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United States Senate

WASHINGTON, DC 20510

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Dr. Richard Pazdur
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Oncology Drug Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

Dear Dr. Pazdur:

As head of the Food and Drug Administration's (FDA) Office of Oncology Drug Products, I would like to request a call with you immediately to discuss a possible FDA decision to take Avastin off-label as a treatment for metastatic (stage IV) breast cancer.

Avastin has been shown to extend the life of metastatic breast cancer patients for an average of five months. For those battling terminal cancer, every additional day that they can beat the disease and extend their time with their loved ones is valuable and treasured. My family has been directly affected by the horrible disease of breast cancer, and I have strong reservations about any recommendation that would take life-extending options off the table for these patients.

Based on a review of the FDA Advisory Committee's report on Avastin no new safety concerns were raised with the drug. Rather the Committee's concerns appear to have been based on cost effectiveness.

A decision by the FDA to take this medicine off-label would essentially take this drug off the table as an option for breast cancer patients. As you are aware, once a drug is off-label, most insurance companies and Medicare will no longer cover the cost of the treatment. So even if a breast cancer patient meets the criteria of one who might respond positively to Avastin, once it is taken off-label, it is highly unlikely that those patients would have access to the drug.

The decision on whether a patient should use a possible life-extending drug is a decision that should be made solely between a doctor and patient, not a government panel. I find it outrageous that a government panel would put a price on those precious months for the families that are living through the trauma of a losing a mother, wife, sister, daughter, or aunt. Taking Avastin off-label for breast cancer treatment is essentially government rationing.

I am not suggesting that Avastin is a perfect drug, but it has a proven record of effective treatment for some patients when used along with chemotherapy. Lacking any safety concerns, we should not deny patients access to a treatment that might extend their lives and their time with their loved ones.

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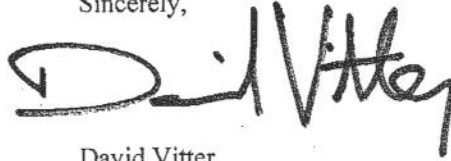
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Again, I would request an immediate briefing from you before any action is taken to deny breast cancer patients access to treatment that may extend their lives. I look forward to speaking with you.

Sincerely,

A handwritten signature in black ink, appearing to read "David Vitter". The signature is stylized with a large, looped initial "D" and a long horizontal stroke extending to the right.

David Vitter
United States Senate