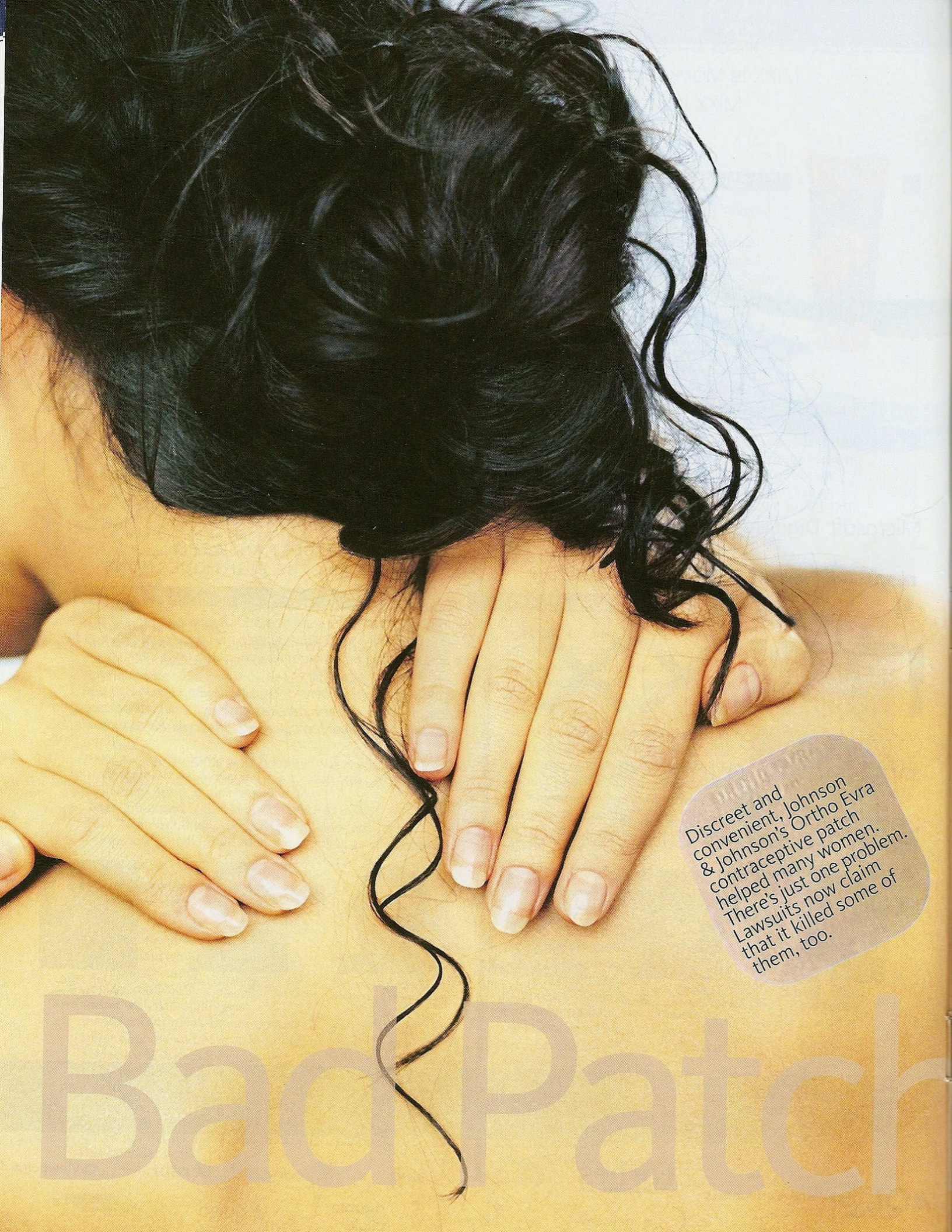


Bad Patch

Discreet and convenient, Johnson & Johnson's Ortho Evra contraceptive patch helped many women. There's just one problem. Lawsuits now claim that it killed some of them, too.

BY JIM EDWARDS

At the time of her death, Zakiya Kennedy had the kind of life that most young women can only dream about: She was 18 years old, beautiful and a freshman at Berkeley College in New York. Kennedy had chosen to study fashion, and was even preparing to audition for *America's Next Top Model*, a popular show on The CW Television Network.

On April 2, 2004, Kennedy had descended the stairs to the labyrinthine corridors of the Bryant Park subway station in midtown Manhattan, just below 42nd Street. It was a Friday night, a little before 8 p.m., and Kennedy and her boyfriend were waiting to catch a Sixth Avenue subway train back to his house in Queens. Suddenly, Kennedy felt pain in her legs and head. She collapsed onto the platform. A cop appeared, and soon Kennedy was being rushed to Bellevue Hospital, about 13 blocks away.

At 9:14 p.m., Zakiya Kennedy was dead. Nobody could say why.

