A message from Pfizer’s Chief Medical Officer, Freda Lewis-Hall, M.D. about Compassionate Access

As a doctor, mother, and caregiver, I know how difficult it is to deal with a serious illness. The choices can be agonizing – and confusing.

A first response is to find out everything you can about the illness and its treatments. Making sense of the options can be overwhelming. And in cases where an illness is severe or life-threatening and there are no other treatment options, a next step may be to explore a clinical trial. Well-designed clinical trials in groups of people are the best way to determine whether or not an experimental drug is generally safe and effective and offers an acceptable balance of risks and benefits. Clinical trials involve the highest standard of care and might be available for your situation.

If an appropriate trial isn’t available, your physician may be able to request access to an experimental drug through what’s sometimes called a compassionate use or expanded access request. At Pfizer, we call it compassionate access… and we have medical experts dedicated full-time to ensuring that compassionate access requests are treated FAST and FAIRLY. Here’s how the process works.

By law, compassionate access requests must be submitted by a treating physician on behalf of a patient.

Physicians can visit our request portal, pfizercares.com, to submit an inquiry.

Your doctor’s request to PfizerCAReS will be reviewed by our medical experts inside the company, and we strive to respond within 5 business days. Sometimes we are able to respond more quickly.
Along with your care team, our medical specialists consider what we currently know about the experimental drug and weigh the potential benefits and risks of providing the experimental drug for a particular condition.

If we are able to approve the request, it will be sent on for review by regulators in the nation where it is being made.

For example, in the USA, it would go to the U.S. Food and Drug Administration for final approval.

With that approval, we will ship the experimental drug to your doctor and will follow up with your care team on your health.

I want to assure you that Pfizer has expert, highly dedicated medical doctors and scientists who carefully review each PfizerCAReS request, working closely with your doctor.

In discussions with your doctor, we will be open and candid about what we know about the safety and effectiveness of the experimental drug being requested—understanding that the clinical trials for it may be far from complete.

All of the information we provide—and our response to the request—will be grounded in the science we understand about the experimental drug.

Hard as this is, it’s important to be realistic when it comes to the compassionate use of experimental drugs for people who are very ill.

The development process for a new medicine takes many years... many steps... and many, many patients. Not all experimental drugs show evidence of effectiveness or safety, and the newer the experimental drug, the less we know.
That’s why it is important for you to have a candid conversation with your physician about your specific situation.

If you are facing a life-threatening condition, when all care options have been tried and participation in a clinical trial is not an option... we urge you to talk with your physician.

Again, our website, PfizerCAReS, makes it easy for your physician to be in touch with us.

Whatever your situation, please know that at Pfizer, we care deeply about you as a person, and as a patient.

We remain dedicated to inventing and developing new, safe, and effective treatments... for many of humanity’s most challenging diseases.

Thank you, and best wishes.