Abigail Alliance for Better Access to Developmental Drugs

www.abigail-alliance.org

501 (C3) non-profit incorporated in Virginia

8881 White Orchid Place Lorton, VA 22079 703-646-5306

Date: February 19, 2015

To: Rep. Knute Buehler, Oregon State Legislature

From: Frank Burroughs, President, Abigail Alliance for Better Access to Developmental Drugs

Re: Oregon HB 2300, Relating to treatments for patients with terminal diseases.

Some say our compassionate use methods work. In reality, our compassionate use methods work badly. Currently only 1,000 to 1,200 patients receive FDA approved Individual IND access (compassionate use) annually because most physicians cannot spend the required 100 hours to complete the application. If and when the new FDA shortened form is implemented, that number could potentially quadruple to 4,000 patients. Even this represents only a small percentage of patients who need access. Despite the proposed shortened FDA application, many FDA obstacles remain.

● The Abigail Alliance for Better Access to Developmental Drugs has 14 years' experience advocating for earlier access and earlier approval of promising investigational drugs. We have heard from thousands of patients with no further FDA approved options left in their battle to live. These patients do not want indiscriminate access to drugs. These patients and their physicians seek access to investigational drugs with high promise. It may be years before these promising drugs receive FDA approval.

● This statement comes from our www.abigail-alliance.org homepage:

"Every drug for cancer and other serious life-threatening illness the Abigail Alliance has pushed for earlier access to and earlier approval of over the past fourteen years is now approved by the FDA, unfortunately years after patients tried in vain to get access and therefore died. Not one drug we pushed for earlier access to and earlier approval of failed to make it through the clinical trial process."

Thousands of lives could have been saved with earlier access and earlier approval.

● As the FDA's Science and Technology Board confirmed in 2007, the FDA could get drugs approved much sooner if the FDA updated its scientific and statistical tools. The Board strongly recommended changes in clinical trial designs and options for a provisional approval mechanism for promising investigational drugs. That report was written eight years ago. The FDA has not yet adopted these recommendations.

● Sometimes investigational drugs demonstrate significant efficacy early in the clinical trial process, even as soon as Phase 1 and Phase 2 trials. One example from 1999 is the now-approved cancer drug Gleevec terminal patients waited for it but many died before FDA approval. Today, there are similarly promising drugs for Duchene Muscular Dystrophy and ALS. They too may require years for approval.

● With updated clinical trial designs, not yet implemented by the FDA, many patients fighting for their lives who cannot get into clinical trials might have access to non-placebo arm trials. This would not compromise enrollment of other patients in clinical trials. If these lifesaving drugs were approved much sooner, confirmatory clinical trials could be performed sooner.

Frank Burroughs
(703) 646.5306
8881 White Orchid Place,
Lorton, VA 22079-5696 frankburroughs@abigail-alliance.org www.abigail-alliance.org