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Allison G. Jones
Assistant Vice Chancellor,
Academic Affairs, Student Academic Support
Office of the Chancellor

Code: AA-2005-48
Date: December 1, 2005

To: Directors, Student Health Centers

From: Allison G. Jones *Almes*

Subject: ORTHO EVRA® Patch Warning Information

The Food and Drug Administration (FDA), on November 10, 2005, added a warning to the labeling of ORTHO EVRA® transdermal contraceptive. In summary, increased estrogen exposure raises the risk of developing blood clots and some other side effects. According to the FDA, there is strong evidence that cigarette smoking increases the risk of serious cardiovascular side effects, especially if you are over 35. Women who use the Patch are strongly advised not to smoke. Some women should not use the 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. Women who have ever had migraine headaches with an aura should also not use the patch. However, it is not known for certain whether women using ORTHO EVRA®, containing approximately 60 percent more estrogen than a typical birth control pill, are at a greater risk of experiencing serious adverse events than those who are taking a birth control pill containing 35 micrograms or less of estrogen.

The Office of the Chancellor strongly recommends each campus to take proactive steps to ensure students currently prescribed the ORTHO EVRA® patch are informed of the recent findings about the added health risks associated with this contraceptive. Students should be advised to discuss their concerns and questions with a Student Health Services physician or nurse practitioner.

To facilitate notifying students about the ORTHO EVRA® risks, Dr. Gregg Lichtenstein, Medical Director, Student Health Center, San Diego State University prepared an excellent student letter in conjunction with Dr. Karen Nicholson, Director, Student Health Center, CSU San Marcos which is available online at the following website:

<http://www.csusm.edu/shcs/ortho%20Evra%20letter.pdf>

Also, attached are two information pieces, a detailed announcement and an information flyer, with adopted text from a San Diego State University/CSU San Marcos letter. Please feel free to use these materials as is or adopt for your own announcements.

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To assist the Office of the Chancellor in understanding the scope of the situation, please submit responses to the following questions to Mr. Ray Murillo at rmurillo@calstate.edu.

- Has the Health Center stopped prescribing the ORTHO EVRA® patch?
- Do you have an estimate as to how many students have been prescribed the ORTHO EVRA® patch?
- Has your Health Center contacted those to whom you prescribed the ORTHO EVRA® patch?

Questions about the ORTHO EVRA® announcement may be directed to Mr. Ray Murillo, Associate Director, Student Programs, Academic Affairs, Student Academic Support, at (562) 951-4707 or rmurillo@calstate.edu.

AGJ/RM:lem

Attachment

cc: CSU Vice Presidents, Student Affairs
Members, Student Health Services Advisory Committee
Ms. Gale Baker
Dr. Keith Boyum
Ms. Charlene Minnick
Mr. Ray Murillo



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Academic Affairs, Student Academic Support
Office of the Chancellor

ORTHO EVRA PATCH WARNING INFORMATION

For Immediate Release
November 29, 2005

On November 10, 2005, the Food and Drug Administration (FDA) added a warning to the labeling of ORTHO EVRA® transdermal contraceptive. The addition of this new warning is a result of FDA's and the manufacturer's analysis directly comparing the levels for estrogen and progestin hormones in users of ORTHO EVRA® with those in a typical birth control pill. This analysis showed that women who use ORTHO EVRA® are exposed to about 60 percent more estrogen than if they were to use a typical birth control pill containing 35 micrograms of estrogen. In general, increased estrogen exposure raises the risk of developing blood clots and some other side effects. However, it is not known for certain whether women using ORTHO EVRA® are at a greater risk of experiencing serious adverse events than those who are taking a birth control pill containing 35 micrograms or less of estrogen. According to the FDA, there is strong evidence that **cigarette smoking increases the risk of serious cardiovascular side effects, especially if you are over 35. Women who use the Patch are strongly advised not to smoke. Some women should not use the 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. Women who have ever had migraine headaches with an aura should also not use the patch.**

There have been recent news reports regarding legal actions being taken against the manufacturer of ORTHO EVRA® because some women using this product have had blood clots in their legs, lungs, heart or brain. According to information gathered from federal death and injury reports by the Associated Press earlier this year, about a dozen women, most in their late teens and early 20s, died in 2004 from blood clots believed to be related to the birth-control patch, and dozens more survived strokes and other clot-related problems. However, more than 4 million women have used ORTHO EVRA® since it went on sale in 2002, so the chance of serious risk seems to be fairly small.

At this time, the FDA is not suggesting that women using ORTHO EVRA® change to another contraceptive method. However, the California State University and Student Health Center Directors felt you should know the latest information. If you have concerns, please talk to a Student Health Services physician or nurse practitioner about how this information relates to your future use of ORTHO EVRA®. If you would like to switch because of the question of increased risk, please make an appointment ASAP by contacting the campus Student Health Center.

The following websites provide additional information and news.

- Food & Drug Administration News - <http://www.fda.gov/bbs/topics/news/2005/NEW01262.html>
- ORTHO-McNEIL New Labeling Information - http://www.orthoevra.com/newsafety/new_safety_information.html
- CNN Health - <http://www.cnn.com/2005/HEALTH/11/10/patch.warning.ap.ap/>



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Academic Affairs, Student Academic Support
Office of the Chancellor

ORTHO EVRA PATCH WARNING INFORMATION

On November 10, 2005, the Food and Drug Administration (FDA) added a warning to the labeling of ORTHO EVRA® transdermal contraceptive also known as the “Patch.”

According to the FDA, there is strong evidence that cigarette smoking increases the risk of serious cardiovascular side effects, especially if you are over 35. Women who use the Patch are strongly advised not to smoke. Some women should not use the 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. Women who have ever had migraine headaches with an aura should also not use the patch.

There have been reports of serious side effects including fatality; however, the chance of serious risk seems to be fairly small. At this time, the FDA is not suggesting that women using ORTHO EVRA® change to another contraceptive method.

As a safety precaution, the California State University and Student Health Center Directors felt you should know the latest information.

If you have concerns, please talk to a Student Health Services physician or nurse practitioner about how this information relates to your future use of ORTHO EVRA®. If you would like to switch because of the question of increased risk, please make an appointment ASAP by contacting the campus Student Health Center.

The following websites provide additional information and news.

- Food & Drug Administration News -
<http://www.fda.gov/bbs/topics/news/2005/NEW01262.html>
- ORTHO-McNEIL New Labeling Information -
http://www.orthoevra.com/newsafety/new_safety_information.html
- CNN Health -
<http://www.cnn.com/2005/HEALTH/11/10/patch.warning.ap.ap/>