

Business & Professional Ethics

Bioengineering 100
Fall 2016

Bayer Mirena IUD Case Study

The IUD revisited

 Mirena®
(levonorgestrel-releasing
intrauterine system) 52 mg
Keep life simple.





FRONT PAGE

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SEPTEMBER 9, 2016



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daily dose

Smart, straight-forward advice from
America's leading Nurse Practitioner

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Parenting

Caregiving

Healthy Living

Health Conditions



Nurse Barb

Meet Nurse Barb Dehn



Barb Dehn is a practicing Women's Health Nurse Practitioner, award winning author, and a nationally recognized health expert. She holds a BS from Boston College and earned her Masters degree at the University of California, San Francisco. An in demand and popular national speaker on all aspects of women's health, she also lectures at Stanford and is a frequent health expert on television. She has appeared on CBS, ABC, CNN, Good Morning America Now and NBC's VillageLive.

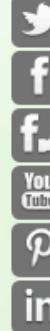
[NurseBarb Talent Reel](#)

Blue Orchid Press

Barb started her own health publishing company, Blue Orchid Press, LLC to "Empower Women with Information." She writes and publishes this series of innovative and award-winning women's health guides with titles ranging from Pregnancy, Breastfeeding, Fertility, Healthy Bones and Menopause. The Blue Orchid Guides are used by millions of women across the country.

[Blue Orchid Guides](#)

Women's Physician





DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

[Bayer address redacted]

RE: NDA 21-225

Mirena® (levonorgestrel-releasing intrauterine system)
MACMIS # 18166

Dear Dr. Almanakly:

The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed a script for a live consumer-directed program (program) entitled "Mirena Simple Style Statements Program" (150-74-0002-09) for Mirena® (levonorgestrel-releasing intrauterine system) (Mirena), submitted by Bayer HealthCare Pharmaceuticals Inc. (Bayer) under cover of Form FDA-2253. The program overstates the efficacy of Mirena, presents unsubstantiated claims, minimizes the risks of using Mirena, and includes false or misleading presentations regarding Mirena. Thus, the program misbrands the drug in violation of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 352(n), and FDA's implementing regulations. See 21 CFR 202.1(e)(3)(i), (e)(5) & (e)(6)(i).

Mirena FDA warning letter excerpts

- Mom Central and Bayer sponsored ‘parties’ had presentations by Barb Dehn regarding Mirena usage

Following the introduction of the program, the script states that “Barb [Dehn] will begin presentation with an icebreaker - an interactive Q&A - which will touch upon issues such as busy schedules, barriers to intimacy and contraception” (emphasis added). The “icebreaker” questions include the following (in pertinent part; emphasis added):

- “How many of you feel so busy that you often can’t find time to take care of yourself? And do you think this impacts your level of intimacy?”
- “Do you ever feel so overwhelmed by your schedule that intimacy is much more of a “to do” on a list than a desire?”
- “If you didn’t have to worry about contraception, do you think you would be more likely to be intimate with your partner?”
- “Do you think if you didn’t have to worry about taking your birth control everyday, it would help you be more intimate?”

- “So you mentioned that convenience and reliability are among the most important benefits of your birth control method. One strategy that I recommend for busy couples is choosing a birth control method that allows for spontaneous intimacy and which you don’t have to think about every day, such as the intrauterine contraceptive Mirena®.”

The above statements clearly indicate that the use of Mirena instead of other means of contraception will result in increased levels of intimacy, romance, and by implication, emotional satisfaction. These claims misleadingly overstate the proven efficacy of Mirena. Mirena has been proven to be an effective intrauterine contraceptive device. While we note that Mirena does not involve a daily routine and is not a barrier method of contraception, FDA is not aware of any evidence that suggests that women using Mirena for birth control experience an increase in reconnection, romance, or intimacy with their partners. Claims that state or suggest such quality of life outcomes, such as those described above, must be

supported by substantial evidence, as demonstrated through adequate and well-controlled trials using validated patient assessment instruments to measure the outcomes of interest. If you do, in fact, have data to support these claims, you should submit them to FDA for review.

We note that, according to the Mirena PI, at least 5% of clinical trial patients reported decreased libido as a side effect of Mirena use. Patients also experienced abdominal/pelvic pain, nausea, headache, nervousness, and depressed mood, which could adversely affect a woman’s feelings relating to romance or intimacy.