At that point, the Kennedy case passed to the hands of a New York County medical examiner. Three days later, he wrote his autopsy report. According to the medical examiner's office, the autopsy concluded: "Cause of death: pulmonary thromboembolism complicating hormonal contraception (Ortho Evra Patch)." Layman's translation? Kennedy was killed by blood clots that had formed in her lungs after she'd used a form of birth control.

At the time, the Food and Drug Administration said that Kennedy's was the only recorded death associated with Ortho Evra, a brand of contraceptive introduced by Johnson & Johnson in 2002. Ortho Evra is an adhesive patch; women wear it topically, much like they would a Band-Aid.

Following the Kennedy incident, the company said that blood clots were a rare but well-known side effect of hormonal contraceptives. The company also stated that it was "following up with the medical examiner's office for more information."

Blood clots are generally not the sort of malady to turn up in a healthy teen. In fact, according to Volume 29 of the *International Journal of Epidemiology*, published in 2000, fewer than one in 100,000 people under age 39 will get a blood clot. Kennedy's death, therefore, wasn't only tragic; it was freakish. And that—coupled with the juicy details that Kennedy was an aspiring model with an evidently active sex life—made the Berkeley College freshman's death a tabloid sensation.

Before long, however, it emerged that Kennedy's death was not an isolated event. Nor was it the first.

Today, at least 1,500 women and their families have sued J&J and its Ortho McNeil Pharmaceutical unit, the maker of the patch. These parties contend that the company failed to warn them in its advertising that women who wear the Ortho Evra patch run a greater risk of developing potentially fatal blood clots than do women who elect to use other contraceptives—and that some patients have suffered heart attacks, brain injuries and strokes. The suits allege that at least 23 women have died after using the patch.

In addition, according to a document filed in one lawsuit, J&J maintains a database it calls "Sceptre" in which 38,554 "adverse events" associated with Ortho Evra have been recorded. ("Events" range from a simple headache all the way up to a heart attack.) The total number of fatalities purportedly caused by Ortho Evra has not been made public, as the litigation has been conducted under a judicial secrecy order.

(Continued on page 21)

Denis Felix/Taxi/Getty Images

Wherefore the Warning Signs?

J&J launched Ortho Evra in 2002 with one of the most elaborate marketing campaigns the drug world has ever seen. Before it stopped all consumer promotion in 2006, the company spent $254 million advertising the brand. But of the 34 print and TV ads produced for Ortho Evra, five ran with no warnings about the patch's possible side effects, according to the Nielsen Monitor-Plus database.

Those that did have warnings mostly carried them in tiny, technical-sounding print, a practice that is not rare in drug advertising. Still, only seven of the ads were totally up-front about the risk of blood clots, heart attacks and strokes. (The New York-based firm Alchemy developed the ads.)

PLEASE READ IMPORTANT SAFETY INFORMATION: The contraceptive patch contains hormones similar to those in birth control pills. Hormonal contraceptives are not for everybody. Most side effects of the contraceptive patch are not serious and those that are, occur infrequently. Serious risks, which can be life threatening, include blood clots, stroke or heart attacks, and are increased if you smoke cigarettes. Cigarette smoking increases the risk of serious cardiovascular side effects, especially if you are over 35. Women who use hormonal contraceptives are strongly advised not to smoke. Some women should not use the contraceptive patch, including women who have blood clots, certain cancers, a history of heart attack or stroke, as well as those who are or may be pregnant. The contraceptive patch does not protect against HIV or other sexually transmitted diseases.

*Not available through all OB/GYNs. Available while supplies last

Only seven ads contained warnings in the same typeface the company used for its promotional messages. This ad targeted Spanish speakers.

Total number of ads that J&J created for Ortho Evra: **34**

Number of print ads that contained no warnings of any kind: **4**

Number of ads that warned of blood clots in the same size typeface as the rest of the ad: **7**

This ad suggested that new moms might "feel stressed" by their newborns, and suggested ways to "simplify your life" after giving birth. One suggestion: "Simplify your birth control." It didn't list any side effects or warnings.

This ad claimed Evra was the "#1 Prescribed birth control brand," but it only mentioned blood clots in tiny print at the bottom of the ad.

Total number of TV commercials: **8**

Number of ads that contained warnings only in fine print: **15**

Number of commercials that contained no warnings of any kind: **1**

The patch's main advantage was that users didn't have to remember to take a pill every day. This ad showed images of women suddenly realizing they'd forgotten to take their pill, and carried the message, "It's never fun to forget." Viewers were urged to ask their doctors about the Evra patch. The ad contained no warnings.

