

“BIO-IDENTICAL” TESTOSTERONE

A MARKETING GIMMICK!

At the Center For Men’s Health (C4MH) we sometimes hear and read that the so called “Bio-Identical” Testosterone is a natural (not synthesized) testosterone and thus more effective and better for you therefore worth the higher price that many medical professionals and clinics charge.

We understand that there is a significant emotional response to the word “natural” but to use or imply it in regards to “bio-identical” testosterone is simply done to take advantage of that emotional connection which is exactly what snake oil salesmen did years ago. Today it is simply known as fraud.

FACT #1: NO TESTOSTERONE USED IN TESTOSTERONE REPLACEMENT THERAPY IS NATURAL AND THOSE WHO SAY or TELL YOU OTHERWISE ARE EITHER UNINFORMED OR WORSE.

FACT #2: ALL TESTOSTERONE UTILIZED IN TESTOSTERONE REPLACEMENT THERAPY IS LABORATORY SYNTHESIZED.

FACT #3: ALL TESTOSTERONE UTILIZED IN TESTOSTERONE REPLACEMENT THERAPY IS MOLECULARLY IDENTICAL TO YOUR BODIES NATURALLY PRODUCED TESTOSTERONE ONCE IT ENTERS YOUR BLOODSTREAM.

FACT #4: “BIO-IDENTICAL” COMPOUNDED TESTOSTERONE IS NOT FDA APPROVED AND IS PRODUCED FROM SYNTHESIZED TESTOSTERONE IN FACILITIES OR PHARMACIES THAT ARE NOT LICENSED OR INSPECTED BY THE FDA.

***Synthesis or synthesize** refers to the laboratory execution of chemical reactions to form a more complex molecule from chemical precursors. In the case of testosterone the chemical precursors used to form the more complex testosterone molecule come from yam and soybean molecules. This chemical process does not take place at your local pharmacy.*

Before proceeding it should be clear that the key element in this issue is that in testosterone replacement therapy we are faced with issue of how to best deliver the synthetic testosterone into the human bodies’ blood; one method uses additives (“bio”) and the other (pharma) modifies the structure. Most importantly both forms are molecularly identical to bodies’ natural testosterone upon entering your bloodstream (bio-available).

Q. What is the difference between “bio-identical” and pharmaceutical testosterone?

A. “Bio-Identical” testosterone is identical in its molecular structure to human produced testosterone and pharmaceutical (IM) testosterone has intentionally had its molecular structure modified.

Q. Why modify the molecular structure?

A. The primary reason for modifying testosterone's molecular structure is to improve the Testosterone's delivery mechanism (how it gets into your blood). Simply stated pharmaceutical testosterone is modified so as that the dosage taken (in our case: IM injected) is absorbed into the blood over an extended period of time and not all at the time of injection.

Q. Does changing the molecular structure have any negative consequences?

A. NO; as pharmaceutical testosterone enters the blood the added molecular structure (an ester) is cleaved (split) off by esterase enzymes in a process known as hydrolization and the pharmaceutical testosterone becomes molecularly identical to your naturally produced testosterone. Simply Stated: IM injected pharmaceutical testosterone upon entering your blood is IDENTICAL to your bodies naturally produced testosterone. It is metabolized in the liver exactly as your bodies' natural testosterone.

Q. Does not changing the molecular structure have implications?

A. Without the modification, testosterone would have to be administered continuously as there is no time release regulating mechanism in un-modified synthesized testosterone. Because there is no regulating system in "bio-identical" testosterone it has to be administered daily. Most "bio-identical" Testosterone's are in creams or gel forms (administered daily) and contains many additional additives including those that assist in absorption, making it even farther from being that supposed "natural" product.

Example of Additives: carbomer 980, ethyl alcohol, isopropyl myristate and sodium hydroxide a/k/a lye or caustic soda

Q. Are there any recognized studies that show "bio-identical" testosterone to be superior over pharmaceutical testosterone?

A. NO; All recognized published medical studies have been performed with the use of FDA approved pharmaceutical testosterone. The fact is that there are NO recognized published medical studies that have been done utilizing "bio-identical" (compounded) testosterone.

Q. Do “bio-identical” testosterone products have greater negative implications?

A. Yes; unlike IM pharma testosterone most “bio-identical” testosterone products come in creams or gel forms and are required to carry additional significant warnings for their use as they may negatively affect others (children, spouses, etc) that you come into contact with.

topical testosterone products (gels / creams) transfer from your body to others. This can happen if other people come into contact with the area where the cream was applied. Signs of puberty that are not expected have happened in young children who were accidentally exposed to testosterone through skin-to-skin contact with men using topical testosterone products. Women and children should avoid contact with the unwashed or unclothed area where topical testosterone products has been applied. If a woman or child makes contact with the topical testosterone application area, the contact area on the woman or child should be washed well with soap and water right away. Stop using topical testosterone products and call your healthcare provider right away if you see any signs and symptoms of puberty in a child, or changes in body hair or increased acne in a woman, that may have occurred through accidental exposure to topical testosterone products.

Q. Who produces the so called “bio-identical” compounded testosterone?

A. Those clinics that promote / market “bio-identical” compounded testosterone are being supplied by a compounding pharmacy and not by an FDA licensed and inspected pharmaceutical company.

The issue of compounding medications recently came to national attention with the deaths of patients who were seeking interventional pain care. The drugs that caused the deaths were compounded and were found to be manufactured under non-sterile conditions. A primary reason to use compounded testosterone is to reduce costs; additionally in Florida it is a way to bypass laws that limited controlled substance dispensing to patients by physicians.

“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 pharmaceutical counterparts; until such evidence is produced the risks should be treated as if they were similar; and that compounded hormone products may have additional risks related to compounding”

At the Center For Men’s Health (C4MH) we believe, based on available science and experience, that IM injections with FDA approved pharmaceutical testosterone is far more effective, convenient, affordable, safer and has none of the additional concerns / warnings that come with creams and gels.