“Looking and feeling great”

The script also includes the following statements, to be presented by Ms. Dehn (emphasis added):

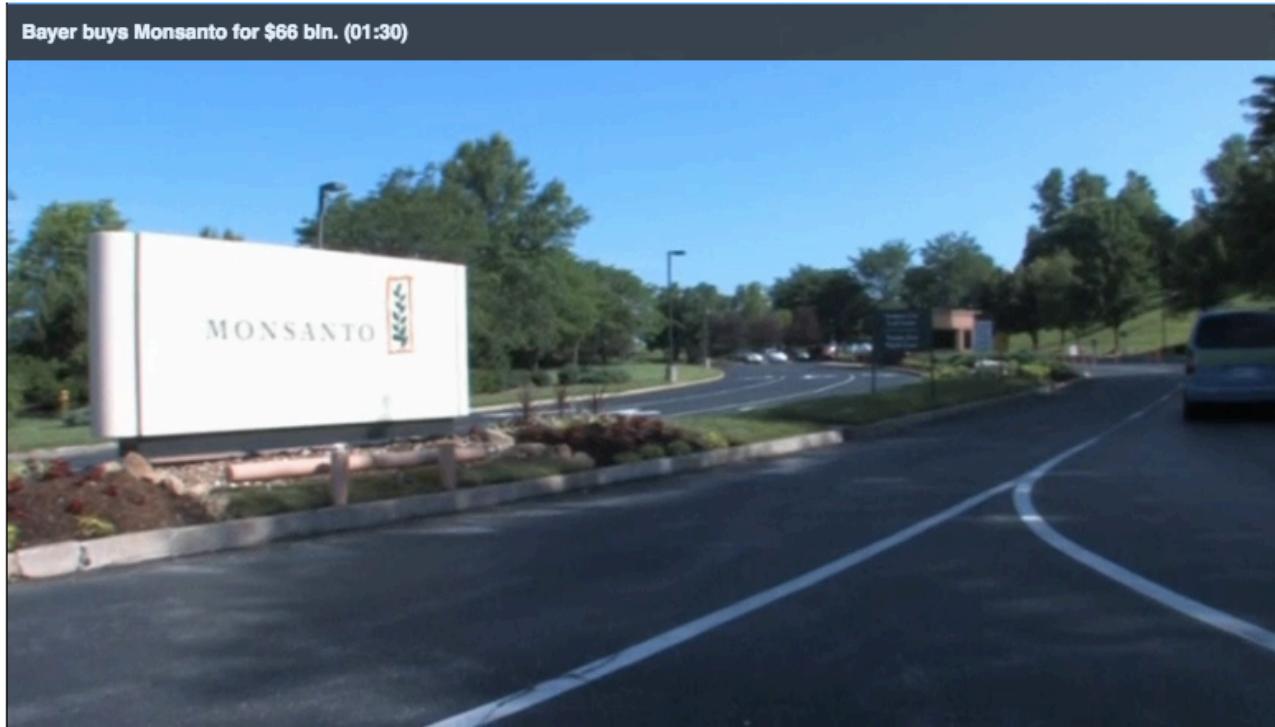
- “But what this party is really about is looking at the whole picture and figuring out steps to take to simplify your lifestyle while still looking and feeling great. One of those ways is finding a birth control that is compatible with your busy lifestyle.”

The above statement goes beyond the suggestion of increased intimacy to suggest that Mirena can help patients “look and feel great.” Again, FDA is not aware of any evidence suggesting that women who are using Mirena for birth control look great or feel great. Patients using Mirena may experience various side effects, such as irregular bleeding, ovarian cysts, back pain, weight increase, breast pain/tenderness, and acne, in addition to the side effects indicated above. The experience of these side effects can prevent patients from “looking and feeling great.” Such claims of improved patient-reported outcomes must be supported by substantial evidence, as demonstrated through adequate and well-controlled trials using validated instruments to measure these outcomes of interest. If you do, in fact, have data to support these claims, you should submit them to FDA for review.

Would you work at a company
that didn't align with your code of
ethics?

COMMODITIES | Thu Sep 15, 2016 | 6:22am EDT

Bayer clinches Monsanto with improved \$66 billion bid



Bayer buys Monsanto for \$66 bln.