*Credit: Print*Views, Nielsen Monitor-Plus; Survey compiled by Renee Kimmel*

(Continued from page 19)

"The company is vigorously defending against these claims except where settlement is deemed appropriate," Ortho McNeil said in a statement provided to *Brandweek* by its representative, Gloria Vanderham. "Ortho Evra is a needed hormonal birth control choice and is safe and effective when used according to the FDA-approved label."

Separately, senior J&J execs have dismissed the complaints in talks with investors as "media-driven," "sound bite public attacks," or based on "publicity." J&J CEO Bill Weldon once told investors that critics of Ortho Evra were being seduced by "the siren song for risk-free medicines."

Perhaps understandably, headquarters may be trying to downplay the whole matter, but Ortho Evra is clearly not a proud chapter in the corporate life of the drug maker, no matter how one chooses to spin it. Caught in the floodlights of publicity caused by the lawsuits, the company has watched Ortho Evra sales fall by 50%—a dismal atrophy for what once had been one of J&J's flagship brands, one whose sales topped over $400 million a year according to IMS Health. At one time, Ortho Evra was the second most-prescribed birth control method in the U.S., according to the company. (The No. 1 brand? Another J&J drug called Ortho Tri-Cyclen, though most women simply call it "the pill.") The Ortho Evra patch's advertising budget was once $90 million a year. Today, J&J doesn't advertise it at all.

ONE PATCH, MANY SCRAPES

In an attempt to understand the rise and fall of Ortho Evra, *Brandweek* examined existing documents filed in lawsuits in New Jersey, New York, Ohio, California and other states, along with interviews and material gathered from J&J and independent sources. What emerges are a number of serious questions:

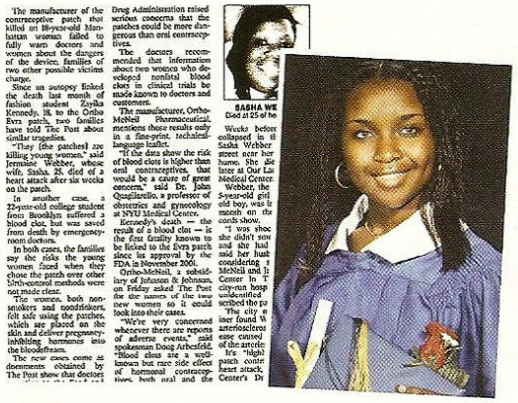
- If women taking Ortho Evra would endure such an apparently heightened risk of developing blood clots, why did J&J decide to launch the brand in the first place? After all, the company already had a top-selling birth control brand on the market, one with a long and established safety record. What's more, J&J was additionally introducing a *third* contraceptive drug at the same time as Ortho Evra.
- Did J&J's advertising adequately warn women of the patch's risks? (*See, "Wherefore the Warning Signs?" page 20.*)
- Why did J&J hire a physician to work on the brand who, according to the Massachusetts Board of Registration in Medicine, had a history of faking test results in his previous studies of contraception?
- And why, after the FDA began a review of the drug that seemed likely to cause headlines, did J&J's marketing executives buy up dozens of "negative URLs" such as DeathPatch.com, according to the company's internal e-mails? At a time when companies have much to fear from Web-site publishers bent on defamation of a brand, many firms will make such acquisitions to defend their names and their products. Yet in the case of Ortho Evra, *all* of these domain-name purchases took place *after* the patch was already the focus of public controversy.

A full count of alleged fatalities linked to Ortho Evra could be unveiled this fall, when Kennedy's case is scheduled to become the first of the 1,500 to go to trial. At the same time, a federal judge in Ohio is due to rule on whether 3,600 pages of confidential J&J documents should be made public.

> *"J&J will be fighting a multifront war to preserve its reputation."—Kwittken*

If damaging documents are released, "J&J will in fact be fighting a multifront war to preserve and protect its reputation," predicted Aaron Kwittken, CEO of Kwittken & Co. in New York, a crisis-management expert who has worked for a different unit of J&J. The drug maker, Kwittken warned, "will do damage to their reputation if they appear overly confident or defensive or try to openly diffuse [or] spin the allegations. They will be far more effective at preserving their reputation if they made themselves accessible and open."

But even in an average layman's view, the 120-year-old Johnson & Johnson clearly has much at stake. Generations of Americans have associated the brand with integrity and trustworthiness. J&J is known for its warm-and-fuzzy products like talcum powder and baby shampoo. It's this same motherly reputation that makes the Ortho Evra debacle so puzzling, especially when one plumbs the company's internal thinking as revealed by court documents.


NEW YORK POST 50 CENTS SUNDAY

'PATCH' SHOCK GROWS

Kin ID new 'victims'

By SUSAN EDELMAN and MARSHA KRANES

The manufacturer of the contraceptive patch that killed an 18-year-old Manhattan woman failed to fully warn doctors and women about the dangers of the device, families of two other possible victims charge.

