

Wesley, Karen V

From: Mary M. [mmazzara@snet.net]
Sent: Saturday, June 03, 2000 10:19 AM
To: ombudsma@oc.fda.gov
Subject: Today Sponge

Dear Sir or Madam,

I'm writing to express my frustration with the fact that the Today Sponge has not yet been approved by the FDA. I've received frequent e-mails from Gene Detroyer, President and CEO of Allendale Pharmaceuticals, Inc., indicating that the Today Sponge is not yet on the market because the FDA has yet to inspect the factory that it will be produced in. First, Mr. Detroyer explained the inspection was scheduled for a date in March, then it was postponed, but was supposed to be completed by April 24. Then, it was scheduled for a date in May, but that too was postponed without further indication of when the actual inspection would take place.

I'm 25 years old, I work in Connecticut as a graphic designer. I'm engaged to be married to a man I've been monogamous with for more than five years. During this relationship I got pregnant and decided to have an abortion. The pregnancy was the result of a contraceptive gel that obviously didn't work. After the abortion, I started taking the birth control pill because it was the only contraceptive that I trusted. The pill, however, has had side effects that I've chosen to live with.

I realize that there are other contraceptive options on the market. I could use the diaphragm, the IUD, spermicide, or condoms. These products, however, are all undesirable because each is either expensive, impractical, unreliable or has side effects (the IUD, for example, causes heavier bleeding during menstruation). I used the Today Sponge for two years before it went off the market. It was convenient, not overly expensive, and had no side effects. Many women were as satisfied with the Today Sponge as I was. As you probably have heard, there was even an episode of Seinfeld, which made the term "Sponge-worthy" famous. Obviously, this was meant to be humorous, but I think it illustrates the frustration women felt when the Today Sponge was suddenly no longer available.

I don't know if abortions in the United States have increased or decreased over the last several years, but I do know that there are probably millions of women every day who are faced with unwanted pregnancies. These women are not all careless, promiscuous women who didn't use contraception. Many of these women are in monogamous relationships and did use contraception, and, for one reason or another, got pregnant anyway.

The burden of birth control ultimately falls on the shoulders of women because they are the ones who truly have to cope with the consequences of an unwanted pregnancy. For this reason, we need as many birth control options as possible. We shouldn't have to take a pill everyday if we don't want to. We shouldn't have to deal with side effects from a contraceptive if we don't want to. We shouldn't have to have something inserted into our bodies for a period of years if we don't want to. We definitely shouldn't have to resort to any form of birth control that we don't feel will protect us from our choice not to have a child.

Let me end by commenting on the issue of abortion. I'm obviously pro-choice, but I respect the opinions of those who are pro-life. But, no matter where you stand on the issue of abortion, the reality is that no one ever wants to have to decide what to do when faced with an unwanted pregnancy.

Please, use whatever powers you may have to continue the process for getting the Today Sponge back on the shelves.

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Thank you.
Mary K. Mazzara