Special Communication

Promoting "Low T"
A Medical Writer's Perspective

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Despite progress in raising the level of transparency about funding, conflicts of interest, and ghostwriting, drug companies remain free to pursue subtle and, therefore, effective means of marketing. Continuing medical education programs and "consensus" panels continue to be funded by companies selling products directly tied to the messages being conveyed by the resulting "educational" materials. And patient education materials continue to be created that, while factually accurate, subtly shift attitudes by including only selected facts and/or omitting ideas that would undermine the funder's preferred paradigm.

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"Low T" (low testosterone level, aka hypogonadism) is high profile these days. Sales of testosterone replacement therapies (TRTs) for Low T have more than doubled since 2006 and are expected to triple to $5 billion by 2017, according to forecasts by Global Industry Analysts.[1] Driving these sales is a sophisticated marketing effort to define low testosterone level as a disease for which the treatment is TRT. I know this because, as a professional medical writer, I have helped craft that message for transmission in a range of media to both physicians and consumers.

This is hardly the first time that an age-related condition has been spun into a disease state when a new product has been developed that is believed to alleviate or attenuate the condition. In fact, the current situation with TRT eerily echoes the way that hormone therapy was, for years, touted as a safe treatment for menopause-related symptoms and the prevention of cardiovascular disease in women.[2] Only after the Women's Health Initiative study found that older women using hormone therapy had small excesses in the incidence of breast cancer, myocardial infarction, cerebrovascular accident, and venous thrombosis did physicians become more cautious about prescribing it and limit its use to appropriate female patients.[3]

An examination of the current ways that industry is reshaping the paradigm of Low T is warranted now not simply because of the potential public health risks associated with widespread use of TRT in the absence of a Women's Health Initiative–scale study. Efforts have been made in recent years to curtail the abuses of pharmaceutical influence[4] and encourage greater transparency in medical communications.[5] As this article demonstrates, these efforts, although salutary, do not fundamentally alter the influences of drug company funding on the content and tone of messages directed at physicians and consumers.

Ghostwritten Articles for Consumer Magazines

In 2009, a well-known endocrinologist was contacted by the public relations firm HealthSTAR Communications. The firm had been hired by a pharmaceutical company to place articles in popular magazines that would appear under the byline of physicians who could talk about the "hazards" of low testosterone levels and the availability of new forms of TRT. The endocrinologist forwarded me the e-mail from the public relations firm requesting that he write a short article for *Life After 50* magazine. The e-mail included a "Facts for Women" sheet that encouraged women to "diagnose" their male partners and urge them to seek medical attention (because men, demonstrably, do not seek such attention as much as they should). The fact sheet included the URL for a consumer-oriented website created by Abbott Laboratories.[6]

I wrote a brief, neutral-sounding article, put the physician's name on it, and sent it off. In the following months, the physician was contacted by HealthSTAR Communications for more articles, or just quotes that could be passed on to a magazine writer. I generated versions of the original article, also to appear under the physician's byline, for *Woman's Day*, *Business Week*, *Positive Change*, and *Health View.* (I was paid for all of these articles by the physician himself—I do not know whether he was being paid by either the public relations firm or a drug company.) Although these articles were relatively neutral in tone and did not mention specific products, none were skeptical, none questioned the reliability of the data on which claims were being made, and none included the views of clinicians who dissented from the emerging paradigm about Low T. In part, that was because I was just learning about the issue myself and had not dug deeply into the literature. But I also knew what I was getting paid to do: trumpet the party line. As a result, the articles adhered nicely to the new paradigm of Low T as a potentially serious condition for which new treatments were available. The fact that the articles appeared under the byline of a physician and appeared in trade magazines with no mention of the funder behind the overall effort raised the marketing value of the pieces considerably because it is likely that readers trust information that appears to be objective and free of industry influence.

Patient Education Materials

In 2010, I was hired by a medical communications company to write a consumer-level booklet about low testosterone levels and TRT. The

project was funded by Solvay, original maker of AndroGel testosterone gel, 1.62% (later purchased by Abbott Laboratories). To my surprise, Solvay did not try to blatantly spin the copy to favor Androgel. Quite the opposite. The Solvay team reviewing the first draft often made changes that made the booklet more neutral.

