

Are you falling asleep after dinner?

The marketing of “Low T”



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Selling Sickness, Washington DC, Feb 2013
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How to turn a treatment for a rare condition into a blockbuster drug

- Shift diagnostic criteria
- Exaggerate prevalence
- Use screening tests to cast a wide net
- Run unbranded 'disease-awareness' ads
- Heavily exploit gender stereotypes
- *with virtually no regulatory response*

HOW DO YOU SEE YOUR **MALE** PATIENTS **AGING?**

- fatigue, depressed mood
- decreased libido, erectile dysfunction
- decreased cognitive function, lethargy, low mental energy
- reduced muscle mass and/or lack of endurance¹²
- decreased bone mineral density.^{12,13}

This array of symptoms, referred to as andropause, male climacteric or **ADAM** (Androgen Decline in the Aging Male)² has been linked to decreasing levels of bio-available testosterone in men approaching the age of 50.¹¹

Getting old is natural.
The goal...
to make *feeling old* optional.

***Andriol**[®] (testosterone undecanoate), the only oral TRT (testosterone replacement therapy) available in Canada:

- increases plasma levels of bio-available testosterone and its



Testosterone supplements for male hypogonadism

Replacement therapy for deficiency or absence of endogenous testosterone (congenital or acquired):

- **Primary hypogonadism**

Testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals.

- **Hypogonadotropic hypogonadism**

idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation.

US Black Box Warning

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use AndroGel 1% safely and effectively. See full prescribing information for AndroGel 1%.

AndroGel[®] (testosterone gel) 1% for topical use CIII
Initial U.S. Approval: 1953

WARNING: SECONDARY EXPOSURE TO TESTOSTERONE

- Virilization has been reported in children who were secondarily exposed to testosterone gel. ([5.2](#), [6.2](#))
- Children should avoid contact with unwashed or unclothed application sites in men using testosterone gel. ([2.2](#), [5.2](#))
- Healthcare providers should advise patients to strictly adhere to recommended instructions for use. ([2.2](#), [5.2](#), [17](#))

