

What Do Baby Food & Hangovers Have In Common?

By Philip A. Belcastro, Ph.D.

A blizzard of claims rages on the Internet, television and cable media evoking the consumer's desire and impulse to purchase scientifically proven "healthy and health enhancing" products and services.

Beech-Nut Baby Food labels: "No added refined sugar"; "Low sodium"; an "Excellent source of iron, vitamin D, calcium, zinc, 7 B-vitamins."

LipoDissolve products: "The medications used in the LipoDissolve causes [sic] lysis of the fat cell wall. This allows the fat that is being stored in the cell to be released, and is taken by the lymphatic system to the liver where it is metabolized and excreted in the urine."; "The main ingredient is Phosphatidylcholine, which is actually what causes the fat cell to break down."; "The results from Lipodissolve will last permanently in the area treated."; and "Its [sic] not a question of whether Lipodissolve will work, but rather how many treatments it will take to attain a goal in reduction."

Drinkin' Mate personal testimonials; "NO HEADACHE - I tried Drinkin' Mate after I had three or four beers and I woke up without a hangover headache. -Brian"; "I took one before I started drinking vodka drinks and green beer (of course) and another mid-way through

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the night. My friends were laughing at me saying it wasn't going to work.but guess who had hangovers the next day....and guess who did NOT! Yep, no hangover here. I felt great!" and "I took one package of these Drinkin' Mate's and 1 kid you not I began to feel better in just minutes. Soon enough, my entire hangover was gone."

POM Wonderful 100% Pomegranate Juice scientific reports: "Prostate Cancer: In a clinical study involving 46 men with rising PSA after prostate cancer treatment (surgery or radiation) who consumed 8 ounces of POM Wonderful 100% Pomegranate Juice daily over two years, PSA doubling time increased from 15 to 54 months PSA doubling time is an indicator of prostate cancer progression."; "Erectile Function: A randomized, placebo-controlled crossover pilot study of 55 men with mild to moderate erectile dysfunction evaluated the efficacy of consuming POM Wonderful variety pomegranate juice After consuming POM daily for 4 weeks, the men reported 50% greater likelihood of experiencing improved erections as compared to placebo." ; and "Atherosclerosis: ... In a pilot study of 19 subjects with carotid artery stenosis (plaque buildup), patients who consumed

8 ounces of POM Wonderful 100% Pomegranate Juice daily for a one-year period experienced a 30% reduction in intima-media thickness of the carotid artery vs., a 9% increase for the placebo group."

On February 22, 2010 the Beech-Nut Nutrition Corporation received a warning letter from the Food & Drug Administration (FDA) that **their baby food product claims are in violation of FDA regulations** for products intended for infants and children under 2 years of age.

On April 6 2010 the Puremed-spa website received a warning letter from the FDA citing their **LipoDissolve** product claims are false or misleading in that they are not supported by substantial evidence or substantial clinical experience and further that their injectable LipoDissolve products are in fact prescription drugs because the method of their use is not safe for use except under the supervision of a practitioner licensed by law to administer such drugs.

On March 16, 2010 Amerilab Technologies received a warning letter from the FDA citing that the therapeutic claims on their *Drinkin' Mate* website establishes the product as a drug—because it is intended for use in the cure, mitigation, treatment, or prevention of disease. In turn, the mar-

keting of Drinkin' Mate product claims violates FDA regulations. Further ***Drinkin' Mate* is not generally recognized as safe and effective when used as labeled.**

On February 23, 2010 the ***POM Wonderful Company*** received a warning letter from the Food & Drug Administration (FDA) that found **serious violations of the Federal Food, Drug, and Cosmetic Act with their products.**

The therapeutic claims on their website establish *POM Wonderful* products as drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of these products with these claims violates FDA regulations. Further *POM Wonderful* 100% Pomegranate Juice is also a misbranded food within the meaning of section 403(r)(1)(A) of the Act [21 U.S.C. 343(r)(1)(A)] because the product label bears a nutrient content claim but does not meet the requirements to make the claim.

This is a sampling of the scores of health products, foods and drugs the FDA has cited in violation of FDA laws in only the past 3 months. Thousands of consumers have purchased these products and in fact will continue to purchase these products after this first FDA

warning letter was issued. Keep in mind that these are the products the FDA has identified—there are unknown numbers of products in violation of FDA laws currently being sold in the marketplace that the FDA has yet to identify.