Since an autopsy linked the death last month of fashion student Zyaira Kennedy, 18, to the Ortho Evra patch, two families have told The Post about similar tragedies.

"They [the patches] are killing young women," said Jermaine Webber, whose wife, Sasha, 25, died of a heart attack after six weeks on the patch.

In another case, a 22-year-old college student from Brooklyn suffered a blood clot, but was saved from death by emergency-room doctors.

In both cases, the families say the risks the young women faced when they chose the patch over other birth-control methods were not made clear.

The women, both non-smokers and nondrinkers, felt safe using the patches, which are placed on the skin and deliver pregnancy-inhibiting hormones into the bloodstream.

The new cases come as documents obtained by The Post show that doctors Drug Administration raised serious concerns that the patches could be more dangerous than oral contraceptives.

The documents recommended that information about two women who developed nonfatal blood clots in clinical trials be made known to doctors and customers.

The manufacturer, Ortho-McNeil Pharmaceutical, mentions those results only in a fine-print, technical-language leaflet.

"If the data show the risk of blood clots is higher than oral contraceptives, that would be a cause of great concern," said Dr. John Quagliarello, a professor of obstetrics and gynecology at NYU Medical Center.

Kennedy's death — the result of a blood clot — is the first fatality known to be linked to the Evra patch since its approval by the FDA in November 2001.

Ortho-McNeil, a subsidiary of Johnson & Johnson, on Friday asked The Post for the names of the two new women so it could look into their cases.

"We're very concerned whenever there are reports of adverse events," said spokesman Doug Arbesfeld. "Blood clots are well-known but rare side effect of hormonal contraceptives, both oral and the

SASHA WE died at 25 of he

Weeks before collapsed in st Sasha Webber street near her home. She die later at Our La Medical Center.

Webber, the 5-year-old girl old boy, was li month on the cards show.

"I was shoc she didn't sou and she had said her husb considering a Mirena and Ji Center in T city-run hosp widely-credited scribed the pa

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It's "highl patch contr heart attack, Center's Dr

Dying young: Zakiya Kennedy (inset) was one of several alleged 'patch victims' in the New York media.

DULY WARNED?

Ortho Evra's April 2002 launch was unusually glitzy, radically different from the debuts of most pharmaceutical products. During New York Fashion Week, the company persuaded swimsuit designer Rosa Cha to affix the patch on her models—including Naomi Campbell, who wore a string bikini—as they worked the runway. The Ortho Evra patch also grabbed the spotlight when the 2004 Norwegian Olympic women's beach volleyball team wore them. *Time* magazine went so far as to name Ortho Evra one of the "coolest inventions" of 2002.

Meanwhile, TV commercials for Ortho Evra took a seductive approach: Two spots featured a woman with her jeans unzipped, applying the patch to her bare stomach. The same two ads showed a woman sporting the patch right on her hindquarters (the model also was wearing a pair of sheer panties for added effect.)

Another ad showed a woman in a wet bikini, with a patch underneath. The patch later peeked out from under the waistband of lacy pink lingerie. The tagline: "On your body, off your mind." (This catchphrase was a window into why J&J bet its patch would be a hit in the first place—convenience and peace of mind. A big problem with the pill was that women sometimes forgot to take it—and hence risked getting pregnant. Wearers of the Ortho Evra patch would, of course, be free of those worries.)

Seemingly drowned out by all the theatrics, however, were warnings about the risk of users developing blood clots. All estrogen-containing birth-control products carry such risks. (*See, "Blame the Wild Mexican Yam," page 23.*)

Fears of side effects including blood clots and heart attacks swirled around the pill shortly after its introduction in 1960. By 1969, studies had revealed that the risk of developing blood clots was related to the amount of estrogen administered, and the pill's earliest incarnations delivered high doses of estrogen that were later reduced. If Ortho Evra patches also delivered high estrogen levels to a user, then the entire matter of side-effect risk would be, in essence, a return to familiar—and worri-

some—territory.

This is significant because, out of the total of 34 ads that ran for Ortho Evra—including the very TV commercial in which it made its debut—*five* of those ads failed to contain a single warning statement about side effects, according to the ad database of Nielsen Monitor-Plus.

In fact, the FDA does not require all drug ads to carry warnings, especially if the medical information contained within them is minimal. However, in the wake of widespread public criticism that many drug ads historically aren't forthcoming enough, the pharmaceutical industry—with J&J participating—has since voluntarily agreed to stop running ads that omit side-effect warning information.

J&J said its ads were legit. The campaign "met FDA requirements and guidelines about communications, including the risk and efficacy of the product. Advertising is pre-cleared with the FDA and we have always complied with FDA regulations concerning appropriate safety information in various forms of advertisements and promotions," the company said.