Testosterone levels – life cycle

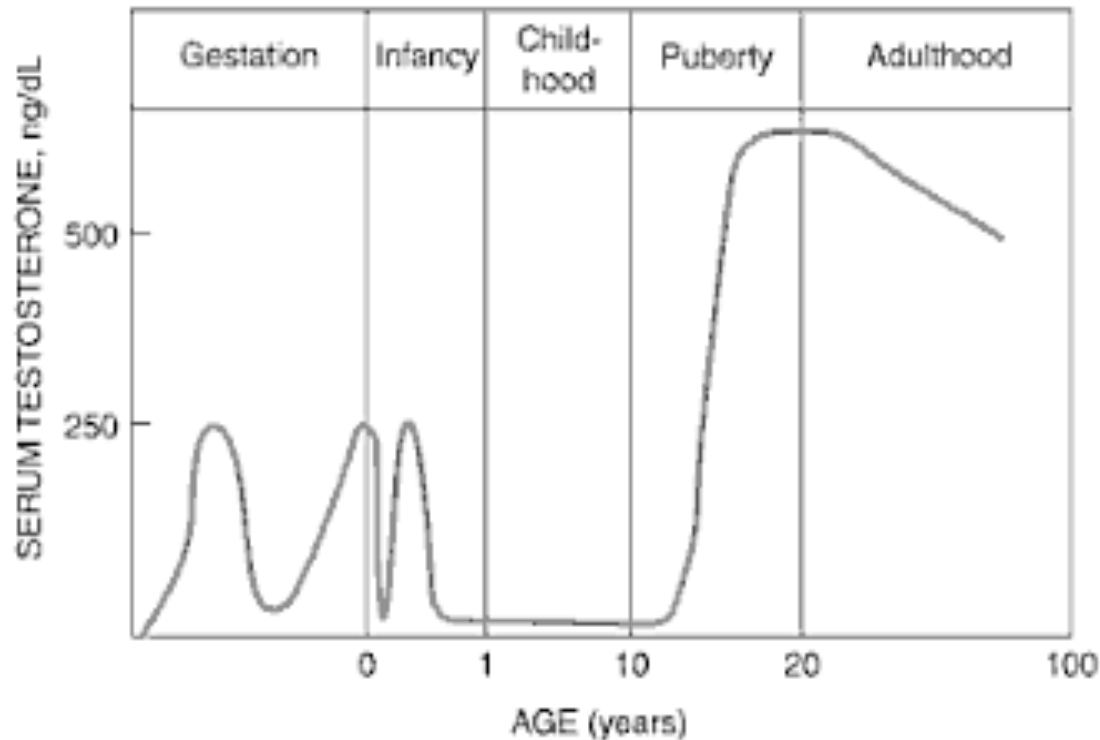


FIGURE 58-2 *Schematic representation of the serum testosterone concentration in males from early gestation to old age.*

Lower testosterone than at age 20-29 (n=316 Canadian MDs)

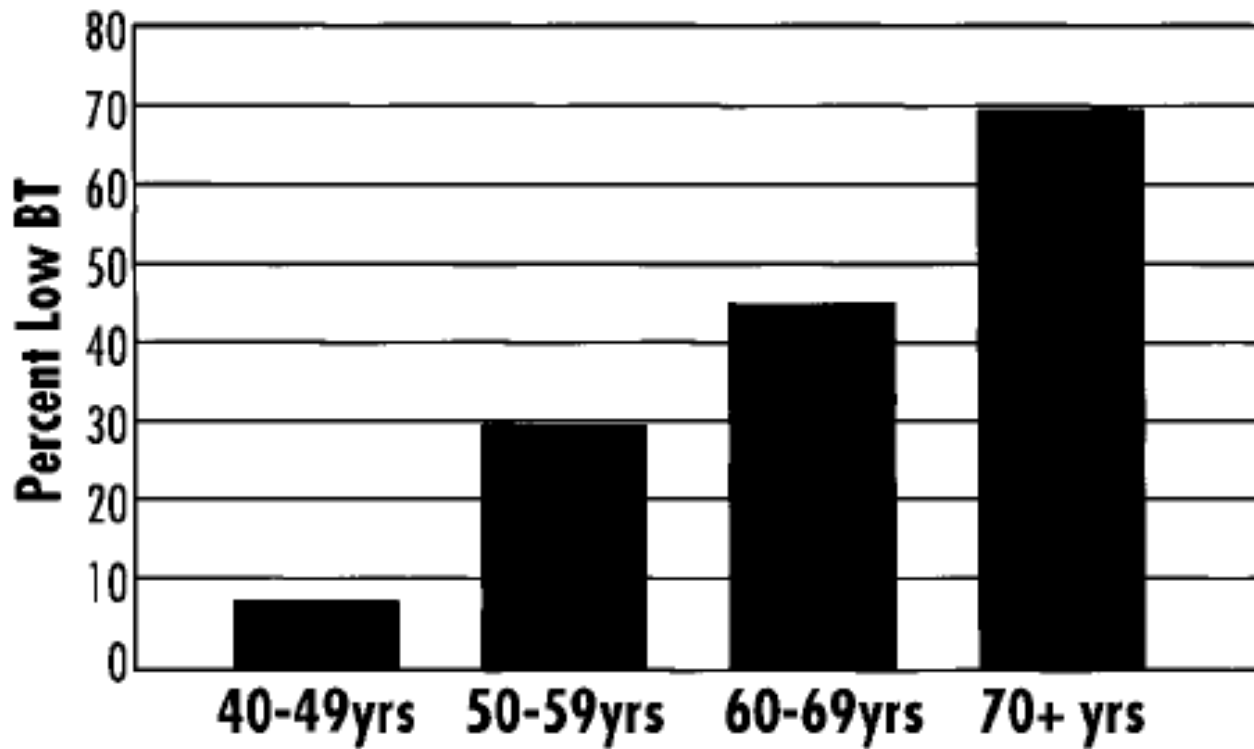


Fig 1. Twenty-five percent of Canadian physicians had lower BT (weakly bound testosterone) levels than normal young men (<70 mg/dL).

