Cancer patients should get quicker access to unapproved drugs through FDA ‘concierge service’

The Food and Drug Administration plans to provide “concierge service” to doctors seeking access to unapproved drugs for cancer patients who have no other treatment options, the agency announced [June 3].

The goal is to remove any “perceived hurdles” for physicians who want to use the agency’s “expanded access” program, said Richard Pazdur, director of the agency’s Oncology Center for Excellence.

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The FDA’s expanded access program, sometimes called “compassionate use,” is designed to help patients with immediate life-threatening or serious illnesses who don’t qualify for clinical trials and have no other treatment options. Typically, a doctor first asks a drug company to provide the experimental treatment. If the firm agrees, the physician submits a protocol to an institutional review board (IRB) — which makes sure the patient is properly informed about the treatment. The FDA then decides whether to approve the request — and almost always does.

Under the new plan, FDA staffers will help the doctor from the start on paperwork and finding an IRB and appropriate contacts in drug companies. If the pharmaceutical firm rejects the doctor’s request, the FDA will ask why.

Read full, original post: FDA to make it easier for doctors to get unapproved cancer drugs for patients