The process of warning customers about a drug's dangers in print advertising is slightly different. As anyone who's ever taken a prescription drug has probably noticed, side-effect warnings (written in technical parlance) usually appear in microprint. Difficult as it may be to read, there's nothing out of the ordinary in a drug company's using tiny print for such warnings. It's still worth noting, however, that in the case of Ortho Evra, only seven of its 26 print ads displayed the side-effect warnings in the same easy-to-notice typeface used for the promotional messages.

According to court documents and the FDA, however, it's clear that J&J did conduct discussions concerning just how "serious" Ortho Evra's risks were before the drug was approved.

A TALE OF TWO DOCTORS

In 2000, Dr. Joel Lippman was the vp of clinical trials on Ortho Evra, according to documents that are now part of a New Jersey lawsuit. His suit states: "The clinical research had revealed that the estrogen dose released by the Evra patch . . . may increase the risk of deep vein thrombosis and pulmonary embolisms. Dr Lippman advised Ortho that it should conduct further research to understand the impact . . . and if necessary modify the package insert before introduction to the marketplace. Ortho disregarded Dr. Lippman's concerns and launched the product."

After Lippman allegedly voiced his fears, he was moved to a different unit of J&J. In 2006, the company terminated him. Lippman said he was eliminated because he raised too many concerns about Ortho Evra.

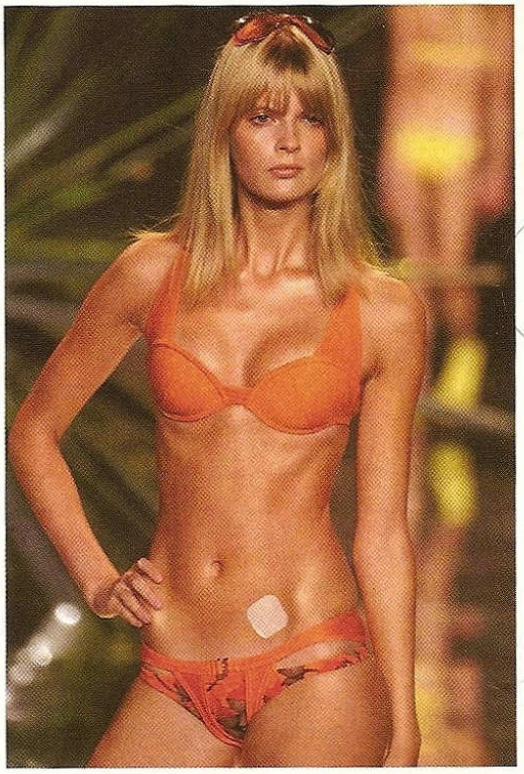
The company confirmed that Lippman worked for its Ortho unit in the year prior to the brand's approval, but said the doctor was terminated for cause—"as a result of inappropriate conduct and mismanagement of responsibilities completely unrelated to the allegations he raises in his lawsuit."

Prior to Ortho Evra's launch, another doctor joined the company payroll. Dr. Andrew Friedman served as senior director of clinical research at Ortho McNeil. J&J had hired Friedman despite the fact that he had faked study data at a previous job in which he was researching contraception, according to the Massachusetts Board of Registration in Medicine. (According to the company, Friedman "fully informed Ortho-McNeil Pharmaceutical of his previous employment history, including an incident of research misconduct that occurred nearly 10 years ago." The doctor "remains an employee in good standing," the company said.)

In 1995, Friedman had been working as chief of the reproductive endocrinology unit at Brigham & Women's Hospital in Boston. While there, he did research into estrogen-based contraception. Friedman "fabricated data for three articles, two of which were published," according to the board. In two of those studies, Friedman "fabricated approximately 80% of the data" and "altered" the files of the remaining 20% "who were actually patients in the study."

Found guilty of "practicing medicine deceitfully" under the board's rules, Friedman saw his medical license suspended for a little over a year. It was reinstated just before J&J brought him aboard in January 2000, according to medical board records. His license, however, was still on probation through February 2001.

Despite his background, Friedman was occasionally used as a spokesperson for the Ortho Evra brand in addition to his official role, which was to research the responses of Ortho Evra users. After conducting a study of extended wear of the patch, Friedman found that many women on a lengthened Ortho Evra regimen bailed out of the experiment. The reason? Side effects: nausea, vomiting, migraines and hypertension—and all at *double* the occurrence rate of the control group. Friedman did not return two calls for comment.



Steve Wood/Action Press/Newscom

A three-piece: A model sports an Ortho Evra patch, plus her bikini, at the 2004 Rosa Cha Beachwear Show.

NO FRIENDS AT THE FDA

The issue of blood-clot risk arose again just after J&J applied to the FDA for permission to launch Ortho Evra in December 2000. An FDA official reviewing J&J's sponsoring application criticized it for downplaying blood-clot events by referring to them as "coagulation abnormalities" instead of "venous thrombotic event[s]," according to documents obtained from the FDA.

