FDA releases guidelines to fast-track new generation of fast-acting antidepressants

As companies race to develop fast-acting antidepressants, they are grappling with how to design clinical trials for a type of drug that doesn't yet exist.

There's no shortage of interest in the idea: Janssen (JNJ) is testing an esketamine nasal spray, which, when combined with an oral antidepressant, has shown promise in quickly curbing symptoms of serious depression.

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Late last month, the FDA stepped in to offer some help. The agency released a draft guidance on developing new treatments for major depressive disorder that lays out the special considerations for clinical trials on rapid-acting antidepressants.

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Current trial designs assume it'll take four to eight weeks for a drug to kick in. But fast-acting antidepressants should, in theory, start working much sooner.

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[T]he FDA said drug makers need to show that the drugs work within a week. And in the case of drugs that seem to work particularly quickly, an appropriate endpoint might be just hours after the first dose.
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There's also a question of determining the right dose — or doses. The FDA said it's particularly interested in studies that test whether a lower dose of the drug than what's needed for short-term efficacy can maintain the treatment response in the long run.

The new guidance offers drug companies insight into how the agency is thinking about this potentially new class of drugs.

Read full, original post: Companies are racing to develop fast-acting depression drugs — but the process is tricky