One golden rule to follow when selecting health related products and services is ***'Buyer Beware'***—truly do your homework. Testimonials and consumer reviews or ratings, which litter the internet, are one of the poorest indicators for judging the safety and effectiveness of a health product or service. Research the health product or service at federal cites such as the FDA (<http://www.fda.gov>). Be sure to check if a health product or service you are contemplating is listed in the FDA Enforcement Actions division (<http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm>). Another golden rule is ***'if it sounds too good to be true—it is most likely not true.'*** Health products or services that claim to cure incurable diseases such as diabetes and arthritis or to have found the cure for genetic or aging inevitabilities such as balding, wrinkled skin, menopause, osteoporosis or atherosclerosis should immediately peak your skepticism. Another option

is to ask a health professional or educator about the health product or service advertised. Here at the college there are four departments that can serve as an invaluable resource to you: Health Education Department; Nursing Department; Allied Health Department; Science Department.

In most cases bogus health products and services will simply just take your money. In some cases bogus health products and services will cause injury or disease or delay treatment using a scientifically proven and safe therapy. In rare cases bogus health products and services will result in death. So the next time you are accosted by an advertisement or website that **guarantees** you will lose **20 pounds in two weeks**, or improve your sex life beyond anyone's expectations, or **prevent a drug from being detected in your urine**—the only guarantee you really have is that you can get your money back. Hopefully the merchant will at least keep that promise. If not, you have the option of filing a claim with the local Better Business Bureau as well as the FDA.

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Making Life Decisions About Birth Control

By Lesley L. Rennis, MPH, Ed.D.

Women have more options than ever before when it comes to birth control. But more options do not necessarily translate into easier decision-making. Many young women do not have a clue about what is available and how to choose between the various methods and brands of birth-control. For some, choosing birth control is less about what is right for their bodies and lifestyles and more about blindly following the recommendation of a medical professional, friend or media advertisement.

Recent controversies over the top selling Yaz and Yasmine pharmaceutical line have motivated some young women to begin questioning their birth control choices (kindly read: Yasmin & Yaz: Suspect of a Fatal Birth-control Choice, in this issue of *HealthNotes*). Yaz and Yasmine are not the only birth-control methods that have been at the center of controversy. The transdermal skin patch Ortho Evra has been phased out as a result of investigations linking it to life threatening blood clots. In April 2004, an 18-year-old New York fashion student died while using the *Ortho Evra* patch. Her death was caused by a blood clot linked to the use of the

patch. Depo-Provera, the birth-control injection, has been linked to decreased libido (sex drive), significant weight gain and adverse health risks.

The fact is all medications have some risk; therefore it is imperative for women to understand potential side effects of birth-control methods and make decisions based on reliable information and their individual needs. Here are some general guidelines to help in decision-making.

1. Do your homework

With so much information available online it is easy to find information about birth-control choices. Find out exactly how each method prevents pregnancy. Research all potential side effects and understand who is most at risk. Compare different methods—keeping your individual lifestyle in mind. Consider what might happen to an unborn child if you were to become pregnant while using the method. Involve your partner by making sure he understands your choices and the potential side effects of the method you choose. Do your homework prior to your medical appointment so you will be informed and armed with questions.

2. Know your history

Before choosing a birth control method, make sure you have a thorough medical exam and you know your medical and family his-

tory. Women who smoke or have a family history of cardiovascular disease may be at increased risk of complications from birth-control use.

3. Know your situation.

Think about your overall health: how often you have sex; the number of sex partners you have; whether you want to have children someday; and your need to protect yourself from sexually transmitted diseases.

Remember, the goal is to stay healthy and to protect yourself from unwanted pregnancies. After following the above steps, make an informed decision about which method works for you. Once you begin using your birth-control choice make sure you see a medical professional regularly (at least once a year). Pay attention to your body, keeping potential side effects in mind. Stay informed about controversies surrounding your method of choice. Gain the knowledge you need to make truly informed decisions!

Helpful Web sites:

http://kidshealth.org/teen/sexual-health/contraception/bc_chart.html

<http://www.womenshealth.gov/faq/birth-control-methods.cfm>

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Yasmin & Yaz: Suspect of a Fatal Birth-control Choice

By Sharie Hansen, M.S.W.

A 17-year-old woman, who had no known risk factors for thromboembolism (the formation of a blood vessel clot) unexpectedly died of a massive pulmonary embolism (a blood clot which blocks a main artery in the lung) (Grootheest & Vrieling, 2003). This woman was not a smoker, nor did she lead a sedentary life. Both of her parents tested negative for risk factors. The deceased 17-year-old woman did not ingest any fatal combination of drugs prior to her death. This is one of five cases reported to the *Dutch Spontaneous Reporting System for Adverse Drug Reactions* regarding the prescribed use of the oral contraceptive Yasmin.

