treatment. Even the ancient Greeks and Egyptians...
used glandular therapy, following their basic premise that “like heals like.” Protomorphogens and glandulars are safer than the more potent and specific drugs and hormones and they have fewer side effects. The body is more able to process them, too, if you unknowingly take too many of them because you are not “in tune” with what your body needs (another good reason to have a practitioner help you with the dose you need).

I remember vividly as a child every time we had a roasted turkey or chicken I hung around the oven just before it came out asking my mom, “Can I have the heart?” I believe children innately know what will help them and what they are allergic to. Even today, I recommend to my heart patients that they purchase chicken hearts and eat an ounce a day. Unfortunately, that doesn’t go over too well. People get rather queasy about eating organ meats these days. The humans would rather just “pop a pill”, although some clients will purchase these items for their pets. Fortunately, Cardio-Plus, one of my favorite protomorphogens, is just about the best heart tonic on the market. I would never be without it for my heart flutters and food chemical induced arrhythmias.

**How to Protomorphogens work?**

At a cellular level, we have discovered that cells build and repair themselves by first secreting enzymes and protomorphogens into the fluid outside the cell. A layer of protein then forms using these enzyme and protomorphogen components and the other nutrients that come into the body. A wall is then built outside this protein layer using materials surrounding the cell on the outside of the cell. The internal proteins and enzymes then reproduce themselves using protomorphogen templates. Other research indicates that the protomorphogens and cytosol extracts are not species specific and will work on any like-organ cells to repair them, so if we take a protomorphogen or cytosol extract made from pig cells, we won’t turn into a pig….the pig cell components will just be like building blocks utilized by our human cells and we won’t even know the difference.

This fascinates me. It’s like when you plant an acorn. How does the acorn know how to become an oak tree? It attracts to it any substances that are like an oak tree. No other substances will be used by the tree as it grows. How does the tree know what to attract and what to reject? Our cells are like that, too. Everyday miracles surrounding every cell of our being.

Dr. Depak Chopra, a famous Ayurvedic doctor, in his tape set Journey to the Boundless tells us that every cell in our body along with every component it contains is replaced totally within 9 months. Some cells have a faster turnover rate than others do, but ALL cells are rejuvenated and replaced, even in those glands that supposedly are unable to regenerate.

If that is the case, then my question is “**Why do we still have disease?**” The answer, I believe, is that our thought patterns are still in vibration with disease. If we can provide blueprints for cellular repair, eat organic whole grains and raw fruits and vegetables, drink plenty of clean water, and have clear, positive, mindful, happy thoughts, theoretically we should be able to repair the disease processes in our bodies. Of course, this is difficult to do–especially on this earthly plane, but I don’t see why we can’t continue to try. I believe this is all a part of our Spiritual journey into consciousness and full awakening.
It has also been demonstrated that one kind of cell may be influenced to morph into another type of cell by bathing in the fluids of the cellular contents of a different organ. We see this with skin grafts. If we take the skin from one part of the body and graft it to another part, eventually as the cells are renewed, they will take the same characteristics on as the cells surrounding it.

Dr. Royal Lee - Developer of Protomorphogens and Cytosol Extracts

Some Questions Answered:

Aren’t all glandulars alike?

Some skeptics caution that glandulars may contain many of the toxins livestock are exposed to such as antibiotics, growth hormones, pesticides, herbicides and fertilizers. These substances build up in the organs and fat of animals, birds and fish. Standard Process is pretty picky about the quality of supplement they put out. Although you may be able to purchase some whole glandulars in your local health food store, you won’t find the more effective protomorphogens and cytosol extracts.

It’s important to know the source and quality of these types of supplements. They should be made with organically raised animals. This is one reason why Standard Process has deleted fish oil from some of their formulas—because they could not guarantee the quality or purity of the ingredients. With this day and age of Mad Cow Disease going around, it is extremely important to be aware of what you put into your mouth. Standard Process understands these concerns and has, in some cases, switched from Bovine (beef) to Ovine (sheep) or Porcine (pig) tissue in making their products for this reason. They know their sources or raise most of what goes into their products on their own 1000-acre farm in Wisconsin.

Why do some Standard Process products contain extracts of several types of organs? One easy way to explain this is the concept of electrical energy patterns in our body. God has made it so that each body part interacts, assists and acts as back up for many other body parts in the body. However, one can only cheat the system so much.

