



Vive la Differencesm

“Delivering the World a Difference in Women’s Health”

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Please note:

FemmePharma Global Healthcare has returned to www.femmepharma.com! We made this change in order to reclaim our corporate identity and to improve the ability of anyone interested in the company to find us on the web.

FPGHC’s e-mail addresses will also be formed using this new domain name.

If you’d prefer to receive *Vive la Differencesm* via e-mail, send a note to info@femmepharma.com.

Letter from the President

As 2008 draws to a close, we want to express our appreciation to the 50 plus individuals who have been part of our team for their support and hard work. We especially want to thank the investors and shareholders of FemmePharma, for without their continued investment these amazing milestones could not have been accomplished.

We have “had the time of our lives” in 2008, furthering the development of our two lead drug candidates, FP1097 for urinary incontinence, and FP1198 for breast disease. To amplify our commitment to women’s health we launched the FemmePharma Mental Healthcare subsidiary. This further demonstrates the FemmePharma goal of “delivering new treatment options for women throughout the world.”

Please enjoy my reflection on 2008; the lyrics were adapted from a personal favorite by Green Day, “Good Riddance” (Time of Your Life).

Another turning point, phase three(s) along the road
Time grabbed us by the wrist, we directed where to go
So we made the best of these clinical trials (test), and didn’t ask why
It’s not a question, but a lesson learned in time

It’s something unpredictable, but in the end it’s right. / We hope to make a positive change in your life.

So take the milestones, and the data in your mind
Don’t hang it on a shelf but use it in good health and good time
Tattoos of encouraging results with FP1097 and FP1198 on trial
For what it’s worth it was worth all the while

It’s something unpredictable, but in the end it’s right. / We hope to make a positive change in your life.

It’s something unpredictable, but in the end it’s right. / We hope to make a positive change in your life.

It’s something unpredictable, but in the end it’s right. / We hope to make a positive change in your life.

Que Dieu vous Benissez! (French: May God Bless You!)

Gerie DiPiano

FPGHC Establishes FemmePharma Mental Healthcare

At a time when industry retrenchment, lay-offs, and even bailouts dominate the news, FemmePharma Global Healthcare is experiencing growth. FemmePharma announces the establishment of a new division, FemmePharma Mental Healthcare, Central Nervous System, that will focus on central nervous system (CNS) disorders in women.

“We are energized to expand our commitment in

women’s health even at a time when the pharmaceutical industry is retreating in this area,” says President and CEO Gerianne DiPiano. “For FemmePharma, these are times which provide a wealth of opportunities in women’s health.”

Since its establishment in 1996, FemmePharma has focused on women’s gynecological health issues, including urinary incontinence and fibrocystic breast disease. With its ex-



pansion into CNS, that focus is growing to develop treatments particularly for depression (including postpartum depression), anxiety disorders, eating disorders, and neuropathic pain specific to women. FemmePharma Mental Healthcare will develop products targeted toward conditions, disorders, or diseases including but not limited to those which:

See **Mental Health** on p. 2

DiPiano Honored by PharmaVOICE

Gerianne DiPiano, President, CEO, and founder of FemmePharma, was named one of the top 100 health-care executives and one of the top 12 entrepreneurs by the publication *PharmaVOICE*. Among the 12 individuals honored nationally, DiPiano is one of only two women.

PharmaVOICE editors describe DiPiano as a “forward-thinking risk taker who has not only carved out a niche in the life sciences by creating a whole new business, but has steered her company to new heights.”

DiPiano serves as the lead inventor on FemmePharma patents and developer of drug formulations. The patents cover a full range of diseases and disorders affecting women. She’s also the lead fundraiser for the company.

“I am motivated to create life changing treatment options for women.”

-Gerie DiPiano

“I am motivated to create life changing treatment options for women which will markedly improve their quality of life,” she says.

DiPiano was named one of Pennsylvania’s Best 50 Women in Business by Governor Ed Rendell in 2007, and she serves as Executive Vice-Chair on the Board of Trustees for Drexel University along with being on the Corporate Advisory Board of the Society for Gynecologic Investigation and taking an active role in the Women’s Law Project of Pennsylvania.