Morley et al. Metabolism 2000; 49: 1239-42

Vim, vigor and sales drive

It might be exaggerating to say that AbbVie—Abbott's new break-out pharma division—overcame a host of challenges to establish AndroGel as the preeminent product in the low-testosterone category. Or maybe not.

AbbVie took a taboo topic and, via a cagey media-and-marketing presence, rendered it less wince-inducing among its target audience. It did so at a time when a number of critics voiced

their concerns that the marketing and use of testosterone-boosting products had gotten ahead of the science. "We don't have any evidence that prescribing testosterone to older men with relatively low testosterone levels does any good," the National Institute on Aging's Dr. Sergei Romashkan told the AP in September.

AndroGel's type of testosterone therapy was approved by the FDA

in 2000, but the products still had to contend with a branding challenge: convincing men with low or no testosterone that their condition (known as hypogonadism) wasn't abnormal or anything to be ashamed of.

AbbVie and its agencies, which include Digitas Health for consumer and AbelsonTaylor for professional ads, portray low testosterone as "Low T"—a treatable problem. The campaign's mix of platforms include unbranded promotion (the IsItLowT.com site) and awareness-first TV spots. In 2012, an ad touted AndroGel's more concentrated dosage (1.62% vs. the prior 1%). That dosage got FDA approval in 2011 and extends patent protection until 2015.

"The 'IsItLowT' campaign was designed to raise awareness of low testosterone among men who may be at risk or have the condition," explains Jim Hynd, divisional VP, metabolics, GI and cardiovascular care, AbbVie.

Hypogonadism affects about 14 million men in the US alone, but less than 10% are currently being treated for the condition, adds Frank Jaeger.

TOP 5 ANDROGEN DRUGS BY US SALES

12 months to October 31 (% growth over previous 12 months)

AndroGel
AbbVie
\$1.37B (19%)

Testim
Auxilium
\$287.8M (16%)

Axiron
Eli Lilly
\$180.4M (491%)

Androderm
Watson
\$94.7M (-1%)

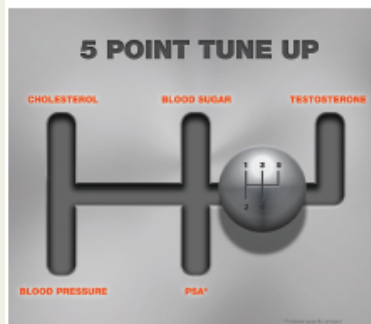
Testosterone Cyp
Generic
\$72.9M (19%)

about availing themselves of any product that they believe will increase their quality of life. AndroGel thrived, at least in part, due to the intersection of demographics and demand.

Yet complications came from AndroGel's corporate past. Since 2000, AndroGel had three owners: Unimed Pharmaceuticals, which was swallowed up by Solvay Pharmaceuticals, which Abbott purchased in 2010. Also, a published report says there remain allegations and litigation claiming that AndroGel was marketed off-label for years; AbbVie is not accused of any wrongdoing.



Left: Frank Jaeger, director, men's health; right: Jim Hynd, divisional VP, metabolics, GI and cardiovascular care, AbbVie



Left: Image from AbbVie's DTC "Drive for Five" initiative, urging men to know their numbers, including cholesterol, blood pressure, blood sugar, PSA and testosterone

Dobrow L. www.mmm-online.com. Jan 2013

“To keep your body running like a well-oiled machine...”

THE ROAD TO MEN'S HEALTH STARTS HERE

Regular check-ups can help you stay ahead of the curve

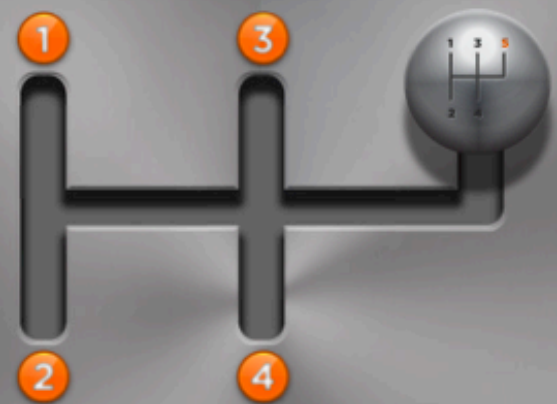
Don't see your doctor as often as you should? To keep your body running like a well-oiled machine, check in with your doctor regularly.