For example, I had initially written the following sentence in an early draft: "You can increase the positive effects of TRT on your overall health by taking a few basic steps." The reference to TRT was removed by the Solvay medical-legal reviewing team, and the sentence was changed to "You can improve your overall health by taking a few basic steps."

This was not altruism, however. It was astute legal caution. Pharmaceutical companies face a real threat of litigation arising from unsubstantiated marketing claims, as well as regulatory discipline from the US Food and Drug Administration. It is in their interest, therefore, to play it safe with all claims and to avoid the overt peddling of a brand or product. Instead, the goal is to raise awareness of a condition and the availability of a treatment, leaving the responsibility for a decision to the patient, who should "talk to your doctor to see if X might be right for you."

In the end, the patient education booklet was both blandly accurate and effective in transmitting the company's core messages to tens of thousands of patients. Here, for example, is part of the booklet's conclusion:

You've seen that the hormone testosterone is important throughout life. A simple blood test can show if you have low testosterone, and a visit with your doctor can confirm whether or not you have hypogonadism. If so, you can choose from several options to deliver testosterone to your blood. Doing so may relieve your bothersome symptoms and may help restore your energy, positive mood and sexuality.

The passage is true, primarily thanks to the liberal use of the words "can" and "may," which are often suggested by legal review teams because they allow the wiggle room required in legal defenses. And yet the passage is also far from the whole truth. Despite my own best intentions (and training as a journalist), it is a shill for the sponsor—an uncritical, unbalanced presentation of "facts" that serves primarily to drive people to their physicians seeking the holy grail of "energy, positive mood, and sexuality" in the form of testosterone.

"Consensus" Panel Statements

In 2012, I was hired by a professional physicians' organization to attend a meeting of experts in the field of hypogonadism and to write a summary of the meeting's conclusions—a "consensus statement"—to be published as a guide to clinical practice. In this case, consensus was not difficult to achieve because the panel members shared a basic perspective on the value of TRT (although some differences of opinion on technical matters existed).

The meeting was funded by Abbott, and every panel member had served as either a consultant or researcher for Abbott or other companies with TRT products on the market or in the pipeline (ie, Auxilium, Endo Pharmaceuticals, and Lilly). Abbott's role as sponsor and the potential conflicts of interest of all panel members were acknowledged in the final printed monograph, as was my involvement as writer.

In writing the monograph, I included as much cautionary or qualifying language as I could, based on my now much deeper knowledge about this subject. Some of this language survived the rounds of review and editing that followed. For example, to balance the claim that low testosterone levels are associated with higher mortality (an association that has appeared more than once in the literature), I noted that a recent systematic review and meta-analysis had found large between-study differences in results and methodological problems that cast doubt on the claimed association.[7]

But other sections or sentences of a cautionary nature were deleted by panel members during the review process. Here are 2 that were cut:

It is worth noting that the quality of the evidence on which current clinical guidelines for TRT are based is low or very low, and that similar guidelines about the alleged benefits of hormone therapy for post-menopausal women have been questioned after high-quality studies of sufficient size and duration were carried out.[8]

Composite measures of T levels and the symptoms related to low circulating androgens are likely to be fluid and lack stability over long periods of time. This suggests that Symptomatic Androgen Deficiency (SAD) represents a transient, rather than a permanent, state for the majority of the general male population and may cast doubt on the use of SAD or similar constructs as proxies for true age-related hypogonadism.[9]

If those paragraphs had remained, they would have helped balance the tone of the resulting monograph. That does not mean that the monograph is hopelessly biased. In fact, I believe that it is more cautionary than some guidelines I have read and that it contains an up-to-date summary of treatment options that nonspecialists might find useful. At the same time, I believe that the overall perspective of the piece is, at best, neutral on the potential clinical utility of TRT and on the larger potential risks posed by widespread use of TRT by eugonadal men. I believe that a more sharply skeptical tone is warranted by the existing data—or lack thereof.