For example, let’s say we are really stressed out with our job or being a student or some emotionally trying time in our lives. Our adrenal glands start pumping out adrenaline like crazy.
After a while we get tired, but try to compensate for our low energy by pushing our bodies with the use of drugs such as sugar and caffeine.

This only goes so far. The body would eventually die if the adrenal glands could no longer function. So the adrenal glands communicate with the thyroid and says to it, “Hey Mr. T., we adrenals glands are having a tough time down here. Would you mind helping out?” “Sure, I can handle that.” Says the thyroid gland and it starts pumping out more thyroid hormone so that the cells speed up giving the body more energy.

Well that goes well for a few months then the thyroid communicates to the adrenal glands and says, “Hey you guys, you didn’t tell me I have to pick up all the slack here!” and the adrenals reply, “We’re sorry! We’re doing the best we can too you know!”

So the thyroid gland enlists the help of the heart. “Hey heart, we need your help. Would you mind speeding up a bit so we can get more blood going by. If we can deliver our hormones faster, maybe we can maintain the energy that we need.” And the heart obliges.

After a few months, the heart is also getting a bit tired of all the excess work. “Hey, I need some help here, too!” The body subconsciously feels this and the shoulders come forward and the body tips down a bit and the heart now lies directly on top of the sternum where it gets enough electrical energy to maintain it’s increased heart rate. By this time the body has only about enough energy to shuffle along. Little by little, the energy is all used up.

So what happens when the heart draws off all the electricity from the sternum? Well, that’s about all for the back up systems. The body quits and dies.

**It kind of works that way with cancer as well.** The body adapts and adapts as best it can for as long as it can when one day, it finally rebels, the cells freak out and can no longer keep up with all the free radicals being produced and cancer takes over the body.

**Note:** Children repair at remarkable speeds for all kinds of things. As our body ages, the response time for the cells is definitely slower. We dehydrate, acquire unhealthy habits and try to cheat the system by not eating our raw foods. Children don’t have as many bad habits and also have a better and happier mental attitude and are more connected to their [God Path](#).

**How is the dosage determined for Glandulars, Protomorphogens and Cytosol Extracts?** This is one main reason why these types of supplements, especially the protomorphogens and cytosol extracts are sold only through approved practitioners. Beginning practitioners will utilize the books and manuals we purchase at the seminars where we have learned how to use these supplements. As we mature, our technical skills are integrated with the Art of Practice and we learn how to muscle-test the proper dosage. Experience and common sense, backed up with lots of study, help us determine what will work best for your particular case. Some states actually have made it illegal to muscle-test the dose. Fortunately I don’t live in one of those states, so I don’t have to “give it my best guess”. I feel I can be more accurate through muscle testing.
Remember I told you I was taking 85 pills and capsules to start with? Well, this was determined by use of a protocol sheet. These sheets list all the supplements that could be used in a “shotgun approach” and at the dosage of a 250-pound man. At the end of three months, my throat resisted swallowing that amount and I got a gut ache each time I took the supplements. A definite sign of being overdosed! Now days I use the protocols to double-check my work and as a suggestion as to which supplements to use. I’ve personally never sent home for than a few bottles of supplements at any one time. I try to pay attention to that voice of reason and use common sense after I listen and piece together all the bits of information I gather during the exam process.

How come glandulars, protomorphogens and cytosol extracts supplements are so effective? Sometimes when the body is damaged, let’s choose heart muscle and use a heart attack as an example, the body will release damaged cellular contents (cytosol) into the bloodstream. The body somehow develops an allergic reaction to this cytosol and the next time heart cells are damaged, the subsequent allergic reaction is faster and stronger creating a mild anaphylactic reaction resulting in cardiac arrest.

So, when we give a protomorphogen of heart tissue (Cardio-Plus), the substances in the tablet, after being digested, will act as a decoy for the bodies attack mechanisms (called auto-antibodies). As these auto-antibodies attack the protomorphogen, the heart tissue itself is spared and the heart can begin it’s healing. The supplements also contain supporting vitamins and minerals so that there are lots of high-quality supplies available for tissue regeneration.

Don’t I need to worry about some of the glandulars, protomorphogens and cytosol extracts products having bovine tissue in them? What about mad cow disease? The cattle used by Standard Process are routinely tested for toxins and food additives. Tissues go through a battery of 21 tests for impurities. Standard Process has been purchasing tissue from the same organic farm for over 50 years (2007 statement).