Yasmin, and its sister pill Yaz, which contain the estrogen ethinylestradiol combined with a new progestin, *drospirenone*, were the first two contraceptives approved by the United States Food and Drug Administration (FDA) in 2001. Yasmin was approved in Europe in 2000. *Drospirenone* was believed to be safer than the birth control hormone levonorgestrel, which is also a progestin and has been commonly used since the

1970s. However, there has been increasing evidence that *drospirenone* may have a higher health risk than levonorgestrel (Pearce, Layton, Wilton et al., 2005).

Since last year Bayer Healthcare, the manufacturer of Yasmin and Yaz, has been faced with numerous lawsuits regarding Yasmin and Yaz alleging their advertisements are misleading. Scores of lawsuits have been filed by women who claimed to have suffered serious health problems as a result of using Yasmin and Yaz and that the health concerns of these hormones are significantly downplayed in Bayer's advertisements.

Yaz is a newer version of Yasmin that contains a lower dose of estrogen. It is the most popular birth control pill in the United States. Bayer has promoted Yaz as more than an oral birth-control method. The commercials emphasize Yaz as a treatment for moderate acne. The official product website for Yaz (www.yaz-us.com), as well as one of its two original commercials, state that "*In recent studies, 9 out of 10 women saw improvement in their moderate acne.*" The promotions also assert that Yaz can

alleviate the symptoms of premenstrual dysphoric disorder (PMDD). PMDD is a more relentless form of premenstrual syndrome (PMS). Symptoms include headaches, bloating, irritability, muscle aches, changes in appetite, and fatigue. In its advertisements Bayer failed to distinguish the difference between PMS and PMDD. In October 2008 Thomas Abrams, Director of the FDA's Division of Drug Marketing, Advertising, and Communications, sent Bayer a warning notice stating that their TV advertisements entirely omit that "Yaz" has not been evaluated for the treatment of premenstrual syndrome (PMS) and fail to convey that the drug is only indicated for women who experience the symptoms of PMDD, rather than PMS. Abrams' letter stated that as a result of their failure to explain what PMDD is, in contrast to PMS, the TV ads mislead the public by suggesting that Yaz is approved to treat women with any severity of the symptoms, regardless of whether their symptoms are severe enough to constitute PMDD (Abrams, 2008).

Birth control hormones in pill form or in other delivery systems such as injection or vaginal rings alter a woman's hormone levels in order to either prevent ovula-

tion or prevent an already fertilized egg (embryo) from implanting in the uterus. The combination of estrogen and a progestin in an oral contraceptive has long been known to increase the risk of blood clots, strokes and heart attacks, particularly because of blood coagulation caused by estrogen. Estrogen-progestin combinations such as Ethinyl estradiol/drospirenone present a risk to women for: thrombosis, embolism, gallbladder disease, hypertension and liver disease (Somma, 2004).

Bayer plans to defend its products in court, citing that its advertisements and warning labels express the health risks associated with Yasmin and Yaz. In addition, it sponsored a study in Europe which concluded there was no increased risk of heart problems or deaths resulting from birth control pills containing drospirenone, as opposed to birth control pills with levonorgestrel. However, two studies on Danish and Dutch women reported that there is a higher risk of blood clots in women taking the newly developed progestin drospirenone (Lidegaard, Lokkegaard, Svendsen & Agger, 2009; Vlieg, Helmerhorst, Vandenbroucke et al., 2009).

To be certain, these recent lawsuits underline the need for

men and women to be properly informed and educated about their birth-control choices (kindly read: Making Life Decisions About Birth-control, in this issue of *Health-Notes*). For most birth-control users their efforts to educate themselves end with the selection of a method. This can be a serious mistake in that a method judged to be reasonably safe when prescribed a year ago can be subsequently judged a considerable risk just a few months later. Such is the case with Yasmin and Yaz for users who were prescribed these hormones prior to the summer of 2008 in America. (Keep in mind that the FDA **has not** removed Yasmin and Yaz from the marketplace.) Thus, one key lesson is that men and women using birth control need to maintain their education about the methods they are using in order to protect their health. Women presently using Yasmin and Yaz should immediately consult with their physicians on the best course of action to take to protect their health and the occurrence of an unwanted pregnancy.

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