



NEWS RELEASE

## Johnson & Johnson Announces NYU School of Medicine Partnership To Evaluate Compassionate Use of Investigational Medicines

5/7/2015

NEW BRUNSWICK, N.J., May 7, 2015 /PRNewswire/ -- Johnson & Johnson (NYSE: JNJ) today announced a first-of-its-kind partnership that enlists a third party to review requests made to the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen) for compassionate use of its investigational medicines. This new approach will begin as a pilot program focused on a single Janssen investigational medicine and, if successful, will become a model that will be applicable more broadly across Johnson & Johnson.

In keeping with the company's long-standing commitment to the highest standards of ethical decision-making that serves the needs of patients, Janssen Research & Development, LLC, has forged this new partnership with the Division of Medical Ethics at the NYU School of Medicine to obtain independent advice, further ensuring that the evaluation of requests for investigational medicines prior to their approval by the U.S. Food and Drug Administration (FDA) or other global health authorities are treated in the most fair and ethical manner.

As part of this collaboration, the NYU School of Medicine will establish the Compassionate-Use Advisory Committee (CompAC), an external group of 10 internationally recognized medical experts, bioethicists and patient representatives to pilot the new approach. Commencing with one of Janssen's investigational medicines, the CompAC will make recommendations regarding individual patient requests from anywhere in the world. Investigational medicines are still in development and usually limited in supply, and the committee's careful consideration and recommendations based on its independent review will inform Janssen clinicians, who will make the final decision.

The FDA describes **compassionate use** as "a pathway for patients to gain access to investigational drugs, biologics

and medical devices for serious diseases or conditions. Such investigational drugs have not yet been approved by the FDA, and they have not been proven to be safe and effective." [i]

"We have a responsibility to patients and their families to ensure their well-being in everything we do," said Amrit Ray, M.D., Chief Medical Officer for Janssen Pharmaceutical Companies of Johnson & Johnson. "By ensuring compassionate use requests for our investigational medicines are evaluated by a well-informed, external committee, we can better weigh what we know about these therapies against the patient's condition and risk factors to make the most responsible decision for each patient."

For compassionate use requests, Janssen has a long-established single point of contact: all interested treating physicians can contact Janssen Medical Information (1-800-JANSSEN in the United States or [janssenmedinfo@its.jnj.com](mailto:janssenmedinfo@its.jnj.com)). Physicians outside the U.S. may contact the **Janssen office** in their country. Physicians are asked to provide information about the patient that is used to evaluate the request.

"As we commence this new approach with an investigational medicine, Janssen will direct relevant requests to the CompAC for their evaluation, especially to help with requests that do not otherwise qualify for ongoing clinical trials or expanded access programs," Dr. Ray said.

If permitted by local authorities, Janssen typically establishes an expanded access program (EAP) for investigational medicines when a favorable benefit-risk profile has been reported in a pivotal trial and there is a viable regulatory path to approval confirmed with a health authority. The EAP can potentially allow the treatment to be made available to patients living with the same serious or life-threatening condition for which the medicine was originally studied and who have exhausted other treatment options. If patients do not qualify for an EAP or an existing clinical trial, their requests will be forwarded to CompAC.

"Our goal is to ensure that compassionate use of specific investigational medicines still in development is guided by ethical principles, and that the selection process continues to be thorough, transparent and fair," said CompAC Chairman Art Caplan, Ph.D., Director, Division of Medical Ethics at the NYU School of Medicine, and the Drs. William F. and Virginia Connolly Mitty Professor of Bioethics. "Compassionate use decisions are incredibly challenging, and we readily acknowledge that the current allocation system remains a work in progress. This new initiative hopes to create a more robust model to help guide these decisions."