In assessing J&J's count of the number of women who had blood clots in testing, the FDA official used block capitals for his response: "THE REVIEWER DOES NOT AGREE WITH THE SPONSOR'S CONCLUSIONS . . . the incidence rates quoted by the sponsor may be misleading . . . The sponsor's estimated rate of deep vein thrombosis/pulmonary embolism for EVRA is 59 cases per 100,000 women-years [but] the reviewer's rate is 118 per 100,000 women-years, double the sponsor's rate."

The FDA approved the patch anyway, allowing it to be marketed with similar warnings to the pill.

"The label stated that in the clinical trials there were two cases of nonfatal pulmonary embolisms reported in women using Ortho Evra," the company said. "The label also specifically said that it was unknown if the risk of venous thromboembolism with the patch is different than with the pill."

PEEL, APPLY AND WAIT

In essence, the Ortho Evra patch was designed to deliver the same level of estrogen as a modern formulation of the birth-control pill. But even though the patch was chemically similar, its delivery method was significantly different. A pill must pass through the stomach, and its active ingredient processed through the liver, before it reaches the bloodstream. By contrast, the patch delivers its drug directly through the skin into the bloodstream in a relatively unmediated state. It was only in 2007 that J&J published a study that found levels of estrogen stay at a constant level in women wearing the patch. For those on the pill, the levels peak after a pill is taken and decline quickly before the next pill. The result, according to the FDA, is that the patch is not the same as the pill: The patch delivers 60% more estrogen to the user's bloodstream.

It is that higher dosage of estrogen that, according to the lawsuits, is at the root of all the trouble that ensued.

All across the country, young, seemingly healthy women who had worn the patch were literally dropping dead. Ashley Lewis, a 17-year-old cheerleader at Beaumont High School in St. Louis, whose nickname was "Baby Tank," died of a pulmonary embolism on Dec. 17, 2003. Sasha Webber, a 25-year-old mother of two from Baychester, N.Y., died a few weeks before Kennedy in 2004. In La Cross, Wis., Alycia Brown, the youngest victim, was only 14 when she died on May 7, 2004, just a month after Kennedy died.

For every woman who died, a larger number of plaintiffs alleged in court that they lived through health-crisis events normally associated with the elderly: strokes and heart attacks; and blood clots in their legs, brains and pelvises that rendered them invalids.

Jody Fain of Latonia, Ky., was 32 when she decided that two kids was enough. She "wasn't a very good pill-taker," so she went on the patch. Almost immediately, "I started having very severe migraines," she said. "I didn't go to work that week."

"I started having severe migraines. I didn't go to work that week."—Fain

The pain grew severe enough to land Fain in the emergency room, where she passed out. When she awoke, doctors asked her simple questions—"Who's the president of the United States?"—that she couldn't answer. She couldn't answer them because she'd suffered a stroke.

Baffled as to why a 32-year-old woman would suffer so severe a medical event, the doctors pressed Fain's husband to think of anything out of the ordinary that might be a cause. Not long afterward, Fain's husband walked into his wife's hospital room and told her to "Rip that thing off." He was referring to the Ortho Evra patch that she'd been wearing.

Kimberly Pierce of Tuscumbia, Ala., told a court in New Jersey that she went to the hospital in 2003 after she became weak, couldn't see properly and her face swelled up. She was told she'd had a transient ischemic attack (a kind of mini-stroke) and a doctor told her "that I should put my affairs in order . . . I feel lucky to have survived." And Melissa Arbino, now 32, had a hole drilled in her skull in a Cincinnati hospital in 2005 to drain excess fluid following a cerebral hemorrhage.

J&J disputes the notion that the patch caused these blood clots. "Whether a woman would have the same symptoms using birth control pills instead of the patch, or because of some underlying risk factor, will be a question in each case. Blood clots are not unique to hormonal birth control; they occur in association with many different medical and physical conditions," the company said.

But anecdotal cases of patch problems were starting to make headlines, and that was an obvious problem for J&J. Sometime in late 2005, the company decided to switch gears on its marketing approach. Gone were the lingerie-filled TV spots. In their place appeared the commercial equivalent of a cold shower. One ad consisted entirely of a female doctor answering questions from serious-looking women. "Is it safe?" one asks. "For most women, yes," the doctor replies. "But the patch does have hormones, like the pill, so there are serious risks such as heart attacks, stroke and blood clots."

While marketers at J&J headquarters struggled with a new message for the public, J&J's sales reps were having problems of their own out in the field, where they'd begun to encounter resistance to the patch from physicians. The problem was especially acute at New York's Mount Sinai Adolescent Health Center. That was the clinic where 18-year-old aspiring model Zakiya Kennedy had obtained her patch.