Mental Health

- are unique to women
- occur disproportionately in women
- are associated with different risk factors in women
- follow a different course in women than in men

Women’s mental health is a significant public health issue. For example, women are approximately twice as likely as men to experience depression, the most prevalent psychiatric disorder. Therefore, contributions lessening the rates of depression among women would reduce the global burden of disease.

“We know that women respond differently than men to medications for depression,” DiPiano says, referring to a study published in 2006 in the *Journal of Affective Disorders*. “And this is just one example. Understanding and developing treatments that respond to women’s unique health challenges is FemmePharma’s mission so our expansion into CNS disorders in women represents a natural progression.”

While FemmePharma con-

tinues to invest and grow, the pharmaceutical industry in general is withdrawing. In April of this year, a *Wall Street Journal* website estimated that as many as 25,000 pharmaceutical jobs were expected to be eliminated in 2008. In October, Wyeth announced it would eliminate

“Our expansion into CNS is an indication of our continued growth and commitment to women.”

-Gerie DiPiano

discovery work in women’s health while reducing its therapeutic areas from 14 to six.

DiPiano says this represents a concern for her personally while providing an exciting opportunity for her company.

“The gap in developing treatments unique to women is widening even though there are significant unmet needs,” DiPiano says. “Without question our expansion into CNS is an indication of our continued growth and commitment to women and their unique health needs.”

Appétit

Femme Pharma is pleased to announce a new column in *Vive La Difference*: “Appétit.”

“Appétit” will be a small serving of insights into the development and communication activities within our organization to wet our reader’s appetite for the “main course” that follows.

We hope you enjoy this new section, and please let us know what you would like us to serve up in future issues of *Vive La Difference*.

Q: What are the challenges associated with developing a drug for urinary incontinence?

A: In addition to reducing the number of micturitions per day (bathroom visits), it is highly desirable to eliminate or significantly reduce incontinence episodes (loss of bladder contents, wetting). Side effects associated with treatment must also be mild and not interfere with quality of life. In the case of urinary incontinence, reducing dry mouth, constipation, and other anticholinergic side effects is a key to better treatment options.

Q: What is the “go-no-go” criteria that will form the basis for continuation of the development of FP1097 (for treatment of urinary incontinence)?

A: We developed a target product profile for FP1097 that established the criteria for continued product development. FP1097 must be able to be delivered intra-vaginally using a tampon-like application no more than twice daily. The efficacy of FP1097 must be comparable to the oral immediate release form of the active ingredient. FP1097 should not have any clinically significant vaginal irritation, and FP1097 adverse events should be far less on a comparable basis to the orally administered active form.

Q: How does FP1097 stack up to its target product profile?

A: It stacks up very well. By early indications, FP1097 will be as efficacious as the best treatment options today but should significantly reduce or eliminate the most troublesome side effects. So far, we are encouraged and will proceed to our phase 3 clinical trial.

Q: Can you tell us anything else about FP1097?

A: Based on the early indications, we have decided to name the “baby.” FP1097 will now be known as “Solista.”

Q: Why “Solista” as the brand name?

A: As you know, naming your “baby” is never easy, and the FDA has established strict criteria on product naming. We chose “Solista” because we wanted a name that would resonate with women who are suffering with the condition. “Solista” will help these women improve their quality of life, brighten their future, and free them from their current state of isolation, seclusion, and solitude.

Q: What’s new on FP1198, the breast disease product?

A: We are quite optimistic about this excellent opportunity. Although the complete data set will not be available until the second quarter of 2009, all indications are that FP1198 has no androgenic side effects; typically with this active ingredient, one would observe side effects such as facial hair growth, deepening of voice, and increased acne.

Stay tuned for our next sampling in March!

À votre santé! (French: To your health!)

