BROKEN HEARTS: SSRIS IN PREGNANCY

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The approach to prescribing in general is one of balancing the risks and benefits of a drug. Early drug disasters such as thalidomide use in pregnancy heightened the awareness of the unknown risks of drug use in pregnancy and resulted in policy change around drug use in general and in pregnancy in particular. In pregnancy because fetal malformations have such potentially devastating and lifelong consequences for parents and child, this assessment of the risks and benefits of a drug took an even more cautious approach. This applies particularly in the first trimester of pregnancy when organ development is occurring and adverse effects can be most serious – resulting in loss of the pregnancy or serious congenital malformations.

The evidence from both animal and epidemiological studies indicates that SSRI use in the first trimester of pregnancy increases the risk of birth defects, in particular it doubles the risk of heart defects. In addition use through pregnancy is clearly associated with a range of other dangers including premature birth, a neonatal withdrawal syndromes, pulmonary hypertension in the newborn and miscarriage. The effects on later child brain development are unknown. Compounding this, the withdrawal symptoms on stopping SSRIs make it difficult to stop an SSRI in time to avoid the dangers of birth defects once a woman discovers she is pregnant.

The divide between the scientific and the corporate response to drug safety issues is illustrated by what happened after the early signals of potential teratogenicity in Paxil. Rather than cautioning about the potential harms of treatment, the company emphasized instead the risks of untreated depression. The marketing campaign aimed to “make Paxil the drug of choice for women”.

There were two key elements to the GSK marketing campaign; direct to consumer advertising aimed to drive women in the reproductive years to physicians to request Paxil for their treatment, and a sophisticated multifaceted marketing campaign to physicians with the aim of increasing prescribing of Paxil to women for a range of situations – depression, anxiety, premenstrual dysphoric disorder, social anxiety disorder and during pregnancy. It overemphasized both the extent of the problem of depression in pregnancy and the usefulness of Paxil in pregnancy and lactation. Paxil was promoted as being safe in pregnancy when this was not supported by scientific knowledge. What was known about it indicated that there were risks to use. The promotion to physicians was highly misleading around safety in pregnancy given the state of scientific knowledge at the time. This has been made even clearer by what has come to light since and exposed unborn children to unreasonable danger.

Misleading information undermines the ability of the physicians to act as a learned intermediary between scientific knowledge and the patient. When manipulation of information both to physician and consumer occur, the processes by which a patient might make a decision on the risk benefit balance of a medication are compromised. This raises ethical issues around our ideas of autonomous decision making and informed choice for patients in our current system of medical care.