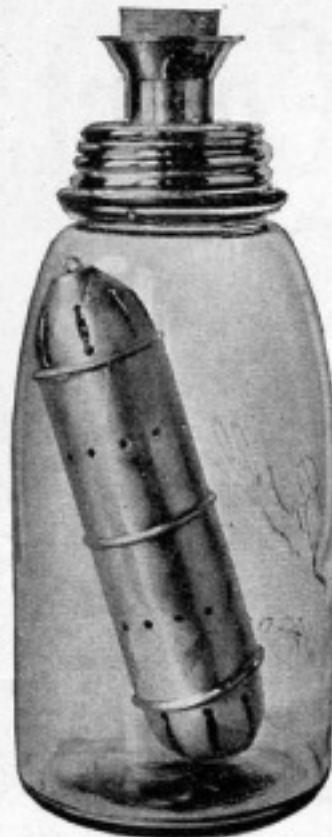
01:30
<http://www.reuters.com/article/us-monsanto-m-a-bayer-deal-idUSKCN11K128>

Would you STAY at a company that didn't align with your code of ethics?

News

Have you ever purchased or
taken dietary or herbal
supplements?

(answers anonymous!)



RADIUM EMANATION WATER

Drives Out Uric Acid

Suffering from too much uric acid and diseases caused by faulty elimination—**Rheumatism, Gout, Periodical Headaches, Neuralgia, Constipation, Neurasthenia, Auto-Intoxication and Lack of Bodily Vigor**—quickly relieved in a natural way without drugs or chemicals by our new discovery

THE WAY TO MAKE RADIIUM WATER IN YOUR OWN HOME

with our Rayode. A little device containing Radium enough to supply 2,700 Mache Units of Radio-activity, in two quarts of water every twenty-four hours, for less than 10c a day. The Rayode will last a lifetime.

SEND FOR FREE LITERATURE

Tells how you can buy or rent a Rayode to make Radium Water in your own home, with your own ordinary drinking water. Address:

THE COLORADO RADIUM PRODUCTS COMPANY
635 First National Bank Building Denver, Colo

Radithor

- Byers drank ~1,200 bottles from 1927-1930
- Died in 1931 from radium poisoning

EBEN M. BYERS DIES OF RADIUM POISON

Continued from Page One.

to trace in detail the effect of the radium salts.

While there have been numerous instances of deaths in industrial plants where workers have been poisoned through handling radium, this is believed to be the first case where a fatality has been attributed to drinking water containing radium salts. Exhaustive studies of its effect are being made by Dr. Flinn.

The Federal Food and Drug Administration on Wednesday issued a warning against "radioactive" drugs because of serious injuries to users. It was pointed out that radium in active dosage has harmful potentialities and can be safely administered only with the utmost caution.

Mr. Byers, who was chairman of the board of the A. M. Byers Company, New York and Pittsburgh manufacturers of wrought-iron pipe, won the national amateur golf championship at the Englewood, N.J., Golf Club in 1906, defeating George S. Lyon, the Canadian champion. He also was prominent in horse racing, trap-shooting and other sports. He long maintained racing stables here and in England and his entries were seen in many important races. He followed baseball with enthusiasm and had the same box at Forbes Field in Pittsburgh for many years. Mr. Byers had won a

RADIUM POISONING VICTIM



Eben M. Byers, Steel Man, Who Died Here Yesterday.

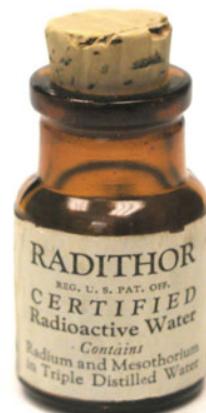
more than slight improvement. X-rays taken daily revealed a critical brain condition, with every indication of the formation of a brain abscess which Dr. Steiner predicted before the commission would prove fatal if it were

