New Drug Watch: Tenofovir

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Seems like only yesterday that biotech Gilead Sciences was bowing to activist complaints over its stringent expanded-access eligibility requirements for tenofovir (Viread), the pre-approval nucleotide reverse transcriptase inhibitor (NTRTI) now shining the brightest ray of hope to HIVers with failing regimens. Now the new villain in the tenofovir chronicles seems to be an FDA advisory committee, which at press time had urged rubber-stamping the drug, but -- and it's a big *but* -- only for advanced-stage HIVers rather than one and all (the standard debut indication for most anti-HIV meds). A Gilead rep points out that the FDA merely sought the panel's feedback on labeling -- not a formal vote on final approval -- and that the company is confident the feds will OK it and soon after broaden its label. Still, "the recommendation makes no sense," Project Inform's Martin Delaney says. "Tenofovir's safety profile is the best we've seen for any drug at this stage.... So now the agency is practicing medicine? Screw 'em."

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