Drowning at the FDA

By Richard E. Ralston

If one of our fellow citizens is drowning, is it proper to throw him a life preserver if it has not yet been approved by the U.S. government? Or should we tell him to wait for approval?

New legislation would throw a lifeline to individual terminally ill patients, giving them the "right to try" treatments that have been deemed safe by the Food and Drug Administration (FDA) but which have not yet obtained final approval. Yet opponents of this legislation believe that the people drowning—and dying—should wait.

When reviewing a new drug or medical procedure, the FDA first completes a "Phase 1" investigation to determine if the treatment is safe, recognizing the importance of the traditional principle to "first, do no harm." They then go on to Phases 2 and 3 to determine if the treatment works, a process that often takes years of clinical trials before final approval. But for terminally ill patients the question then becomes, "How long must we wait to have access to the treatment?" Over the years, many thousands of these patients have died waiting for safe treatments that were eventually approved by the FDA.

How can anyone oppose the access of dying patients to a new, safe drug that might help them? Some bureaucrats hold the paternalistic mindset that no one should be able to secure treatment that will save their lives without prior government permission. This is an inversion of the Declaration of Independence, which states that governments exist to secure individual rights and derive their power from the people—not the other way around.

Meanwhile, some in Congress have opposed allowing such access because they believe it encourages "false hope." But how would Congress know whether any safe treatment would work before it has been tried? They could not, and it is cruel to argue that the dying should be denied that freedom when the alternative they face is "no hope."

Other opposition to the right to try is more disgusting. We are told that allowing the terminally ill to access potentially life-saving medication would reduce the pool of dying patients that can be recruited to participate in clinical trials and should therefore be forbidden. In other words, the terminally ill should carry on dying so they can participate in a control group of those NOT getting a new drug in a clinical trial. That looks less like drug safety and more like a war crime to me.

It must be made clear to all terminally ill patients who might be given access to a new drug that, however auspicious its use might be, that new hope may indeed be false. But patients need the "right to try" to find out, for the attempt could save their lives and provide new information that could help other patients. What is certain is that they will die without the treatment. The standard is the patient's life, not administrative procedure.

As both the U.S. House and Senate have passed this legislation, Congress must urgently work to pass a final bill and send it to the president, who has promised to sign it. People are dying—and they need compassion and hope. Most of all, they need the freedom to choose life.

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