HOUSING BOA SIGNED BY GO

56 Measures, of Whi
Appropriations
\$1,000,000, Ap

COMMISSIONS

These Are for Study
vision, Justice Adminis
Estate Law—16 Bill



McCoy, Quack! Tales of Medical Fraud

<http://www.cultofweird.com/wp-content/uploads/2010/12/radithor-radium-cure.jpg>

Public Notification: Stiff Bull Herbal Coffee contains hidden drug ingredient

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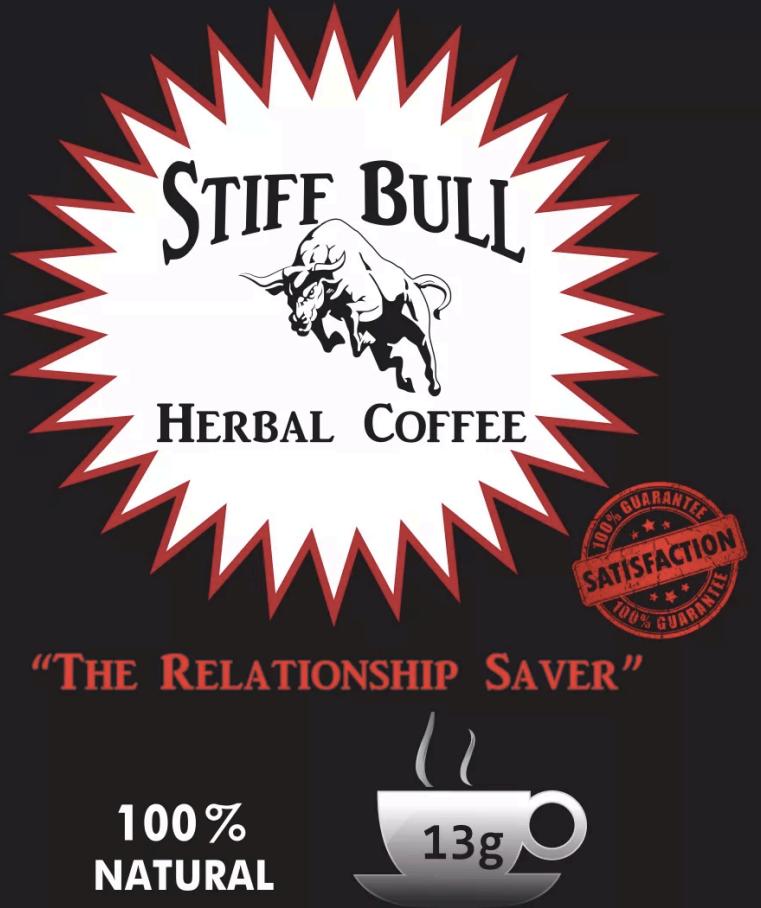
[EMAIL](#)

[PRINT](#)

[9-16-2016] The Food and Drug Administration (FDA) is advising consumers not to purchase or use Stiff Bull Herbal Coffee, a product promoted for improving energy. This product was identified by FDA during an examination of international mail shipments.



“contains desmethyl carbodenafil...structurally similar to sildenafil, the active ingredient of Viagra, an FDA approved prescription drug for treatment of erectile dysfunction (ED).” – FDA



Nutrition Facts

Serving Size: 1/2 Package (6.5g)

Serving Per Package: 2

Amount Per Serving

Calories 60	Calories from Fat 10
-------------	----------------------

% Daily Value*

Total Fat 4g	6%
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Total Carbohydrate 4g	6%
-----------------------	----

Sugars 4g

Protein 2g

Proprietary Herbal Blend 880mg	
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Tongkat Ali Root	450mg
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Maca Root	200mg
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Guarana	150mg
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Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:

INGREDIENTS: INSTANT COFFEE POWERED, NON DAIRY CREAMER (CORN SYRUP SOLIDS, HYDROGENATED COCONUT OIL, SODIUM CASEINATE (A MILK DERIVATIVE) DIPOTASSIUM PHOSPHATE, SUGAR, TONGKAT ALI, MACA, GUARANA

Directions

Simply add 1/2 of the package to a cup of hot water, stir and drink.

Drinking Stiff Bull before major activities can help improved energy levels and fatigue reduction.

CONSUMER RESPONSIBILITY

Don't consumer more than 1 pack in a day.

Not recommended for children, pregnant women, people sensitive to caffeine, with high blood pressure, or heart problems.

“This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease;”

USA Distributors:
Stiff Bull LLC Upper Marlboro MD USA
www.stiffbull.com
Packaged By:
Worldgate Vision Beverage Sdn



8 68012 00020 9

MADE IN
MALAYSIA



Dietary Supplements

- Not required to have FDA approval before marketing
- Must be labeled as a supplement
- “Just because it’s on the store shelf doesn’t mean it’s safe or effective.”
- Multiple industry recalls
 - >40 marketed weight loss products
 - >70 marketed sexual enhancement products
 - >80 marketed body building products



ild

Johnson & Johnson Tylenol Case Study



Read HBS case study

Page 13 @ “The Tylenol Poisonings”
to Page 18

What would be the ‘responsible’ course of action in this case for J&J?

- What are the arguments for/against a recall?
- How can J&J keep/win back their customers?
- How does this affect other Tylenol products?
- How does this affect other OTC drugs?

