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August 6th 2020

Mr C Phillips
Swansea Coroners Crown Court
Coroners Office
Civic Centre,
Oystermouth Rd.,
Swansea SA1 3SN

Re: **Samuel David MORGAN**
DoB: 24/09/1994. DoD 16/01/2020
Westway, Heol Y Barna, Pontlliw

Dear Mr Phillips

I have been asked by Mr. Ieuan Rees to prepare a report on the death of Samuel Morgan to be submitted to the inquest on his death.

Background Expertise

I am a medically qualified doctor with a further doctorate in psychopharmacology, and specific post-doctoral expertise in suicide and drug treatments. I qualified in 1979 from the National University of Ireland before moving to Cambridge University and later Cardiff and Bangor Universities as a Professor of Psychiatry. I am now a Professor in the Department of Family Medicine at McMaster University in Canada.

My professional experience with psychotropic medications dates back forty years. My post-doctoral thesis, conducted from 1980 to 1985, was on psychotropic drugs and their effects, in particular on serotonin reuptake mechanisms.

I am a former secretary of the British Association for Psychopharmacology. I have published over 25 books on healthcare, mostly linked to psychopharmacology, including the standard histories of the antidepressants, antipsychotics and mood-stabilizers. One of my books on the use of psychiatric prescription drugs has been translated into several different languages and is now in its 6th edition. Another gives the definitive history as to how drugs like citalopram ended up with a Black Box Warning for suicide for people of Samuel Morgan's age.

I have also authored 60 chapters in books on similar issues, over 220 peer-reviewed articles and over 250 other pieces, dealing mostly with psychopharmacology and the problems on treatment. I have been invited to talk at over 400 international meetings on all continents – again largely on issues related to psychotropic drugs.

I have been a consultant to most of the major psychiatric drug manufacturers including Eli Lilly, Pfizer, Janssen, GlaxoSmithKline and Lundbeck the makers of citalopram, the pertinent drug in this case.

I have reviewed virtually every study, both published and unpublished conducted on the most popular psychotropic drugs. I have reviewed hundreds of thousands of pages of internal company documents concerning these drugs and dozens of depositions of company employees, scientists, academics, experts, and regulatory personnel.

My clinical practice for over 30 years covered both inpatients and outpatients, who are depressed, anxious, psychotic, of all ages, using a full range of treatment methods, including all available psychotropic drugs. At present I see referrals from family doctors to the mental health services in outpatient settings.

Since 1997, I have been involved in a series of cases involving suicide or homicide on SSRI drugs. Two American SSRI civil cases that have gone to trial, the Forsyth case (Prozac) and the Tobin case (Seroxat). I have reviewed documents and prepared reports in other US civil cases, Berman, Cassidy, Lown, Prior & Blowers (Prozac), Miller, Motus & Witczak (Zoloft), Coburn, Tucker, Van Dyke, Turek and Collins (Seroxat).

I have been consulted on and declined to offer a view on or else offered a view that the drug was not involved in precipitating violence or suicide in over 100 other cases involving SSRI antidepressants. I have offered reports for inquests on approximately 20 individuals who have committed suicide following intake of one or other of the major SSRI drugs, including citalopram in several cases, or antibiotics like doxycycline.

I have testified in several criminal cases in the US, the UK and Australia covering most of th major antidepressants and have given views in a larger number of cases that medication individuals were on was not a factor in events.

I have also been involved in a set of cases involving dependence on Paxil – Seroxat in both the United States and United Kingdom.

I have been involved as an expert in a series of cases involving SSRIs and birth defects.

I have been involved in two patent cases involving olanzapine (Zyprexa).

I have been consulted by New York State prior to a fraud action against GlaxoSmithKline in 2004.

In 2012, with colleagues, I set up an online adverse event reporting website, RxISK.org, from which some of the material for this report comes.

Background to Samuel Morgan's Case

By way of background materials, I have been provided with:

1. The medical records of Samuel Morgan as held by his family doctors.
2. A letter from Dr R Adams to the Coroner
3. Notes by Joanne Lane, Practice Manager, re March 24th 2020 meeting between Dr Adams and Dr Evans and Mr and Mrs Morgan
4. A post-mortem/ toxicology report on Samuel Morgan by Dr P Smith
5. A police statement by Tania Morgan following Samuel Morgan's death.

I have not been given any witness statements or other materials but would be willing to review any further materials that are sent to me.

I have talked to Tania and Ian Morgan on Skype.

Samuel Morgan's Medical History

From his medical records, Samuel Morgan's health appears to have been unexceptional. He had some atopy in childhood that persisted, perhaps a slightly greater number of consultations for relatively minor complaints than the average, and a smoking habit.

