A Message from Anne B. Cropp, Pharm.D
Chief Scientific Officer of Early Access Care

Hello, my name is Anne Cropp and I am the Chief Scientific Officer for Early Access Care.

As a pharmacist, mother and life-long member of the scientific research community, I have always been passionate about bringing solutions to advance patient care.

After many years of leading pharmaceutical research teams in the development of many new medicines, I know full-well that it takes several years of well-controlled clinical trials to determine whether an experimental drug is generally safe and effective. Well-designed clinical trials grounded in science are the *best* way to understand an experimental drug's potential risks and benefits.

Participation in a clinical trial may be *one* option for an individual with a *serious* medical condition. When a clinical trial is not an option, either because a patient does not qualify or perhaps there is no clinical trial, a physician may be able to request access to an investigational drug through a process called compassionate use. At the Food and Drug Administration this is formally referred to as Expanded Access and other countries refer to this using different terminology. At Early Access Care we refer to this as Early Access.

It's important to know that only a treating physician can submit a request for investigational drugs on behalf of a patient. Not all physicians are willing or able to take on the responsibilities for early access. The first step is for a patient and their physician is to have a candid conversation about their willingness to make a request for compassionate use.

So what's the process? In the United States, the first step is for the physician to contact the pharmaceutical company that makes the investigational drug. Some companies post their contact information on websites and on www.ClinicalTrials.Gov . At Early Access Care if the drug company is one of our pharmaceutical partners we will facilitate this first step, and all subsequent steps, for you and your doctor.

A pharmaceutical company has no legal obligation to provide investigational drugs through Expanded Access, and not all do. But if a pharmaceutical company has agreed to review the request for investigational drug, and has drug available, they will ask your physician to provide information about your medical history, a list of prior treatments and outcomes, and a proposed treatment plan. Your consent is required.

The pharmaceutical company will review the information and provide a response to the physician's request. If the company agrees to the request for investigational drug, they will provide your physician with a Letter of Authorization. The next step is for your physician to obtain authorization from the Food and Drug Administration or FDA.

Your physician must complete FDA Form 3926. It takes about 45 minutes to complete the form. The link to this form and information on its completion are on this website.

If the FDA approves the request, it will issue an IND number to your physician along with a letter explaining physician responsibilities. Most requests received by the FDA are approved, and they do so within a short period of time…. often within a few business days. The FDA authorization letter with the IND number is provided to the pharmaceutical manufacturer.

There are two additional steps that are required. First, your physician will need to submit the request to a local Investigational Review Board, or IRB, for approval. And finally, your physician will inform you of all known potential risks of the investigational drug, and any procedures that are required to monitor your progress. This is called **informed consent.**

It is important to know, that at the early phases of an experimental drug, not all risks are known. In some cases, investigational drugs *may even worsen* a condition. That's why it's important that you have a candid conversation with your physician about all treatment options and potential risks.

The process of requesting an investigational drug is a *partnership* between a patient, physician, the FDA and the pharmaceutical company.

Early Access Care is passionate about bringing solutions to advance patient care. Our mission is to accelerate access to investigational drug products to patients in need.

We are dedicated to making the process of compassionate use simpler for patients and their physicians.