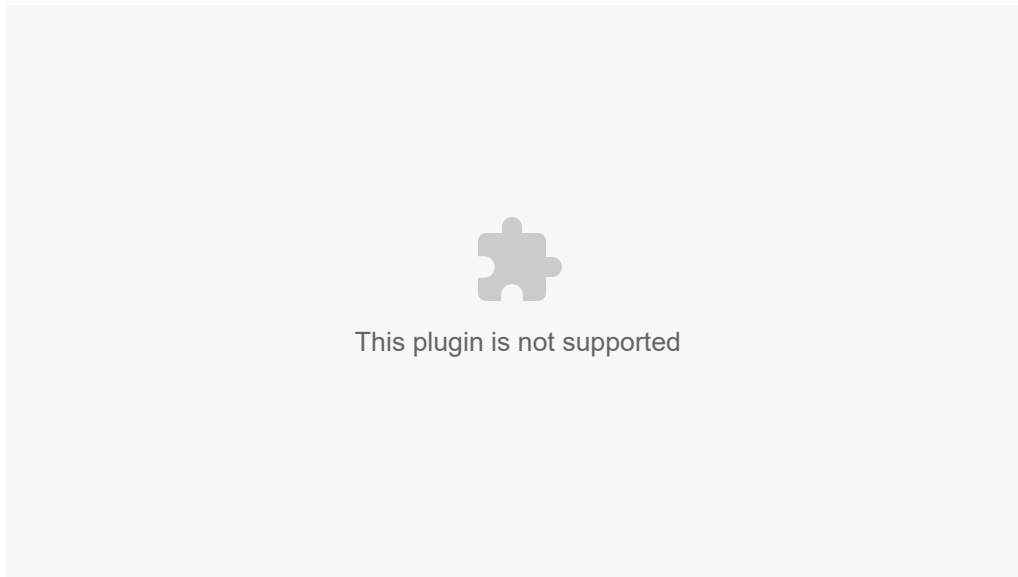
Dr. Caplan likens the CompAC to what the United Network for Organ Sharing (UNOS) has achieved with its allocation process. "We want to establish a model that will create a structured policy of allocation based on equality, need and efficacy to ensure that the utility of our scarce resources are maximized," he said. "If successful, CompAC will serve as a model for others in industry and in government to follow."

Janssen has a long-standing commitment to providing expanded access to its investigational medicines prior to approval where it is appropriate to support the needs of patients with serious illnesses. This new collaboration extends existing approaches by adding an external evaluation to the process. More information about the current Janssen policy on pre-approval access to investigational medicines can be found at:

<http://www.janssenrnd.com/our-innovation/access-to-investigational-medicines>.

"This initiative demonstrates the commitment of Johnson & Johnson to the highest ethical standards and patient-centered decisions," said Joanne Waldstreicher, M.D., Chief Medical Officer for Johnson & Johnson. "In striving to meet the needs of desperately ill patients, we believe that an external group of ethicists, physicians and patient representatives brings the highest level of both medical and ethical input to our decision-making process."

A video including Drs. Waldstreicher and Ray is available at [https://www.youtube.com/watch?v=le6ky2\\_rbWE&feature=youtu.be](https://www.youtube.com/watch?v=le6ky2_rbWE&feature=youtu.be).



## About Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we are dedicated to addressing some of the most important unmet medical needs in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and health care solutions to help people throughout the world. Janssen Research & Development, LLC, is one of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit [www.janssen.com](http://www.janssen.com) for more information. A list of Janssen country offices can be found at <http://www.janssen.com/our-companies.html>.

## About Johnson & Johnson

Caring for the world one person at a time inspires and unites the people of Johnson & Johnson. We embrace research and science - bringing innovative ideas, products and services to advance the health and well-being of people. Our approximately 126,500 employees at more than 265 Johnson & Johnson operating companies work with partners in health care to touch the lives of over a billion people every day, throughout the world.

Video - [https://www.youtube.com/watch?v=le6ky2\\_rbWE&feature=youtu.be](https://www.youtube.com/watch?v=le6ky2_rbWE&feature=youtu.be)

[i] U.S. Food and Drug Administration. Available at

<http://www.fda.gov/ForPatients/Other/ExpandedAccess/ucm20041768.htm>. Accessed on April 15, 2015.

To view the original version on PR Newswire, visit: <http://www.prnewswire.com/news-releases/johnson--johnson-announces-nyu-school-of-medicine-partnership-to-evaluate-compassionate-use-of-investigational-medicines-300079098.html>

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