



TESTOSTERONE CONSENT AND INFORMATION FORM

I have advised the patient of the risks and benefits of testosterone as well as the following: Testosterone is FDA approved to treat symptoms of andropause (Low-T) and until recently there were no restrictions for prescribing testosterone. Testosterone administration was based on treatment of symptoms and signs of andropause and not by a laboratory test value. Under new restrictive FDA guidelines however, testosterone is indicated only if a TT level is < 300ng/dl. Based on these guidelines that are intended to restrict the use of testosterone, the FDA states that the patient does not qualify for testosterone treatment if lab tests are normal. Are we now supposed to ignore the patient and not treat their symptoms based on a new restrictive guideline? We don't believe so. The FDA should not dictate how physicians practice medicine and Congress has reaffirmed that.

However, because the patient has symptoms of andropause (but normal lab values) and is requesting treatment for these symptoms, and testosterone is indicated for treating symptoms that the patient has, I have prescribed testosterone to help improve these symptoms, quality of life, health and wellness. Even though the patient does not qualify based on new strict guidelines of having very low levels, I have prescribed testosterone "off label" in order to help improve symptoms. The medical literature adequately supports the use of testosterone for off label use to treat symptoms in men with normal testosterone levels despite not having low levels of <300ng/dl. The patient knows and understands the risks vs. Benefits that we have discussed and printed information has been given to the patient that further reviews and discusses these issues.

The patient is also advised that testosterone can cause testicular atrophy (shrinkage in size) and infertility, although that is usually reversible upon discontinuation of testosterone. However, infertility may be permanent, although this is very rare. We advise men to consider postponing treatment with testosterone if he desires to maintain fertility and to resume testosterone at a later time when fathering children is no longer anticipated.

Transdermal testosterone cream can transmit to the spouse and children and we have advised the patient of the harm of transference to others and how to avoid transference to others. Testosterone can increase hemoglobin and red blood cells. This increase in red blood cells, however, is not the blood disorder polycythemia but is rather termed erythrocytosis. However, family doctors may think that it is polycythemia, a blood disorder that is harmful. Over 50 years of studies do not show any harm of testosterone induced erythrocytosis. Testosterone does not cause blood clots or the blood disorder called polycythemia. The FDA has advised that testosterone may cause blood clots due to this increase in red blood cells although there is no study that shows harm or increase in blood clots in the heart, brain, or legs (DVT). If this or any other side effect occurs, or the PMD does not understand any of the above, then the patient is advised to contact us so that we can help better explain the safety of testosterone based on medical studies. In spite of the FDA precautions that testosterone may cause increased risk of blood clots, there is no RCT study that demonstrates this in hundreds of studies over 50 years of use. There have been individual case reports to the FDA of blood clots and therefore the FDA is obliged to list this risk on the package insert. The patient is advised of the FDA warnings and precautions, although there is little evidentiary support of any harm for this warning in any medical study.



We prescribe testosterone and other hormones for their health benefits and improvement in quality of life and improvement of symptoms. Hundreds of studies show that low levels of testosterone (and other hormones) put mm at risk of heart disease, cancer, and increased mortality. These same studies demonstrate benefit to optimizing testosterone levels to protect against cardiovascular disease. Based on the medical literature we do not find any significant risk or harm of HRT other than infertility. The patient is advised that their PMD may not understand optimization of hormones or the medical literature and the patient is advised to contact us if the PMD, or the patient has any concerns.

Print Name

Signature

Date