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SAFETY FIRST, EFFICACY SECOND? FEAR AND NEED OF TREATMENT IN THE ABSENCE OF CONTROLLED DATA

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In the clinical practice, physicians are routinely asked to make decisions whether to initiate or continue antidepressant treatment in a situation where no safety data are available. As an example can serve pregnancy and breast-feeding, where controlled clinical trials provide little guidance. Females of fertile age are rarely included in the early phases of clinical testing, the Phase IIb and III trials have a standard provision to use a reliable contraception. Pregnancy during drug trial is considered as a 'serious adverse event' with subsequent study discontinuation. The reasons are not just ethical and legal but also marketing, the drug manufacturers fear to have their products associated with potentially grave side effects, such as malformations. Drug treatment in pregnancy and lactation thus pose a highly relevant clinical problem that cannot be addressed in controlled trials. Excessive concerns of negative consequences could erroneously result in generalizing recommendation not to get pregnant or to abort existing pregnancy. However, fetus may be already exposed to drugs early in the first trimester during frequently unplanned pregnancies; in addition, recent epidemiological data indicate increasing consumption of psychotropics, including antidepressants, by pregnant women. Psychiatrists have to weigh the known risks of treatment discontinuation versus potential risks for the fetus and infant. They should also consider whether alternative non-pharmacological interventions (psychotherapy, ECT, rTMS) are accessible or effective. The only available safety data on antidepressants come from animal studies, epidemiological trials, drug registries, case series, anecdotal case vignettes and clinical observations.

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