

## New Study Links Spine Product From Medtronic to Risk of Sterility in Men

By BARRY MEIER and DUFF WILSON

A surgeon at Stanford University, in a study released Wednesday, suggests that one of Medtronic's best-selling spinal products poses a risk of male sterility. That finding is in stark contrast to earlier research by doctors paid by Medtronic, who found no connection between the product, Infuse, and a condition that causes sterility.

Infuse is a bioengineered bone growth protein that has been widely used in spinal fusion procedures since 2002. The Infuse label notes the sterility-related complication as a possible side effect, but the Medtronic-sponsored researchers in published reports attributed that complication to surgical technique, not the product itself.

The Stanford surgeon, Dr. Eugene J. Carragee, found that men treated with Infuse developed a condition that causes temporary or permanent sterility at a far higher rate than men who received a bone graft, another material that is used to fuse spinal vertebrae. He urged doctors to counsel men about Infuse's risks. The study was posted Wednesday on the Web site of The Spine Journal, which he edits.

"It is important that men who are considering having children have the opportunity to weigh the risks of the various available procedures," said Dr. Carragee, who based his study on 240 patients he treated several years ago with Infuse or a bone graft.

The type of spinal fusion at issue is known as an anterior lumbar fusion, a procedure performed on about 80,000 patients a

year in this country. Infuse is used in about half of those procedures, and men make up about half of the patients who undergo spinal fusions. The sterility complication at issue in Dr. Carragee's study affects only men, not women.

Among the 69 patients treated by Dr. Carragee who received Infuse, five men developed the complication related to sterility, in contrast to one patient among the 174 men who received a bone graft. The condition resolved itself in half of those six patients.

Two surgeons who were involved in the original Infuse trial defended their findings in statements, saying that not enough men had experienced sterility-related complications in their study to statistically link the problem to Infuse. The surgeons, Dr. J. Kenneth Burkus and Dr. Thomas A. Zdeblick, noted the complication in a medical journal article published soon after Infuse was approved by the Food and Drug Administration in 2002, but they divided those patients by the surgical technique used, not by whether or not the men had received Infuse.

In his Web article, Dr. Carragee questioned why the researchers had not broken out the patients in their study between those who had received Infuse and those who had not, a method that he said was a standard way to present clinical trial results.

In an e-mail, Dr. Zdeblick said Dr. Carragee's study was of limited value because it reflected the results of a retrospective look at patients rather than a clinical trial. Such reports "are notorious for being misleading," he wrote.



FILIP HORVAT FOR THE NEW YORK TIMES

Dr. Tomislav Smoljanovic of Croatia has also questioned claims from an earlier study of Infuse.

The new study is likely to intensify a debate over whether industry-financed researchers present study findings in ways that favor the interests of corporate sponsors. Dr. Burkus, who practices in Columbus, Ga., and Dr. Zdeblick, a professor at the University of Wisconsin, have each received millions of dollars from Medtronic in consulting fees or royalty payments.

Both men have adamantly insisted that those financial relationships have not affected their scientific judgment.

Nevertheless, in a commentary accompanying the new study, Dr.

James D. Kang of the University of Pittsburgh wrote that industry support was one way to explain the different conclusions reached by Dr. Carragee and the Medtronic-sponsored researchers.

"There does not seem to be any rational explanation for these observational differences," Dr. Kang wrote.

Dr. Dan M. Spengler, a professor and former chairman of orthopedic surgery at Vanderbilt University, who was not involved with the study, said it added to growing evidence about various risks from Infuse. "It's just startling to me," he said.

Marybeth Thorsgaard, a spokeswoman for Medtronic, based in Minneapolis, said the company believed that it had provided the F.D.A. and doctors with all available medical information about Infuse. Analysts have estimated that sales of Infuse reached about \$900 million in Medtronic's most recent fiscal year; overall company sales hit \$16 billion during that period.

"You have to consider the totality of the data that has been presented, not how one study was reported," said Ms. Thorsgaard.

Dr. Carragee's report is not the first time doctors have chal-

lenged how Medtronic-sponsored researchers characterized the risks of Infuse in medical articles.

Since 2006, an orthopedic surgeon in Croatia, Dr. Tomislav Smoljanovic, has written more than 35 letters to medical journals questioning the claims. In their 2002 report, Dr. Burkus and Dr. Zdeblick reported that a major clinical study involving Infuse had found no adverse effects with the product, including the sterility-related complication.

Among other things, Dr. Smoljanovic and colleagues pointed out in letters that the Medtronic-sponsored researchers, while identifying that six men in their study had developed the sterility-related complication, had not identified how many of those men had received Infuse as opposed to a bone graft.

Last year, Dr. Burkus and his colleagues publicly disclosed in response to the Croatian physicians' letters that five of the six men affected in their study had received Infuse. However, they have insisted that the figure was not statistically significant to link the problem with Infuse.

Dr. Carragee, the Stanford surgeon, said his Infuse study was prompted by a complaint he received from Dr. Smoljanovic about an Infuse-related article in The Spine Journal.

