

J&J seeks bioethics advice on compassionate use of drugs

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In this July 30, 2013, file photo, people walk along a corridor at the headquarters of Johnson & Johnson in New Brunswick, N.J. Dying patients sometimes seek emergency access to experimental medicines, desperate for a last-chance treatment even if there's little proof it could help. Now drug giant Johnson & Johnson is taking an unusual step, turning to independent bioethicists for advice on when to say yes or no.(AP Photo/Mel Evans, File)

Dying patients sometimes seek emergency access to experimental medicines, desperate for a last-chance treatment even if there's little proof it could help. Now drug giant Johnson & Johnson is taking an unusual step, turning to independent bioethicists for advice on when to say yes or no.

J&J's Janssen Pharmaceutical Cos. is beginning a pilot program with New York University's medical ethics division to review requests the company receives for so-called compassionate use of certain experimental drugs.

Under the plan being announced Thursday, NYU medical ethics chief Arthur Caplan will establish a committee to evaluate such cases and advise Janssen, which makes the final decision. The program initially will be for one medication, yet to be named, but the company said it could expand if deemed successful.

Caplan said the pilot program could help create a model for industry in using ethical principles to guide compassionate use, so that everyone has a fair chance. He said Janssen would pay NYU's medical school a standard fee for the committee members' work; Caplan won't be paid.

Usually, patients gain access to experimental drugs by enrolling in clinical trials. Some companies also develop "expanded access programs" for promising drugs that have finished major studies and are undergoing Food and Drug Administration review.

When patients don't qualify for those routes, their doctors sometimes request compassionate use of a particular experimental drug. The FDA seldom blocks legitimate requests, but drug companies aren't required to participate. They may not have enough doses available or consider the patient a good match, or fear that a bad reaction could derail the drug's eventual approval.

Compassionate use made headlines last year when the parents of a Virginia boy sparked a social media protest to persuade a different company, Chimerix, to provide an experimental drug that saved the youngster from a viral infection.

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