One theory concerning mad cow disease is that it may be linked to the strong insecticidal chemicals used in the farming practice—specifically the one used to treat bots. As the bots come out of the skin they leave a gaping hole about 1/4 inch in diameter. As the cattle are doused with the insecticide, some of it gets into the body and causes neurological damage leaving the body in a weakened state. The farm Standard Process purchases from does not use this type of chemical.

Truthfully, you would have a better chance of getting killed crossing the street or driving your car. Many still expose themselves to cattle byproducts when they take supplements that are in gelatin capsules, eat gelatin (Jell-O), and certain prepackaged foods.

Some of my favorite Glandulars, Protomorphogens and Cytosol Extracts made by Standard Process products:

- I use Ligaplex II every day to help keep my hip tendons and ligaments in place as I have inherited weak hips from my mom. Cardio plus is great for congestive heart failure and making heart murmurs go away, but I use it for a heart arrhythmia that gives me fits every now and then. These days I occasionally use Ribonucleic Acid to keep my brain “electric” for testing and to help my thyroid stimulating hormone convert to the active form. I also use Organic Minerals and Whole Desiccated Adrenal when I test I need them.
• **Albaplex**– Natural form of amoxicillin that can be taken for months with no adverse side effects and no damage to the gut flora that usually results in yeast infections. Great for dissolving sebaceous cysts and clearing up chronic bladder problems.

• **Antronex**– Natural form of antihistamine.

• **Arginex and Renatrophin PMG**– Wonderful for cats with progressive renal failure. I’ve kept a lot of cats alive for more years than they should have been with this product. These type of supplements taste pretty good to animals, so it’s not too much of a hassle to get them to take them.

• **Bio-Dent**– Great product for tightening the teeth in their sockets, for pyorrhea (inflamed and infected gums) and for making the teeth strong.

• **Cal-Amo**– Used for recharging the lymphatic system and alkalizing the body.

• **Cal-Ma Plus**– One of my very favorites protomorphogens for broken bones and bone deformities. It contains whole desiccated parathyroid so draws the calcium into the bones much more effectively than taking calcium supplements by themselves. This is a miracle product. I once had a puppy come in with a broken bone in its front foreleg. One bone had been damaged (the ulna on the inside of the leg), but the other bone (radius on the outside) had not been damaged. As the leg grew, the damaged bone would not grow and the healthy bone grew twice as long causing the leg to curl inward. Just 2 months of this supplement completely repaired and straightened out the leg.

• **Catalyn**– Great overall natural vitamin made of whole foods and used often with other supplements.

• **Cataplex E2**– Great for those with heart problems and chest pains that come and go. Acts as a natural nitro glycerin.

• **Cataplex GTF and Paraplex**– Great protomorphogens and cytosol extracts for supporting those with diabetes. It really helps to stabilize the blood sugar levels and helps some to cut back on their cravings. The herb Gymnema is also a good supplement to help with sugar cravings.

• **Chezyn**– Great for eye problems, especially for the repair of retinal degeneration. I’ve helped many people repair detached retinas with this product as well. Oh, and I used it as one of the supplements to help repair a cerebral aneurysm in myself and an aortic aneurysm in a 70 year old man.

• **Choline** is great for liquefying the bile coming out of the gallbladder. It has cleared up belching, hiccups, and nightmares for me.

• **Cyruta Plus and Folic Acid B-12**– Wonderful products for healing those aged and wise bodies that bruise easily. Folic Acid B-12 is also good for pregnant mothers.

• **Hypothalamus PMG**– Great protomorphogens for those people whose memory has been damaged after car accidents or falls that involve head trauma. The theory is that it repairs the fraying of the hypothalamic stalk. Also good for vision problems (like double vision).

• **Immuplex**– Great for upper respiratory problems in cats. Give about 1/2 capsule/day.

• **Inositol**– Good brain sugar. Specifically feeds the brain stem.

• **Min-Chex**– Wonderful for animals (and people) who have Petit Mal seizures.

• **Min-Tran**– Very effective natural tranquilizer.

• **Oculotrophin PMG**– Protomorphogens that help with glaucoma. (Note: Acupuncture is a good backup.)

• **Okra Pepsin E2**– Coats the stomach for those with peptic ulcers.
**Parotid PMG**– These protomorphogens help to process and remove chemicals from the body, especially those cases where the palms are bright red.