Business Tip of the Quarter

Multicultural Marketing of Health and Wellness to Women

The pharmaceutical industry is finally coming to realize the increasing importance of women in health care, as both buyers and prescribers. A trend report issued in August 2007 by Guideline, Inc. developed insights into the health-care needs of women. The researchers broke down results by ethnicity to discover how needs differ among Caucasian, Hispanic/Latino, African American, and Asian women. More than 1,200 interviews were conducted consisting of about 1,000 women and 200 men (as a comparison group).

The vast majority of respondents, 94%, reported taking some proactive measures to ensure health and wellness. About 61% of the women respondents indicated that they "cut down on/eliminated eating foods high in fats." 61% of the women respondents take vitamins. 62% of the women respondents indicated that they read nutrition labels, and 54% of them indicated that they visit the doctor/healthcare professional on a regular basis.

As a whole, 81% of women respondents feel comfortable talking to their doctor about general health needs. Interestingly enough, most women also reported feeling comfortable discussing breast cancer (70%), gynecological issues (69%), weight (67%), and mental health (64%). Topics that women, as a whole, felt less comfortable discussing are those relating to alcohol/drug/tobacco consumption and sexual diseases.

The survey also looked at key informational sources other than physicians that women relied upon to manage health-care needs. 55% of the women respondents used websites but preferred health-related websites

See **Multicultural** on p. 5

Perceptions vs. Reality

The women of *FemmePharma Global Healthcare* take on popular myths about women's health.

I love fish, but I've stopped eating it since I became pregnant. I've heard that the mercury in fish is harmful for my baby. Is that true?

"Virtually all fruits and vegetables, whole grains, some dairy, and most protein sources are good choices for mom and good choices for baby. There are really very few foods you need to avoid," says Peter Bernstein, MD.¹ A large study showed that children born to mothers who ate fish during pregnancy had a higher intelligence quotient than those whose mothers did not include fish in their diet.² Some types of fish, however, should be avoided because of their high mercury content; these include swordfish, shark, king mackerel, and tilefish.³

I eat healthy and exercise regularly, so I don't need to worry about heart problems. Right?

Maintaining a healthy lifestyle is important for overall health; however, it does not necessarily protect a woman against cardiovascular diseases. The number of women who died from cardiovascular diseases (CVD) has exceeded that of men since 1984. Heart disease is the cause for almost 39% of all female deaths in America. Women are more likely to die from CVD than all forms of cancer combined. Women should consider all factors relating to CVD including age, race, genetics, and lifestyle in determining their risk of having heart problems. In addition, other health conditions such as high blood pressure, cholesterol, and diabetes can also affect the heart.⁴

Therapeutic Area

Neuropathic Pain

Acute, or nociceptive pain, like that due to trauma, results from activation of pain-sensitive peripheral nerve fibers, is generally brief, and protects the individual from further injury. It usually subsides as the injury that incites it heals. Until it does, acute pain can be successfully treated by non-steroidal anti-inflammatory agents (NSAIDs) like Motrin and Aleve or, when severe, by opioids.

Neuropathic pain, in contrast, is a debilitating chronic condition that results from damage or malfunction of the peripheral

nerves, spinal cord, or brain, is not protective, and can last for many years. The pain is episodic or

continuous and is often described as a burning, electric, or stabbing sensation that is extremely distressing and can lead to depression and social isolation. Among its causes are traumatic injuries to peripheral nerves, including some that seem minor, shingles (post-herpetic neuralgia), complex regional pain syndromes (reflex sympathetic dystrophy), and fibromyalgia. Some chronic neuropathic pain syndromes present particular challenges to women, including chronic pelvic pain, interstitial cystitis, chronic urogenital pain syndromes, and vulvodynia.

A great deal of study has aimed to understand the complex mechanisms that cause neuropathic pain. These investigations have emphasized processes in the peripheral nervous system that activate and sustain abnormal firing patterns of

Treatment [of neuropathic pain] is multifaceted but often unsatisfactory.