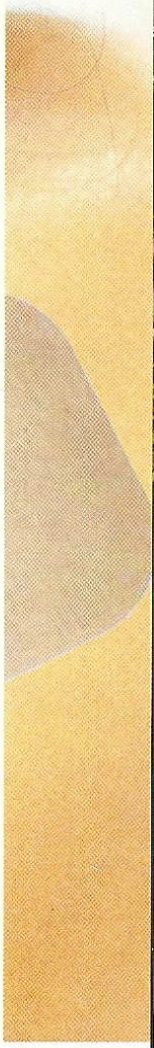
Faced with the urgent and complicated challenge of responding to the Mount Sinai staff concerns, the sales reps—court records show—devised a carefully tailored strategy: They would treat the doctors and nurses to free breakfasts and lunches.

On April 16, 2004, just two weeks after Kennedy died, one J&J rep wrote a sales report note referring to Dr. Anne Nucci, head of the clinic. The note read: "missed dr nucci will bring breakfast on sat." (Nucci declined to comment on this incident, as did J&J. The company's field sales director did not return two calls for comment.)

By May, worry inside the clinic over the Ortho Evra patch had peaked, according to the reps' shorthand notes: "terry nurse and Bethany np said pts were very concerned about oe also the staff was concerned good idea to set up a lunch w nucci for clinic staff to clear up misconceptions about oe."

Over the summer, J&J reps made efforts to meet with every single staff member at Mount Sinai. The rearguard action worked, the notes say: in September, reps reported, "No mention of oe issue" and "no issues w oe safety" at the clinic.

In the two years prior to Kennedy's death, J&J sales reps had paid calls to the Mount Sinai clinic just 10 times, records show. During the 12 months following the young student's death, the number of clinic visits reps made came to no fewer than 33.



Blame the Wild Mexican Yam

A brief history of estrogen-based birth control.

The FDA approved the first oral hormonal contraceptive drug in 1960. Its effect on the sexual culture quickly earned it an authoritative nickname, "The Pill" (although it was actually branded Enovid-10 by its maker, G.D. Searle). Nearly 50 years later, everybody still knows what "the pill" is, and what it does.

Developed originally from a chemical found in the barbasco root (a wild Mexican yam), early versions of the pill used a combination of two active ingredients, progestin and estrogen. The estrogen level was originally set at 50 micrograms.

Throughout the 1960s, as millions of women began using the pill, a small number of doctors began expressing concerns about the potential for dangerous blood clots to form in the veins of users. Estrogen, in addition to tricking the body into thinking it need not produce viable eggs, has the side effect of coagulating human blood.

After the publication of *The Doctors' Case Against the Pill,* a book by the feminist Barbara Seaman, Congress held hearings in 1970 on whether the pill was safe for public use. The FDA later recommended that pills contain the lowest dose of estrogen possible, about 35 micrograms.

The Ortho Evra patch was approved by the FDA in 2001 and given the same warning levels as the 35 microgram estrogen pills that it was designed to mimic. It only emerged later that, because of the differing designs of the pill and the patch, the actual estrogen dose received from the patch was 60% greater—a level the government had frowned upon 30 years ago.

According to the FDA, this greater estrogen level doubles the risk of potentially lethal blood clot events such as heart attack or stroke. —*J.E.*

Ortho Evra's Faithful Flock

At its peak in 2004, more than 10 million prescriptions were written for Ortho Evra. There were still more than 5 million prescriptions for the patch last year, bringing the company $241 million in revenue.

Prescriptions written for Ortho Evra over the past five years:

	'06	'05	'04	'03	'02
Prescriptions (in millions)	5.0	9.4	10.0	8.5	1.2
Sales (in dollars)	$241	416	404	320	50

Source: IMS Health

WAS IT EVEN NECESSARY?

While lawyers maintain the number of fatalities will grow, for now, take the 23 deaths linked to Ortho Evra that have been reported in the media. The company maintains that those deaths—in statistical prevalence, at least—are essentially no different from what one could reasonably expect from a female population using birth-control methods at its disposal. "Ortho-McNeil Pharmaceutical continues to track the safety and effectiveness of Ortho Evra," the company said—and it provides the data it tracks to the FDA. "For Ortho Evra," the statement continued, "the types of reported adverse events are consistent with and within the range of those seen with other hormonal birth control methods."

Of course, the trial lawyers take an opposing view. In the first 17 months Ortho Evra spent on the market, the total number of adverse reactions reported to the FDA (everything from nausea to fatalities) was 9,116, according to the women's lawyers. By contrast, J&J's Ortho Tri-Cyclen pill—which had six times as many users than Ortho Evra—prompted only 1,237 reports, the lawsuits claim.

Those numbers beg a critical question: if Ortho Tri-Cyclen was so much more successful than Ortho Evra, why did J&J even bother to launch the brand in the first place?