Dr. Carragee said he and his colleagues had posted their study online, ahead of the publication's print edition, because of the public health implications of the findings. He said that forthcoming edition of The Spine Journal would be dedicated to complications involving bioengineered bone growth products like Infuse.

### ADVERTISING

## Army Looks For Recruits In Social Media

By STUART ELLIOTT

WHEN ads for the Army used the theme "Today's Army wants to join you," a joker rewrote it this way: "Today's Army wants to join you. At your place." These days, the Army is getting social — if not quite that social — as potential recruits increasingly spend time with social media like Facebook, Flickr, Twitter and YouTube.

The next phase of the Army's recruitment ad campaign keeps a theme, "Army strong," that was introduced in 2006 and adds a focus on the Army uniform as a "symbol of strength" as well as symbolic of qualities like commitment, achievement and leadership.

The direction of the campaign is typified in a line recited in commercials by the voice-over announcer, the actor Gary Sinise, who talks about the significance of the uniform before concluding, "Try it on at goarmy.com."

The recital of the Web address underlines the concentration on digital media for the campaign, although there are traditional elements like television spots.

"We're working hard to increase our social media," said Lt. Gen. Benjamin C. Freakley, because "we fully recognize that young people TiVo over commercials or are multitasking on their smartphones when the commercials come on." General Freakley is commanding general of both the Army Accessions Command, which oversees recruitment, and Fort Knox, Ky.

"Since the late '80s, 9 percent of the population is propensed toward military service," General Freakley said, compared with about a third in the 1970s. As a result, he added, "we have to reach out in forms like we're discussing to get them to want to know more, to join us in



The Army's latest campaign to attract recruits is focused on the uniform as a symbol of strength, commitment, achievement and leadership.

social media and extend the dialog."

The campaign continues previous elements like video clips, blogs and a microsite, armystrongstories.com, that are intended to connect would-be soldiers "with real soldiers," General Freakley said.

At this time of year, potential recruits — men and women ages 17 to 24 — are also spending time at the movies, which has led the Army to its first sponsorship deal with a Hollywood film. The film, "X-Men: First Class," will be released on June 3 by 20th Century Fox.

On the Army Facebook page (facebook.com/goarmy), visitors are invited to "view exclusive content from the upcoming movie" as well as watch a trailer for the film and a commercial that promotes the Army by comparing the experience to becoming an X-man.

The movie "is about young people who are ordinary doing extraordinary things," General Freakley said. "Ordinary people come in the Army and do extraordinary things every day."

That said, he took note of the differences between the two: "Soldiering is real. 'X-Men' is for Hollywood."

Clifford E. Marks, who helped broker the sponsorship in his capacity as president for sales and marketing at National CineMedia in New York, said the deal represented "the big screen and the small screen working together" in that the promotional content can also be watched on Web sites that are part of a National CineMedia network like rotten tomatoes.com and traileraddict.com.

The Army is also running the commercials featuring the voice of Mr. Sinise in National CineMedia movie theaters, which include those owned by AMC, Cinemark and Regal.

Mr. Marks brought the sponsorship proposal to Universal McCann, one of seven agencies working on the Army account that belong to the McCann Worldgroup unit of the Interpublic Group of Companies. The others include McCann Erickson Worldwide, MRM Worldwide and Weber Shandwick.

(Four other agencies working on the assignment are independent, among them Gravity Media and Carol H. Williams Advertising.)

The agencies were hired by the Army in late 2005 and rehired on March 31 for

an additional year with four one-year renewal options.

"There's a lot of ways to talk about the kind of strength we mean when we say 'Army strong,'" said Craig Marcus, executive vice president and executive creative director at McCann Erickson Worldwide.

"The human truth is, we all react when we see a soldier wearing a uniform," Mr. Marcus said. "It means a lot to us, and it means a lot to them."

"With symbol of strength, it's about all these other things" that the uniform stands for, he said, including "a key, a passport, an all-access pass, a family tree, a sense of brotherhood and sisterhood, the power of the team, how people like you, yet different from you, are all moving in the same direction."

Jason Culbertson, creative director at MRM, said the digital aspects of the campaign "allow people to have a direct line of communication with those who wear the uniform," and such dialog helps potential recruits "understand what it means to be in the Army, to be

'Army strong.'"

As more of the campaign appears in social and other digital media, the spending for ads in major media has declined, according to the Kantar Media unit of WPP, to \$41.8 million last year from \$168.7 million in 2007.

Those at the Army Accessions Command "are novices at using Twitter," General Freakley said, in that only a bit more than 3,030 Twitter users follow the command's account at @GoArmy. (The main Army account, with the handle @USArmy, has more than 74,270 followers.)

Describing rappelling and other activities that recruits go through in boot camp, the general said: "It's exciting stuff. Would I love to have those young people tweeting about that?"

Why can't they? Well, "in the first three weeks of basic training, we take away your smartphone," General Freakley said. "You don't even get mail from home."