A potential weakness of the consensus panel model for generating clinical practice recommendations is that some panelists work harder than others. Some attendees of the hypogonadism meeting, for example, were careful, responsible, and fair minded, both during the meeting and in the reviewing of monograph drafts. Others did a far more cursory job, and 1 member did not participate in the review process at all. Such variability in effort may be inevitable, but it can result in so-called consensus statements that actually reflect only the strongly held views of a minority of the panel. In addition, of course, a panel as a whole may not represent the true range of opinions that exist on a matter of interest, either because the members are suggested by the funder or because the organizers recruit panel members via the personal recommendations of key members. (Some companies that organize consensus panels are attempting to improve transparency. One of my clients, New England Research Institutes, actively seeks a diversity of opinion among panel members and requires the participation of an independent panelist whose role is to flag imbalance or favoritism appearing in the conference itself or whatever papers or materials arise from it.)

A final point: the monograph resulting from the hypogonadism "consensus conference" was published in 2012 and given continuing medical education credit. I created a PowerPoint slide show based on the monograph that was used by physicians who presented Abbott-

funded continuing medical education–accredited lectures on the subject at conferences or other types of professional meetings. This is common practice, although, I believe, fundamentally problematic. Physician education programs (regardless of funding source) have been shown to influence physicians' prescribing behavior, even though the physicians who attend such symposia often deny such influence.[10] And the more objective and less obviously biased a program appears, the greater its potential impact because the messages more easily slip through the skepticism that would be aroused by more ham-handed presentations. "Speakers who sound like drug reps alienate physician audiences and thus work against industry interests," noted the authors of a 2006 article on the subject.[11(p413)]

Conclusions

In this article I have described how drug companies can pay for the creation of apparently objective physician or consumer education media products while obscuring or minimizing their role and/or the identity of the actual writers or producers of the products. I have also described how industry influence may skew content even when funding sources are nominally identified or acknowledged. I believe that these dynamics are widespread and deserve closer scrutiny by physicians, consumers, and regulators.

Despite progress in raising the level of transparency about funding, conflicts of interest, and ghostwriting, drug companies remain free to pursue subtle—and, therefore, effective—means of marketing. They can continue to hire public relations firms that, in turn, place articles or ideas in popular media with no mention of the funding source. Continuing medical education programs and consensus panels continue to be funded by companies selling products directly tied to the messages being conveyed by the resulting "educational" materials. And patient education materials continue to be created that, although factually accurate, subtly shift attitudes by including only selected facts and omitting (intentionally or unintentionally) ideas that would undermine the funder's preferred paradigm.

Everyone involved in the creation of drug company–sponsored educational materials for physicians or consumers—myself most certainly included—must constantly guard against these kinds of influences. We must do our own research, ask hard questions, be skeptical about all claims, and question whether our judgment and our words are being subtly skewed by the knowledge that the funder is watching. Physicians, for their part, must be equally vigilant, skeptical, and independent.

ARTICLE INFORMATION

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Invited Commentary

Low "T" as in "Template"
How to Sell Disease

Lisa M. Schwartz, MD, MS; Steven Woloshin, MD, MS

A man on TV is selling me a miracle cure that will keep me young forever. It's called Androgel…for treating something called Low T, a pharmaceutical company–recognized condition affecting millions of men with low testosterone, previously known as getting older.

The Colbert Report,[1] December 2012

Mr Ferguson, a healthy 55-year-old man without active problems, is in your office for his annual checkup. He tells you that he has no problems and feels fine.

"Well," his wife chimes in, "he has been a little grumpy. Especially since Sammy—our son—starting beating Shaun here in their one-on-one basketball games."

"Of course, I'm grumpy. We bet on a game and now I have to do the lawn," Shaun says, shaking his head. "Takes forever, and it's exhausting."

"I understand," you reply, laughing. "So, are you still off cigarettes?"

"Wait," his wife blurts out before Shaun answers. She stares. "Don't you think he needs a blood test? Could this