September 29-30, 1982



- 5 people in the Chicago area had died after taking cyanide laced Tylenol
- All bottles from lot MC2880 manufactured in a Pennsylvania plant

September 30th response

- Open response to press
- Set up 800 numbers for consumers to call
- Recall batch MC 2880 from all 31 states
- 450,000 telexes to physicians, hospitals and trade, warning against use until situation clarified
- Late that afternoon a sixth victim was found, but the bottle was from lot 1910 MD, manufactured in a Texas plant

Weekend - Monday

- FDA and J&J organize recall of ALL Tylenol capsules in Chicago area
- Pennsylvania and Texas manufacturing plants close until situation clarified
- Seventh victim was identified, also from Chicago
- Burke meets with FDA and FBI, recommends a national recall of the capsule product, but both agencies were against the idea

Recall

- October 5: Strychnine laced Tylenol capsules found in Oroville, California.
- October 6: Nationwide recall announced: 31 million bottles of Tylenol capsules
- End of the week: J&J, FBI, FDA tested >8 million capsules. 75 capsules, all from Chicago area, were positive for cyanide.



Impact

- Tylenol's market share fell to <7%
- Estimated cost of over \$100 million to withdraw, test, destroy capsules.

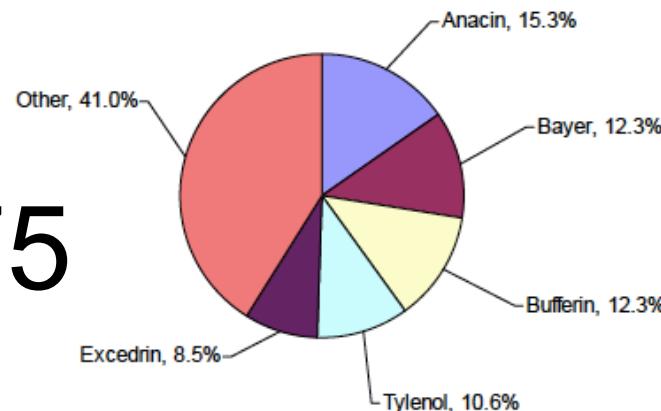


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Exhibit 6 Brand Share and Advertising Expenditures for Five Major Analgesic Brands, 1975 (\$000)

In a \$680 Million Retail Market			
Company	Brand	Market Share (%)	Advertising Expenditure
American Home Products	Anacin	15.3%	\$27,685
Sterling	Bayer	12.3%	17,291
Bristol-Myers	Bufferin	12.3%	14,659
Johnson & Johnson	Tylenol	10.6%	142
Bristol-Myers	Excedrin	8.5%	15,576
Other	Other	41.0%	NA

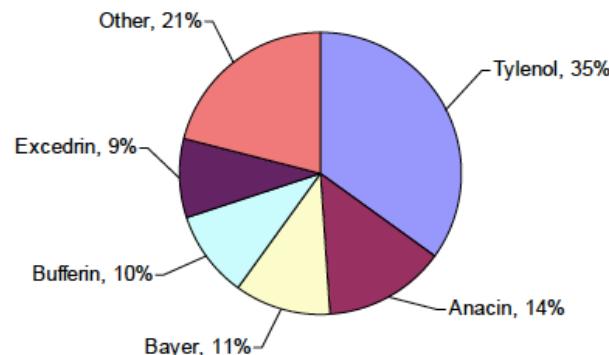


Source: "A Pained Bayer Cries 'Foul,'" *BusinessWeek*, July 25, 1977, p. 142; and "Top 200 Advertised Brands," *Marketing & Media Decisions*, July 1979.

1981

Exhibit 8 Brand Share and Advertising Expenditure for Five Major Analgesic Brands, 1981 (\$000)

In a \$1.2 Billion Retail Market			
Company	Brand	Market Share	Advertising Expenditure
Johnson & Johnson	Tylenol ^a	35%	\$36,766
American Home Products	Anacin ^b	14	44,641
Sterling	Bayer	11	24,650
Bristol-Myers	Bufferin	10	20,321
Bristol-Myers	Excedrin	9	19,603
Other	Other	21	NA



Source: "The Race To Grab Up Tylenol's Market," *Chemical Week*, November 3, 1982, p. 30; and "Top 200 Advertised Brands Directory," *Marketing & Media Decisions*, July 1982.

^aIncludes all products bearing the Tylenol name.

^bIncludes Anacin-3.