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## **FASTER FDA TRIALS AND DRUG SHORTAGES**

The FDA must be commended for having a disciplined process to test pharmaceutical drugs and have them go on clinical trials before approving them. We certainly need to protect public safety and, as a practice, not rush approvals of pharmaceutical drugs. However, there are two areas that need to be improved and addressed with FDA trials.

We need a faster process to get needed medicines to patients. I am not a doctor or a scientist, but we need to review the process to accelerate time to approval without sacrificing drug safety. Patients in need are going without medicines while trials take place. In some cases, patients go abroad where medicines in an FDA trial are already available. In other cases, they join the trials. In way too many cases, they just go without and suffer the consequences. Fifteen years ago, my dad (Fred T. Kuglin) had macrodgenerative disease. There were medications and a surgery under review/trial (the implantation of a telescopic lens) that would slow the disease and preserve most of the eyesight for patients. By the time the medications and surgery were approved, my dad had lost most of his eyesight. My dad had numerous medical issues, and ultimately died of old age (87). However, he would lament that no matter what illness he battled, his quality of life was impacted most by his loss of eyesight. He would have benefitted from a faster FDA trial process. I wonder how many other “Fred T. Kuglins” across the spectrum of pharmaceutical drugs under FDA trials would ultimately benefit from a faster FDA trial process.

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## **EBOLA, FDA TRIALS, AND PUBLIC POLICY**

There is an excellent example going on right now where public policy and FDA trials cross paths with a potential epidemic. The following are key facts from the World Health Organization (WHO) on Ebola:

- The Ebola virus disease (EVD), formerly known as Ebola hemorrhagic fever, is a severe, often fatal illness in humans.
- The virus is transmitted to people from wild animals and spreads in the human population through human-to-human transmission.