From the police statement given by his mother, he appears to have been in a secure relationship, with a loving family, and to be making his way steadily in the wider world of work. He does not appear to have had any debts, or to have been involved in any trouble, or disputes that might make taking his own life understandable.

He had a degree of anxiety around a missed exam, linked to his new place of work, along with the understandable anxieties as to whether he was performing well enough in a new training/ work situation – he was in fact performing well. During this early January period it would seem according to his doctor's later description Samuel may have had fleeting suicidal thoughts.

His concerns led him to approach his family doctor's practice, where he met Dr Adams. Samuel appears to have come to the consultation with the idea that something like citalopram might help. Dr Adams appears to have been slow to prescribe, believing that non-drug approaches might help best, but, ultimately, he did diagnose an anxiety state and prescribe citalopram in a low 10 mg dose.

During the week on treatment, it appears that Samuel googled schizophrenia. This suggests he was agitated and may have been having odd experiences such as hallucinations. Toward the end of the week he appeared to his parents to be out of sorts.

His death came as a complete shock to his family and from their public account to date to his doctors also.

Samuel Morgan's Death

Medicine is a judicial process like an inquest or a trial. Deciding if a drug has caused a problem in clinical care is a matter of examining the evidence in an individual case with an opportunity to examine and cross-examine the key people, looking for the pattern that best explains what has happened. Those involved need know very little about the "science".

In this case, absent any evidence for serious distress stemming from a significant gambling debt, infidelity on the part of his girlfriend, involvement in criminal behaviour likely to lead to legal difficulties or other such evidence, given his age group the most likely cause of a problem is a treatment, or other drug, induced toxicity.

There is no medical condition that Samuel Morgan had that could explain what has happened unless he perhaps had some brain tumour that has not been picked up on post-mortem. Even if he had a brain tumour that might have produced this outcome, the pattern of events is much more consistent with a drug induced toxicity than with another problem like a brain tumour.

There is at present no likelier pattern to explain what happened in this case than the person goes on a toxin, suffers problems known to be caused by this toxin, consistent with later taking his own life, followed by loss of life shortly after taking the toxin. Clearly if there are other plausible patterns that need consideration, hinging on information I do not at present have, I would be willing to take this information into account and see if it changes anything. But it seems from their meeting neither the Morgans nor Dr Adams and his colleagues have thought that other patterns need to be considered.

Samuel Morgan and Citalopram

It has been known for 60 years that antidepressants, treatments often used to mitigate the risk of suicide that is found in severe depressive disorders, can themselves cause suicide in some individuals.

It has been known for 40 years that the selective serotonin reuptake inhibitor (SSRI) group of antidepressants, that includes citalopram, can trigger suicidality and suicide in healthy volunteers and can do so in exactly the timeframe found in Samuel Morgan's case.

For over 30 years, the clinical trials of SSRI antidepressants have shown an excess of suicides and suicidal acts on these drugs compared to placebo, in both patients who were depressed or patients who were anxious or taking them for quite other reasons. This is the case, even though the trials appear designed to hide the problems, the articles purporting to represent the trials have been ghost-written with the writing again designed to hide the problems by coding suicidal events under rubrics like emotional lability, and finally the data from these trials have been sequestered. Where there has been access to the raw data, and few people other than the present author have ever had access, the suicide event rate on treatment increases significantly.

Neither the Minister of Health in the UK nor Wales, the medicines regulator - the Medicines and Healthcare Products Regulatory Agency (MHRA), the makers of treatment guidelines like the National Institute for Healthcare and Clinical Excellence (NICE), nor any doctors who might prescribe these drugs, have access to the data or can get access to the data from company clinical trials.

It has also been known for close to 20 years that there were additional grounds to beef up the warnings about the risk of suicide on SSRIs like citalopram. There is a warning specific to the United States, called a Black Box Warning, which was added there for individuals taking these drugs, who like Samuel Morgan were 25 years of age or younger. This was not because the suicide risk was any greater in this age group but because there is no good evidence for a likely benefit in this age group. We do not have warnings that are comparably stark in this country. This means that patients, their families and doctors are less aware of the risks. While not on medicines here, these warnings are readily available on the Internet now and often found by families like the Morgans and appear to point strongly to the failings of prescribing doctors or other parts of the system in the UK.

In the USA in 2012, the fact that drugs like citalopram and paroxetine, another SSRI, caused such serious risks to younger people with little prospect of a benefit but that trials had been ghostwritten to claim benefits that do not exist and minimise harms that happened more often than the published articles conceded led in 2012 to a $3 billion settlement, the then greatest such settlement in corporate history against Glaxo SmithKline (GSK) the makers of paroxetine and a $370 million dollar settlement against Forest Laboratories, the marketers of citalopram, the drug Samuel was on.

