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ONE HUNDRED TENTH CONGRESS

U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515-6115

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February 13, 2008

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The Honorable Michael H. Michaud
Member of Congress
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Chris Van Hollen
Member of Congress
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Tim Ryan
Member of Congress
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Dan Burton
Member of Congress
U.S. House of Representatives
Washington, D.C. 20515

Dear Representatives Michaud, Ryan, Van Hollen, and Burton:

Thank you for your letter regarding the Food and Drug Administration's (FDA) decision to obtain additional data before approving the licensure of the cancer therapy Provenge. We note the serious concerns you raised in your letter and your request that the Committee hold hearings on possible conflict of interests relating to the decision to delay approval of Provenge.

FDA has not yet made a final decision on this product, and it is the practice of this Committee to allow a regulatory agency such as FDA to complete its statutorily-mandated processes and render a final decision before initiating formal investigative action. An investigative hearing prior to an agency's final decision runs the risk of interfering with the normal regulatory process. As you can understand, as the Committee conducts oversight of the FDA or any other agency, it must be careful to balance the need for aggressive oversight with the equally compelling need to avoid the appearance of political interference that favors a particular interest.

A preliminary investigation into the record of the March 29, 2007, Open Session of the Cellular, Tissue and Gene Therapies Advisory Committee that reviewed Provenge shows that the two advisory panel members you mentioned in your letter were granted waivers in compliance with the conflict of interest rules in force at that time. Under 18 U.S.C. 208(a), Federal executive branch employees, including special Government employees, are prohibited from participating in any deliberations that involve a particular matter having a direct and predictable effect on a financial interest to that employee or family member. Under 18 U.S.C. 208(b)(3), however,

The Honorable Michael H. Michaud
The Honorable Tim Ryan
The Honorable Chris Van Hollen
The Honorable Dan Burton
Page 2

waivers may be granted by the appointing official where “the need for the individual’s services outweighs the potential for a conflict of interest involved” after the individual files a disclosure of the financial interests involved. Those waivers must be made in writing by the appointing official. An initial examination of the panel in question here indicates that the each individual’s financial interests were disclosed and that appropriate waivers were granted in writing.

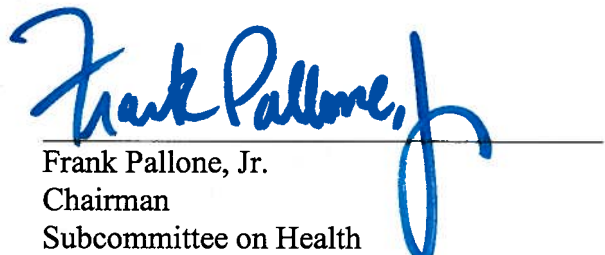
Importantly, since the advisory panel that considered Provenge met, a new law strengthening conflict of interest provisions now governs FDA advisory panels. As you know, in September 2007 the Congress passed and the President signed the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85). This new law is an important first step in addressing the concerns about conflicts of interest in FDA advisory committees. We have attached a report prepared by the Congressional Research Service that highlights the new conflict of interest provisions that now govern FDA advisory committees.

Again, we appreciate your contacting us regarding your concerns. If, once FDA’s final decision is issued, additional and material information becomes available, we would of course be willing to consider it. Please let us know if you need additional information, or have your staff contact Jack Maniko at (202) 226-2424.

Sincerely,



John D. Dingell
Chairman



Frank Pallone, Jr.
Chairman
Subcommittee on Health

Attachments

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable Nathan Deal, Ranking Member
Subcommittee on Health
Committee on Energy and Commerce