A good place to start is asking about these 5 risks to men's health.

[Learn about these 5 risks →](#)

YOUR 5 POINT TUNE UP

Select a number to shift gears and learn about each risk.



LOW TESTOSTERONE

- May be overlooked because the symptoms are subtle and similar to those caused by other conditions
- Symptoms may include increased body fat, reduced muscle mass and strength, decrease in bone strength, and reduced sex drive

How do you measure up? →

Bayer, Ireland

**OVER 40?
HAVE YOU LOST
YOUR LUST
FOR LIFE?**



Introduction

What is Testosterone Deficiency (TD)?

What is Testosterone?

What causes Testosterone Deficiency?

Treatment of Testosterone Deficiency

Conclusion

Could it be low testosterone?

Introduction

If you are aged 40 or more, you may have become aware of some changes in your physical appearance and general health such as increased weight gain, feeling depressed, disturbed sleep, loss of interest in sex. While most men will experience some of these symptoms during their life, if they are having a significant impact on you, then discuss these with your doctor. Testosterone Deficiency is one cause which may be considered.

Abbott, US 'bigger is better'



“Low testosterone can
take the life out of you”

Bayer, Australia, 2009



Bayer HealthCare
Bayer Schering Pharma
Bayer Australia Ltd ABN 22 001 598 714, 875 Pacific Highway, Sydney
NSW 2070, AU 5M 00 0008 0083, 84441827 WA PP 09/09, 761916

A man's testosterone levels start to decline in his 40s and can have a significant effect on health, wellbeing and relationships.

Symptoms may include lack of vitality, reduced sex drive, mood swings, poor concentration and reduced strength.

It's no wonder some men feel at a loss for who they once were.

If you have any of these symptoms there may be a simple and practical solution.

See your doctor for a full check up and if required, a testosterone test or visit www.test4t.com.au

**LOW TESTOSTERONE CAN
TAKE THE LIFE OUT OF YOU**

TESTOSTERONE



**LACK OF ENERGY
LOW SEX DRIVE**

**Has He Lost That
Loving Feeling?**

He May Have Low Testosterone (Low T)

Take Action.
Contact your doctor and ask for a Testosterone Test (T-Test).

Low T is a medical condition that often goes undiagnosed because its symptoms are similar to other conditions.

All men can have Low T.
Those who are overweight or who have type 2 diabetes are at greater risk.

Some Symptoms of Low T include:

- Low sex drive
- Lack of energy
- Decrease in strength and endurance
- Decrease in the ability to play sports
- Falling asleep after dinner
- Decrease in work performance
- Decrease in the enjoyment of life
- Low driving emotions
- Feeling sad and/or grumpy
- Loss of height

Visit www.lowt.ca for more information.