Those policies may one day be changed, he said, in that "as digital natives join us" in larger numbers, "we'll get the balance of that right."

## New Scrutiny for S.E.C. and SAC Capital

By PETER LATTMAN

Senator Charles E. Grassley, Republican of Iowa, has stepped up his inquiry into trading at the hedge fund SAC Capital Advisors.

In a letter sent Tuesday, Mr. Grassley asked the Securities and Exchange Commission to explain how it handled past referrals about SAC's trading activity.

Mr. Grassley is examining 20 stock trades by SAC that were provided to him by the Financial Industry Regulatory Authority, Wall Street's own regulatory body. Last month, Mr. Grassley asked the agency, known as Finra, for information about the "potential scope of suspicious trading activity" at the hedge fund, which is run by the billionaire investor Steven A. Cohen out of Greenwich, Conn.

The SAC transactions, which took place after Jan. 1, 2000, had been previously referred to the S.E.C. by Finra. They included stock sales and purchases made around the time of merger announcements or other market-moving events. Mr. Grassley did not provide details about which SAC trades were involved, at the request of the investigative agen-

cies.

Mr. Cohen's firm, which manages about \$12 billion in assets, has become entangled in the government's insider trading investigation at hedge funds. Two SAC portfolio managers pleaded guilty this year to making illegal trades based on confidential information. Neither SAC nor Mr. Cohen has been accused of wrongdoing. A spokesman for the firm has said that SAC was "outraged" by the conduct of the two portfolio managers, Noah Freeman and Donald Longueuil.

Mr. Grassley has been a leading critic of the S.E.C., saying it was not vigilant enough in protecting investors, including the agency's failure to uncover frauds like the Ponzi scheme perpetrated by Bernard L. Madoff. In 2009, the senator pursued a similar inquiry to the one involving SAC when he examined Pequot Capital Management, a prominent hedge fund that has since shut down.

Mr. Grassley asked Mary L. Schapiro, the S.E.C. chairwoman, to respond to his recent request by June 7 by providing a written explanation as to how the S.E.C. had resolved Finra's referrals,

how the number of referrals compared with other hedge funds and whether a so-called Wells notice had ever been drafted with regard to any of the referrals. A Wells notice from the S.E.C. is an indication that the agency is considering an enforcement action.

"The function of Congressional investigations is not to establish whether any private firms have violated the law, but rather to examine particular facts and circumstances in order to assess how well the agencies created by Congress are executing the authorities granted to them," Mr. Grassley wrote in his letter to Ms. Schapiro. "Looking into specific examples is essential for Congress to understand how effectively the S.E.C. pursues referrals such as these."

This month, SAC executives met with staff members in Mr. Grassley's office to discuss his inquiry.

"We welcomed the opportunity to meet with the staff to educate them about the firm and our compliance efforts, and had an entirely appropriate, professional and cordial meeting. We will continue to cooperate in any way we can," SAC said in a statement.

## S.E.C. Leased Unneeded Space, Report Says

By EDWARD WYATT

WASHINGTON — The Securities and Exchange Commission leased \$556 million worth of office space last year based on a "deeply flawed and unsound analysis" of its needs, without competitive bids and using backdated approval forms to justify its rushed attempt to rent the offices, according to a report by the agency's inspector general released Tuesday.

The report, dated May 16 and posted Tuesday on the commission's Web site, concludes that the S.E.C. may have violated federal law by committing the agency to lease office space before Congress had appropriated enough money to pay for the 10-year contract.

The actions "represent another in a long history of missteps and misguided leasing decisions made by the S.E.C. since it was granted independent leasing authority by Congress in 1990," H. David Kotz, the S.E.C. inspector general, wrote in the report.

John Nester, an S.E.C. spokesman, said in a statement

that the agency was "currently reviewing" the report. But it already has instituted some changes, he said. The changes include requiring leasing decisions to be approved by the agency's chief operating officer, a recently created position, and acquiring a system that auto-

mates the square footage needs of the agency, "so that management is better able to calculate spacing."

The leases for more than 900,000 square feet of office space, plus an option on 500,000 square feet more, came after Congress passed the Dodd-Frank act, which greatly expanded the S.E.C.'s role in financial regulation. The agency estimated that it would need to hire 800 staff members over the

next two years to put into effect the new regulations required by the law. Congress authorized a doubling of the S.E.C.'s budget over the next five years to pay for the additional duties, but it didn't appropriate the money. Nevertheless, officials in the S.E.C.'s Office of Administrative Services leased the space.

In October, less than three months after signing the lease, the S.E.C. tried to give back two-thirds of the space, and in March of this year, it said it was trying to sublease the remainder of the offices. The owner of the building has asserted that the S.E.C. owes nearly \$100 million in damages for its actions, which the S.E.C. disputes.

Part of the supporting documentation justifying the signing of a lease without competition was falsified, the inspector general found. A "justification and approval report" was not completed until a month after the lease was signed, but documents were pre-signed or altered to make it appear that the leasing authority was in place, the report said.

**A report says a federal law may have been violated.**