See **Pain** on p. 4

¹ Bernstein, Peter, MD as cited in Bouchez, Colette, "Separating Pregnancy Myths and Facts," www.webmd.com/baby/guide/separating-pregnancy-myths-and-facts? 11/6/2008.

² Hibbeln, J. (Feb. 17, 2007), *The Lancet*, vol 369: pp 578-585.

³ Bouchez, Colette, "Separating Pregnancy Myths and Facts," www.webmd.com/baby/guide/separating-pregnancy-myths-and-facts? 11/6/2008.

⁴ Borda, Cynthia (March 2008), "A Woman's Heart," *PharmaVOICE*, 49-57.

It Feels Good to Be Honest: Lying to the Doctor Is Dangerous to Your Health

A visit to the doctor's office is a cause for anxiety for many women, and the reasons involve more than just the dread of getting poked and prodded. You are questioned about some pretty personal issues, and suddenly you feel like a child again as you squirm nervously on the examining table. You are afraid you might get scolded if the person in the white coat finds out you have not been doing what you were supposed to.

Women are often compelled to fib a little when talking to their doctors because they are embarrassed, or feel that certain information isn't important. Stretching the truth might not seem like a big deal at the moment, but it can result in serious risks to your health. Next time you make a visit to the doctor's, try to tell the truth!

You say: "I'm not taking any medications."

The truth: You don't consider over-the-counter drugs or herbal supplements medications.

The risk: You never know if Tylenol or Benadryl or that daily vitamin can have an effect on your medications. For exam-

Remember, doctors aren't here to judge you, but to help you live a healthy and happy life. . . . Find a doctor you can trust and be honest with.

ple, if you take a pill at night to help you sleep, it can cause complications if your doctor prescribes you sedatives or tranquilizers.¹ You should always tell your doctor about any and all drugs you are taking including vitamins and supplements. It's better to be safe than sorry.

You say: "I've never had an STD."

The truth: It is one of those ugly times you would like to erase from your memory forever. You think you've been cured, and no one else has to ever know about it.

The risk: Unfortunately, it might not be over yet. STDs can increase your risk of pregnancy complications in the future. For example, gonorrhea or chlamydia can lead to ectopic pregnancy. If you come clean with your doctor, he or she can watch out for these problems and help you to minimize or avoid the risks.

You say: "Nope, I don't smoke."

The truth: Your definition of a smoker is someone who purchases her own cigarettes. You, on the other hand, can claim being a non-smoker as long as you only bum cigarettes off of your friends, even if it's more than occasionally.

The risk: You have an increased risk of sinus and upper respiratory infections, emphysema, cardiovascular diseases, and lung cancer even if you only light up once in a while. Moreover, it can be dangerous if someone who smokes is put on certain medications. A woman who smokes dramatically increases her risk for blood clots and stroke if she is also using hormone-based contraceptives such as birth control pills, patches, or rings.²

You say: "I feel fine."

The truth: You don't have any physical aches and pains, but emotionally, you are a wreck.

The risk: Don't overlook your emotional health because it is just as important as your physical health. In fact, if you are having unexplained physical symptoms, the cause of the problem might actually be emotional. For example, depression can lead to migraines, fatigue, and sleeplessness. Furthermore, emotional problems affect not only the person suffering from it, but everyone who loves and cares for that person. Children of depressed moms are more likely to be discontent, withdrawn, or unresponsive.

Remember, doctors aren't here to judge you, but to help you live a healthy and happy life. If you feel uncomfortable with your doctor for any reason, be open and up front about your feelings. Doctors sometimes forget their bedside manners after dealing with the same problems repeatedly. If you still fail to communicate, find a different doctor you can trust and be honest with.

¹ "Advice for Americans about Self-Care: Access + Knowledge = Power," www.fda.gov/buyonlineguide/whatsrightforyou.htm, 3/7/2006.

² Norine Dworkin-McDaniel, "Not-So-Sweet Little Lies," www.msnbc.msn.com/id/27052008/?pg=13,10/6/2008.