One factor could be money. The company's exclusive patent rights on Ortho Tri-Cyclen were set to expire in 2003. Rival companies would soon be able to copy and sell the drug, slashing prices and essentially dismantling a franchise that had earned over $600 million a year, according to J&J's annual reports. J&J needed a new, exclusive drug to replace it. In fact it launched two new drugs, Ortho Evra and Ortho Tri-Cyclen Lo (a pill with an even lower dose of estrogen than its predecessor). J&J vice chairman Christine Poon recently told investors, "The more successful we are with these products, the better we are going to be able to weather the loss of exclusivity of Ortho Tri-Cyclen."

That strategy worked. The demand for Ortho Evra in 2003 was "unprecedented," Poon told investors. "In fact, it has stretched our manufacturing capabilities and plants almost to its limits." According to drug-market research firm IMS Health, 10 million Ortho Evra prescriptions were written in 2005 alone.

Now, of course, the death of Zakiya Kennedy, and the wave of lawsuits that followed, have changed that picture. The FDA began a review with a view to changing Ortho Evra's label. That may sound like a technicality, but a label change can be disastrous for a drug. If the brand's prescribing conditions are tightened, the drug makers will often be required to send all doctors a letter informing them of the new restrictions. It complicates an already complicated process; sales often plummet.

In July 2005, anticipating bad news from the FDA, J&J apparently decided it needed to start defending the brand on the Web. It created a plan, subtitled "Defensive actions to minimize impact of negative presence," according to a copy filed in a New Jersey state court. The strategy was to buy the top keywords for Ortho Evra searches on Yahoo!, Google and Overture. These links would then point to J&J's own sites, and not to the increasing number of sites run by lawyers trawling for those claiming to be Ortho Evra victims. To augment the effort, J&J planned to optimize its existing "natural search" rankings, so that the company's sites rose higher in Google's lists.

"Any increased risk [with Ortho Evra] is within the accepted range of risk."—J&J statement

At the same time, J&J planned to buy sites like PatchSucks.com and 84 other "negative URLs," removing them from public use on the Web.

In a statement, J&J defended its URL purchases: "It is a standard and accepted business practice for companies to prevent product disparagement, to safeguard product reputation and to ensure that women and physicians receive accurate medical information about Ortho Evra, as required by FDA regulation."

The plan encountered a hitch, however. Ortho McNeil consumer marketing director Georgia Lehnert found that four URLs (OrthoEvraInfo.com,Patchinfo.com, PatchInfo.net and PatchInfo.org) were already taken. So Lehnert authorized one of her staffers to approach the owners and make offers for the names. The staffer could dangle up to $1,000 for each. All told, according to the plan, J&J was prepared to spend $206,000 to make it easier to find its own sites and harder for those trying to find negative views about the drug. Lehnert did not return calls for comment.

PATCHING IT UP?

J&J's guess about the FDA review was correct. In November 2005 the agency announced that it was tightening the Ortho Evra label. The drug was different from the pill because it delivered 60% more estrogen, and "increased estrogen exposure may increase the risk of adverse events," the new label said. In August 2006, the FDA again tightened the label for the drug, this time spelling out the link between the higher estrogen level in Ortho Evra and blood clots: "Increased estrogen exposure may increase the risk of adverse events, including venous thromboembolism."

The bad news kept on coming. J&J had paid for a gigantic study of the patch—covering 98,790 women. The results, which started coming in during the summer of 2006, were not heartening: "There was a more than two-fold increase in the risk of venous thromboembolism associated with use of the transdermal [patch] contraceptive system" compared with the pill.

With all-but-definitive evidence now in its lap, J&J choked off the throttle on Ortho Evra's advertising machinery. It spent zero dollars in advertising last year.

In terms of publicity for J&J, however, the worst could be yet to come. The Zakiya Kennedy case is due to go to trial this fall. Two more trials with similar victims in Illinois and Los Angeles will start around the same time. And soon a federal judge overseeing 421 cases in Ohio will rule on whether he will unveil a pile of potentially embarrassing documents. He has already indicated in court that they will not remain secret forever: "There'll be a mechanism at some point at the right time in the litigation to have the [confidential] designation removed."

Of all the surprises in the Ortho Evra story, though, perhaps the biggest one is that J&J never took Ortho Evra off the market. In fact, doctors wrote 5 million prescriptions for it last year when, even with no advertising behind it, Ortho Evra patches rang up $241 million in sales.

"We believe that the scientific and clinical evidence demonstrates that the company acted in a proper and responsible manner in developing and making Ortho Evra available as a birth control choice for women, and in disclosing all pertinent data to the FDA and the medical community in a timely manner," the company said. "Whether Ortho Evra does or does not cause an 'increased risk' remains a matter of scientific and medical debate and is something we continue to study. However, any increased risk is within the accepted range of risk associated with hormonal birth control." BW