

PE1651/SSSSSS

David Healy submission of 30 January 2018

This further input to Petition PE01651 is triggered by Dr Mitchell's comments on some of the points raised in my original submission.

Duration of Treatment

First, there is little or no evidence base in favour of his proposition that taking antidepressants for a longer period of time is evidence based. There is not and almost by definition can be no evidence in favour of his proposition - if these drugs cause dependence and withdrawal.

If even healthy volunteers have withdrawal problems characterised by anxiety and depressive symptoms after only two weeks exposure to the drugs, then further "episodes" on stopping in those exposed for much longer are highly likely to be the consequences of withdrawal rather than new illness episodes that treatment would have forestalled.

The idea that depression is a chronic condition needing chronic treatment is an idea that a small number of individuals closely linked to the pharmaceutical industry peddled in the 1990s rather than something that is evidence based. It was certainly not part of clinical wisdom in the 1990s when the guidelines were being drawn up. Someone like Dr Mitchell would ideally be alert to these possibilities.

Vulnerable Groups

I also want to put on your radar the position of several groups of individuals affected by these drugs whose conditions deserve your consideration.

One of those groups comprises those individuals with Post-SSRI Sexual Dysfunction (PSSD) and Persistent Genital Arousal Disorder (PGAD), two conditions that are legacy effects of antidepressants – that is conditions that emerge on treatment or may only appear on withdrawal, but which can persist for decades afterwards.

These conditions are in this respect very similar to tardive dyskinesia which may only appear on stopping treatment with an antipsychotic (or sometimes an antidepressant).

It is probably that a substantial part of what many of those petitioning you call protracted withdrawal are legacy effects. In this respect PSSD and tardive dyskinesia are conditions that make it clear that protracted or enduring problems following withdrawal may continue for decades, despite what companies or physicians like Dr Mitchell might say about them clearing up within several weeks.

If you consult the RxISK website you can see more. We have a peer reviewed paper on over 100 cases of PSSD and another one with over 300 cases in press, which can be sent on request.

Unfortunately, none of these 300 subjects are likely to contact you as pretty well everyone with this condition is reluctant to lose their anonymity. This reluctance in part stems from the treatment they have had at the hands of medical professionals who have denied the possibility of these effects and insinuated all kinds of things of those, who in good faith seek help with these treatment induced problems. These conditions and the response of the medical profession leads to suicides, marital breakups and job loss.

Another group you will possibly not hear from are those individuals who have been disabled by treatment and who were in receipt of Personal Independence Benefits or other payments who have found their payments withdrawn once they get off treatment. They end up without support because they are now no longer on treatment. The bind is that when off treatment these patients may be suffering severely but re-instituting treatment may not solve the problem and if it does it does so at the cost of prolonging the problem.

This is a pernicious consequence of antidepressant dependence and withdrawal that deserves to be on your radar. A failure to address this issue would effectively endorse the idea that those affected should be forced to continue with a treatment that is harming them?

Finally linked into stopping antidepressants, I would like to make one more point. People on these pills are often told not to stop without consulting their doctors. One problem is their doctors are completely uninformed about the nature of the problems or how to handle them. Another is that the unpublished and largely inaccessible data from company trials show that withdrawal leads to a higher rate of suicidal events than any other period of treatment. People should probably be told the reason why they should not just stop. And you need to consider what a woman who has just found she is pregnant should do.

Adolescents

A growing group of those taking antidepressants are now pre-teen, or teenage girls or women in the early twenties. There is no evidence these drugs work in these age groups.

Dr Mitchell will likely tell you that Fluoxetine works for these groups. It doesn't. On the primary outcome of the fluoxetine trials that led to its approval for adolescents, it performed no better than paroxetine did in the clinical trials that landed GSK with a fraud charge and \$3 billion fine. The fluoxetine trials were ghost-written just like every other clinical trial of antidepressants. The data is sequestered just like the data from every other clinical trial.

I can appreciate that the bureaucrats within the Scottish and UK governments will find this point embarrassing, but lives are at stake.

[In Scotland, fluoxetine and sertraline are the most commonly used drugs in this age group but sertraline has no evidence for benefit in these ages (and very little evidence in other age groups)].

A large proportion of the people being put on antidepressants in Scotland stand little or no chance of benefitting in any age group but especially adolescents. In all populations, active treatments increase the rate of suicidal behaviours, along with exposing their takers to the risks of dependence. Once dependent there are risks to their offspring of birth defects in organ systems or abnormalities of behaviour including asexuality and depression.

There is a related development which speaks to the information Dr Mitchell relies on. NHS Scotland has approved a trial of vortioxetine for children aged 7-11. This is another serotonin active antidepressant. The extraordinary thing about this approval is that there have been 29 prior randomized controlled trials (RCTs) of antidepressants in these age groups – all negative.

It is difficult to understand why a further trial of these drugs is being undertaken in this age group anywhere. Why in Scotland?

If he or you would be interested to see the patient information and assent forms for vortioxetine in this trial I can forward them. I will be making them public in any event. I think very few people would find them acceptable – there is no mention of suicidality on vortioxetine although these drugs come with a Black Box Warning in the United States for this risk and vortioxetine in open label studies is linked to suicidality. It is almost certain to cause dependence also. In primary school children !