Pain

damaged pain-sensitive nerve fibers and abundant changes within the spinal cord that lead to heightened activity of nerve cells that transmit pain sensation to the brain. Because understanding of these mechanisms is incomplete, treatment is multifaceted but often unsatisfactory. Available treatment

modalities include physical and psychological therapy, injections of steroids and anesthetic agents, and surgical procedures that block pain transmission by peripheral nerves and nerve cells within the spinal cord. Analgesics are a mainstay of therapy. Unlike nociceptive pain, however, neuropathic pain

does not respond reliably to NSAIDs or opioids. The effective agents were not designed as analgesics and include medications originally developed as anticonvulsants (e.g., gabapentin, carbamazepine, phenytoin) or as antidepressants (e.g., amitriptyline, imipramine). Their use is frequently limited

by unpleasant side effects that accompany systemic administration. A promising avenue of treatment is therefore to develop new formulations of these products that can be applied locally to maximize patient compliance.



Your source for fresh, current, and comprehensive information about breast health

GoodBreastHealth.com features:

- Video demonstration of breast self-exam
- Information on diseases and disorders of the breast, including breast pain
- Description of breast imaging techniques
- Current news and resources about breast health



FemmePharma proudly sponsors GoodBreastHealth.com

Kahlua Cocoa

Try this low fat, toasty treat for the holidays!

1 tablespoon brown sugar
1 tablespoon unsweetened cocoa powder
1 tablespoon Kahlua or cognac
1/4 teaspoon vanilla extract
1/4 teaspoon ground cinnamon
3/4 cup low-fat milk

Place brown sugar, cocoa powder, Kahlua (or cognac), vanilla extract, and cinnamon in a blender. Heat milk in a saucepan until steaming. Add the hot milk to the blender and blend until frothy.

Nutrition Information:

Per serving: 197 calories; 3 g fat (2 g sat, 1 g mono); 11 mg cholesterol; 32 g carbohydrate; 8 g protein; 2 g fiber; 100 mg sodium; 89 mg potassium.

Nutrition Bonus: Calcium (25% daily value).

Source: http://www.eatingwell.com/recipes/collections/healthy_winter_beverages_recipes.html

Multicultural

not associated with government or pharmaceutical companies. Many women also rely on family or friends (57%) and groups of people who suffer from the same conditions as they do (30%). Only 14% of the women respondents utilized pharmaceutical company websites, and only 6% of the women respondents' utilized pharmaceutical or food company toll free numbers.

Across all groups, Asian, Hispanic, and African Americans are all significantly more likely (than Caucasians) to believe that their physician does not understand the needs of their ethnic/racial group.

African American women are the least content with the level of individualized care they are receiving. African American women are also significantly more likely than other women to feel they need help with managing various aspects of their health care.

Asian women in this study indicated that they rely heavily on family and friends to manage

Women influence up to 80% of the health-care decisions for their households, resulting in buying power estimated at more than \$1.2 trillion.

their health-care needs. They also appear to be less at ease with their physicians than other women. Asian women are also more likely than other women to rely on health food and vitamin store sales people to manage their health-care needs.

Hispanic/Latino women feel they don't have adequate access to doctors and health-care facilities (39% versus 28% total). Hispanics are also less likely to take an OTC medication. Also like Asian females, Hispanic women rely more on health food and vitamin stores as a source of health-care information beyond their physician.

In contrast to other ethnic groups, Caucasian women perceive less need for help and advice in managing their health

care. They also are the most content with the level of customized care they receive from their physicians.

As marketers, marketing to women creates many challenges. The trick to successfully marketing to a multicultural group of women is to recognize that you do not know as much about them as you believe you do and to make sure you know whom to ask, how to ask the right questions, and how to listen to the answers because if you don't then your marketing campaigns will fail.

Why bother? Because as consumers, women influence up to 80% of the health-care decisions for their households, resulting in buying power estimated at more than \$1.2 trillion.

Happy Holidays.

From the Team at

FemmePharma Global Healthcare

May Peace and Joy Be Yours in the New Year

