FDA Questions Chili Pepper Patch Efficacy for HIV-Related Neuropathy

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On the eve of an advisory committee meeting being held to determine whether or not to recommend U.S. Food and Drug Administration approval of NeurogesX's Qutenza for the treatment of HIV-associated peripheral neuropathy, the FDA is questioning whether the capsaicin patch actually works.

According to Bloomberg Businessweek, the FDA issued a briefing document on February 7, in advance of the advisory committee's February 9 meeting, raising questions about whether the prescription-strength patch containing capsaicin, the active heat ingredient in chili peppers, proved "substantial efficacy" in treating pain caused by neuropathy linked to HIV and its treatment. Such briefing documents are standard and are often used by advisory committees to the FDA to address lingering safety or efficacy concerns.

"It would not be in the best interest of these patients for us to approve a product for which substantial evidence of efficacy has not been demonstrated, or one for which the benefits do not clearly outweigh the risks," Bob Rappaport, director of the agency's division of anesthesia, analgesia and addiction products, wrote in the briefing document.

Among the data to be reviewed by the advisory committee, in deciding if an approval recommendation should be made, are conflicting data from two clinical trials, Bloomberg notes. According to the FDA document, one study showed Qutenza worked when used for 90 minutes and failed to show effectiveness when used for an hour or 30 minutes, though later analyses based on alternative testing showed the 30-minute application was effective. And in the second study, the FDA argues that Qutenza failed to show efficacy in both hour-long and 30-minute uses, though here too an alternative analysis suggested the patch worked in the 30-minute application.

Community advocacy groups, such as the AIDS Treatment Activists Coalition (ATAC), are testifying that Qutenza did, in fact, prove effective and useful for people living with HIV suffering from debilitating neuropathy.

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