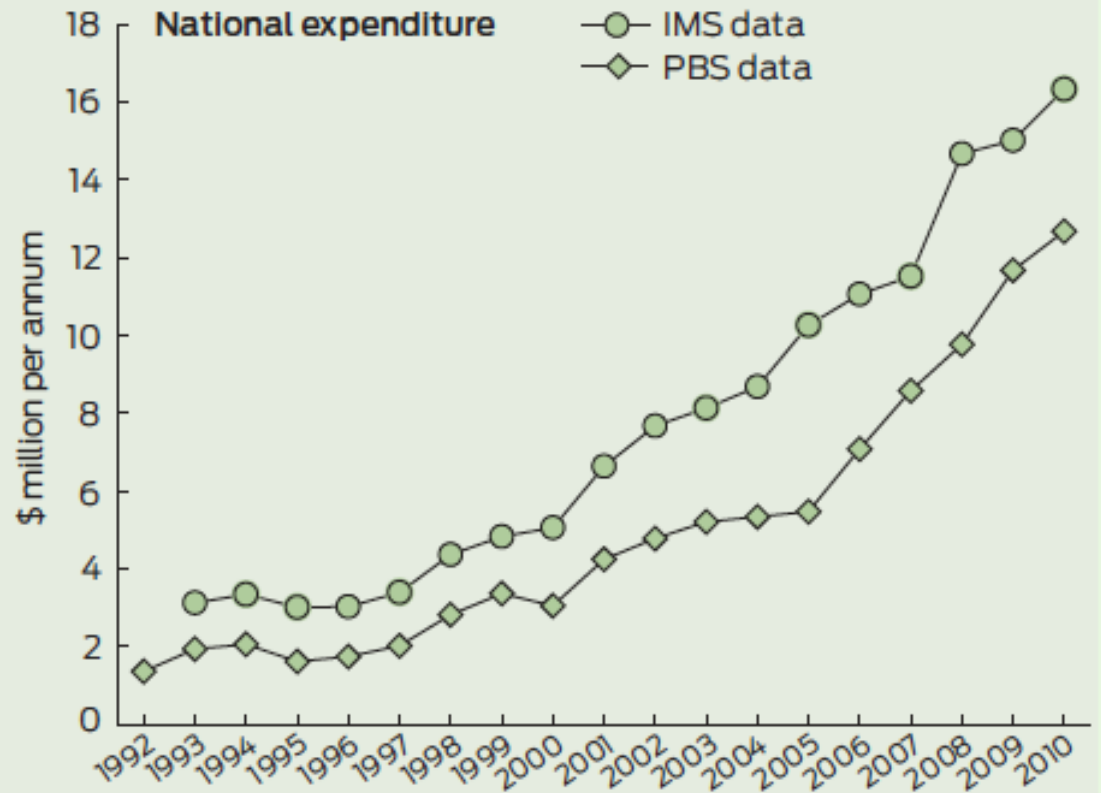
“Has he lost that loving feeling?”

Abbott, Canada, 2011

Prescribing in Australia 1992- 2010

“The progressive increase ...without changes in proven medical indications or improvements in diagnosis of pathologically based androgen deficiency are likely to be due to promotion-driven non-compliance with PBS prescribing guidelines.”

2 National expenditure and defined monthly doses for testosterone products, according to PBS and IMS data, 1992–2010



Handelsman. MJA 2012; 196: 642-646

Complaints about off-label promotion, illegal DTCA, potential harm

Disease mongering and low testosterone in men: the tale of two regulatory failures

Disease-awareness campaigns on low testosterone and ageing highlight the need for changes to regulations

Currently, direct-to-consumer advertising of prescription-only medicines is legal in only two industrialised countries, the United States and New Zealand. However, in countries where direct-to-consumer advertising is not allowed, including Australia,

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The Australian and Canadian advertisements encouraged readers to contact their doctors and ask for a testosterone test if they experienced these symptoms, and the advertisements were linked to websites that included a quiz that called on readers to test their testosterone levels if they exhibited only such non-specific symptoms as “falling asleep after dinner”.⁵

[Ageing and low testosterone](#)

Results of complaints

- Australia: Bayer fined \$10,000
 - Poor education, as implied low-T a likely cause
 - Not considered promotion as no brand name
 - Fine less than half cost of ad in *Weekend Australian*
 - Unsuccessful appeal
- Canada: ad pre-approved – PAAB logo
 - Health Canada - “help seeking message”
 - No brand or company name – not promotion
 - Website “fairly balanced”
 - No appeal procedure

Abbott, Canada 2011-2013

The screenshot shows the homepage of the 'Is It Low T?' website. At the top left is the logo 'Is It Low T?'. To its right is a navigation bar with links: HOME, WHAT IS LOW T, DO YOU HAVE LOW T, WHAT YOU CAN DO, and PARTNER. Below the logo is a vertical list of five teal buttons: 'Low Sex Drive', 'Lack of Energy', 'Body Changes', 'Mood Changes', and 'Sexual Dysfunction'. The main heading is 'Not Feeling Like the Man You Used to Be?'. Below this is a photograph of a man in a white shirt looking down thoughtfully. Under the photo is the text 'You May Have Low Testosterone (Low T)' followed by a paragraph: 'Low testosterone is a common medical condition that often goes undiagnosed because its symptoms are similar to other conditions.¹ Low T affects an estimated 1.7 million men in Canada.^{1,2}'. To the left of this text is an illustration of a clipboard with a sign that says 'TAKE THE QUIZ'. At the bottom are two large buttons: 'Take the Low T Quiz' and 'Talk to Your Doctor'. The footer contains links: 'Terms of Use | Site Map | Privacy Policy | References | Français'.

