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Alan Addison / M Hancock M.P.
Dept of Health,
39 Victoria Street
London SW1H 0EU

Re TO-1200330

Dear Mr. Addison

I have just received your letter indicating your Department does not wish to engage in further correspondence. Your letter does, however, require a response.

The MHRA may have mis-advised you. It has never addressed my concerns about SSRI randomized controlled trials (RCTs) in respect of any side effects these drugs can cause, the ghostwriting of study results or the lack of access to RCT data.

I assume you know nothing about these issues and have, understandably, turned to MHRA or some equivalent bureaucracy for input. Let me counter-brief you.

When the regulatory apparatus was set up, doctors were seen as a critical part of it. The bureaucrats within MHRA had expertise in ticking boxes to indicate that certain claims might be made about a drug, just as they might about butter – yes this lump of yellow stuff meets criteria for butter and is not lard coloured to look like butter. Regulators do not say butter or antidepressants are good for you or that this is good butter or a good antidepressant.

The box ticking that allows a company to label a chemical an antidepressant involves presenting regulators with two trials in which a drug scores marginally better than placebo on a rating scale. This is termed the benefit. But it is more likely to be an effect that companies rather than patients benefit from – curing patients is not a good business model. In the subset of antidepressant trials companies gave regulators, there were more suicides, suicidal acts, and deaths on active treatment than on placebo and no evidence for anything you might regard as a benefit such as return to work.

Prior to presenting clinical trials to regulators, companies run healthy volunteer trials, which in the case of the SSRIs noted agitation, suicidality, dependence, withdrawal, and severe sexual dysfunction. These trials alerted companies to problems that would need to be hidden in their later clinical trials, which is rather easy to do as RCTs necessarily focus on only 1 of a drug's 100 effects.

After approval, companies (not regulators) write the label for their drug. The SSRI labels indicated no problems in respect of suicidality, or dependence. Less than 5% of us were likely to have sexual dysfunction when over 90% do.

Today, between 10 and 15% of the UK population are hooked to these drugs. The combination of dependence and sexual dysfunction effects mean that upwards of 20%

of the UK population are not making love as they might wish to. It is the Caucasian portion of the population that is primarily affected – a matter that would likely horrify Dominic Cummings or Andrew Sabisky. In the event someone on treatment conceives, the risk of a miscarriage, birth defects or learning disabilities, is doubled.

Despite these horrific risks, I am not calling for these drugs to be removed from the market. I'm pointing to the flaws in the briefing you've had about risk benefit balances.

The approach that underpinned licensing and adverse effects, before Pharma (not regulators) introduced ideas about risk-benefit around 1990, was that doctors depended on the collective discretion of their colleagues to know when to use a drug and paid heed when colleagues reported that drugs were causing adverse effects. In this set-up, the significant adverse effects of drugs became common knowledge within a few years of a drug's launch where now they are still contested decades later.

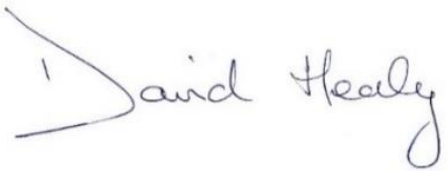
The new arrangements are read by many doctors as indicating that MHRA and NICE are guaranteeing benefits and denying the possibility of significant adverse effects such as sexual dysfunction so that patients complaining about this are ridiculed by their doctors. Most doctors have greater professional experience at determining whether a drug is causing an adverse effect than any regulator but they end up with a target on their back if they note the hazard. A culture in which side effects cannot be admitted or the public will lose confidence in the system is experienced by healthcare staff as morally compromising and contributes significantly to staff burnout.

As the O'Neill case demonstrates, many doctors have become functionaries rather than professionals. They, like you and Mr Hancock, say they depend on MHRA and NICE where MHRA and NICE should depend on them. The O'Neill case illustrates that we now have a broken system.

I blame my profession for this situation rather than MHRA and am copying BMA into this letter. Unless the profession wakes up soon and solves a problem you don't seem to realise you have, doctors will end up as middle-managers, removed from seeing patients and given the job of ensuring that nurses and physician assistants adhere to the labels of MHRA approved drugs and keep to NICE guidelines.

This will be bad for doctors, worse for patients and will cause health service costs to balloon.

Yours sincerely



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I am now best contacted on healyd1@mcmaster.ca,