**Pneumotrophin PMG**– A note about lung glandulars and protomorphogens. Some people will respond to these with a mild bronchitis or allergic reaction. This is common for this particular glandular. Pneumotrophin is used for emphysema and lung damage, but when used for asthma we need to start out with smaller doses and work up to a larger dose over a period of weeks.

**Prostate PMG**– Prostate protomorphogens to help repair any kind of prostate damage including benign prostate hyperplasia and prostate cancer.

**Spleen PMG**– A protomorphogen great for repairing the immune system. I’ve used this product successfully in treating Lupus.

**Symplex F**– Wonderful support for women during perimenopause, menopause and for those seeking natural hormone replacement therapies. Symplex F contains extracts of pituitary to keep those hormones balanced, as well as thyroid, adrenal and ovarian tissue protomorphogens.

**Thymex** is great for dissolving fatty tumors although it needs to be taken for several months. My human patients say that the lump tingles after they take it. Since lipomas are thought to be low-grade staph infections, it would make sense that a product stimulating the thymus gland would work to get rid of these over time.

**Thymus PMG**– Thymus protomorphogens excellent for stimulating the body’s own immunity. Feline Infectious Peritonitis (FIP) in cats is thought to be incurable... Not with this product.

**Thyrophin PMG**– Thyroid protomorphogens help to repair the thyroid gland and is especially good for Hashimoto’s and Graves disease as it repairs the gland and acts as a decoy so that the body’s antibodies glom onto the product and not the body’s thyroid hormone.

**Wheat germ oil**– I use this often for treating infertility in both men and women. It helps dilate both the fallopian tubes and seminiferous tubules allowing connection of the sperm with the egg.

The above situations and disease processes are wake up calls. If we are showing signs of illness, our body is signaling to us that it needs help. Instead of ignoring those pleas, we need to respond to them whether that is learning to say no, eating better, developing better boundaries, working on our Spiritual lessons or taking supplements.

Glandulars, protomorphogens and cytosol extracts are some of the great products to help repair these weak organs. These products work to repair systems, not just individual organs.

Well, those are pretty much my favorites for this product line. I’m sure you can relate to one or more of them. What I like to do is find the supplements your body specifically vibrates to, copy off the handout that explains the supplement, go through it phrase by phrase and pinpoint exactly why you are testing you need it so you are not just taking a bunch of pills blindly.

Standard Process labs continue to use the patented process Dr. Royal Lee [http://www.standardprocess.com/display/pourheritage.spi](http://www.standardprocess.com/display/pourheritage.spi) developed in the 1950’s. I don’t quite understand how we could have been using products such as these for this many years without double-blind studies on them, but I suppose it’s like with any other supplement or herb. They don’t cost a lot so the profit margin is slim and it doesn’t pay the drug companies to put money into research like that. I don’t really care, because my clients and I are very satisfied with the results. My feeling is we need to use whatever works to heal our bodies. We have an entire
buffet of stuff out there for healing. Some is better for us than others. These supplements are a staple for me and I won’t give them up.

Dr. Lee described in detail what these extracts contain and how they function in regards to cellular regulation, maintenance, and interactions with tissue antibodies. Much of this information is within the Product Bulletin, which I often share pages from with my clients.

If you think this type of supplement is for you, please fill out the Symptom Survey and email or “snail mail” the results back to our office. We can then set up an appointment to discuss a plan of action for your health challenges.

Resources:

- Alternative Management Strategies for Practitioners of Contact Reflex Analysis by Dr. D.A. Versendaal and Dawn Versendaal-Hoezee.
- Dr. Royal Lee’s Product Bulletin
- Journey to the Boundless by Dr. Depak Chopra
- Dr. Royal Lee: [http://www.organicconsumers.org/articles/article_4057.cfm](http://www.organicconsumers.org/articles/article_4057.cfm)
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ISSN # 1417-0876, 2041-4293
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Open Letter to Homeopaths:
Homeopathy has had a bad reputation lately due to a lack of respect for science and statistics. Math-Phobia has put Homeopathy into trouble. This journal is dedicated to help point out Homeopathy’s Myth and Mis- Conceptions. And we hope to point the way forward to help the art of Medicine to regain its former glory. Please let’s work as adults to help our art of Homeopathy face its critics and present a valid evidence based way into the future.

Brad Victor Johnson

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