Is It Low T?

HOME | WHAT IS LOW T | DO YOU HAVE LOW T | WHAT YOU CAN DO | PARTNER

Low Sex Drive

Lack of Energy

Body Changes

Mood Changes

Sexual Dysfunction

Not Feeling Like the Man You Used to Be?

You May Have Low Testosterone (Low T)

Low testosterone is a common medical condition that often goes undiagnosed because its symptoms are similar to other conditions.¹ Low T affects an estimated 1.7 million men in Canada.^{1,2}

TAKE THE QUIZ

Take the Low T Quiz **Talk to Your Doctor**

Terms of Use | Site Map | Privacy Policy | References | Français

1.7 million Canadian men? Based on HIM Survey¹

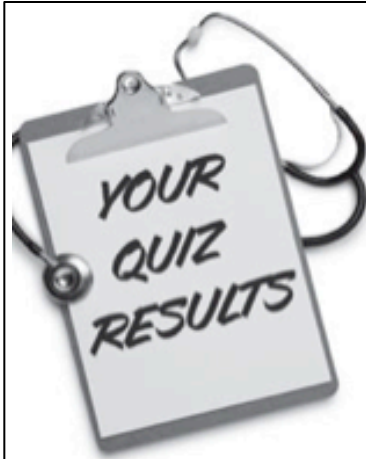
- 4% of invited US physicians participated
- Enrolled male patients aged 45+ (n=2165)
- Hypogonadism defined as <300 ng/dl
- Study mean 364.8 ng/dl; 39% hypogonadal
- Covance Periapproval Services, Inc.
conducted study for Solvay pharmaceuticals

1. Mulligan et al. Int J Clin Pract 2006; 60: 762-9

Alternate prevalence estimates

- Most common pathology is Klinefelter's syndrome: 1-2 per 1000
- Wu et al. NEJM 2010: 2.1%
 - *low testosterone level + 3 symptoms*
 - *If adjust for obesity, age and health status – testosterone no longer significantly linked to symptoms*

The validated “ADAM” questionnaire



Consider Getting Tested For Low Testosterone (Low T).

If you answered “**yes**” to questions 1 or 7 or at least three of the other questions, your symptoms may be caused by Low T. ⁴ Bring this completed quiz and to your doctor to discuss your results.

Reference:

4. Morley JE, Charlton E, Patrick P et al. Validation of a screening questionnaire for androgen deficiency in aging males. *Metabolism* 2000;49(9):1239-1242.

1. Do you have a decrease in libido (sex drive)?
2. Do you have a lack of energy?
3. Do you have a decrease in strength and/or endurance?
4. Have you lost height?
5. Have you noticed a decreased "enjoyment of life"?
6. Are you sad and/or grumpy?
7. Are your erections less strong?
8. Have you noticed a recent deterioration in your ability to play sports?
9. Are you falling asleep after dinner?
10. Has there been a recent deterioration in your work performance?

How accurately does 'ADAM' predict low testosterone? (false + =)



Wu et al. NEJM 2010; 363: 123-5; 2.1 % prevalence; Morley et al. Maturitas 2006; 53: 424-9; specificity & sensitivity for calculated 'bioavailable T', nonlinear function of questionable significance (total T non-predictive)

In conclusion

propagating a myth or two

- **Myth 1:** Andropause exists (*only we won't call it that as everyone knows it doesn't*)
- **Myth 2:** Age-related testosterone loss causes impotence, loss of libido, lack of energy, sadness, grumpiness, etc.
- **Myth 3:** T-supplements reverse this
- **Myth 4:** No harm done (none mentioned)
- **Myth 5:** *No brand names = not a regulatory concern, public 'education', not promotion*