Clinical trials are not the best way to show that a drug can cause a suicide but in this case the clinical trial data confirm what is evident from cases like Samuel's that these treatments while helpful in some cases, can cause suicide in others, and in general do so by causing severe, sometimes horrific agitation, leading up to the event.

Mechanisms of Induction of Suicide & Violence:
The excess of suicidal acts found in clinical trials of SSRIs stem primarily from an induction of agitation/akathisia, in addition to emotional blunting and/or drug-induced psychotic decompensation.

A) Agitation/Akathisia

The evidence that SSRIs cause agitation comes directly from company clinical trial programs, where approximately 5% of patients have dropped out for reasons of agitation. Rates of drop-out for agitation are significantly greater than for placebo.

The best descriptions of this drug induced state come from its first description in the 1950s following the use of the drug reserpine in patients being treated for raised blood pressure. This drug induced states characterised as follows: “increased tenseness, restlessness, insomnia and a feeling of being very uncomfortable” (Achor et al 1955), “the first few doses frequently made them anxious and apprehensive... they reported increased feelings of strangeness, verbalized by statements such as ‘I don’t feel like myself’ .. or ‘I’m afraid of some of the unusual impulses that I have’” (Faucett et al 1957).

Comparable reports can be found in trials of healthy volunteers taking SSRI drugs.

The fact that SSRIs cause akathisia has been conceded by company reviewers, by regulators, and by DSM-IV and a link between akathisia and suicide has been recognized by DSM-IV and company reviewers.

Events such as these in clinical trials of antidepressants have commonly been coded under headings such as agitation, emotional lability and hyperkinesis (overactivity), and only rarely to akathisia. In clinical practice the term akathisia has sometimes been restricted to states of demonstrable motor restlessness, but by definition it cannot be a simple motor disorder, or it would be classified as a dyskinesia[1]. There is good evidence that akathisia can exacerbate psychopathology in general[2], and a consensus that it can be linked to both suicide and violence[3]. A link between akathisia and violence, including homicide, following psychotropic drug use has previously been reported[4].

Substantial evidence from SSRI clinical trials shows that these drugs can trigger agitation. Approximately 5% of patients on SSRIs in randomised trials drop out of the trial because of agitation against 0.5% developing agitation while on placebo. The current data sheets for SSRI antidepressants specify that the drugs can cause akathisia and agitation and warn about developing suicidality in the early phase of treatment, on treatment discontinuation as well as in the wake of a dose increase in the course of treatment. In addition, in the United States, these warnings explicitly apply not only to depressed patients but also to people being treated for

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[1] Cunningham Owens DG (1999) A Guide to the Extrapyramidal Side-Effects of Antipsychotic Drugs. Cambridge, Cambridge University Press.

[2] Duncan EJ, Adler LA, Stephanides M, Sanfilipo M, Angrist B (2000). Akathisia and exacerbation of psychopathology. Clinical Neuropharmacology 23: 169-173.

[3] American Psychiatric Association (2000). Diagnostic and Statistical Manual IV TR. American Psychiatric Association, Washington D.C. Lane RM (1998). SSRI-induced extrapyramidal side effects and akathisia. J. Psychopharmacology 12: 192-214

[4] Siris SG (1985). Three cases of akathisia and “acting out”. J Clin Psychiatry 46: 395-397. Herrera JN, Sramek JJ, Costa JF, Roy S, Heh CW, Nguyen BN (1988). High potency neuroleptics and violence in schizophrenia. J Nervous and Mental Disease 176: 558-561. Schulte JR (1985). Homicide and suicide associated with akathisia and haloperidol. Am J Forensic Psychiatry 6: 3-7. Hoehn-Saric R, Lipsey JR, McLeod DR: Apathy and indifference in patients on fluvoxamine and fluoxetine. J Clin Psychopharmacol 1990; 10:343-345; Wilkinson D. Loss of anxiety and increased aggression in a 15-year old boy taking fluoxetine. Journal of Psychopharmacology 13, 420 (1999) Reply by Healy D. J Psychopharmacology 13, 421 (1999).. Garland EJ, Baerg EA (2001). Amotivational syndrome associated with selective serotonin reuptake inhibitors in children and adolescents. J Child & Adolescent Psychopharmacology 11, 181-186.

anxiety, smoking cessation or pre-menstrual dysphoric disorder (PMDD). In Canada, in addition to suicide, warnings specify an increased risk of violence.

B) Emotional Blunting

The evidence that SSRIs cause emotional blunting lies in the fact that these drugs are used to treat a wide variety of anxiety states and that many of these drugs advertise themselves as anxiolytic antidepressants. An anxiolytic effect is by definition an instance of emotional blunting. The term blunting is applied when the degree of this effect gets to the extent that an individual perceives it to be excessive.

This action of SSRIs is in fact abundantly supported by randomized placebo-controlled trial evidence. This clinical trial evidence is supplemented by a growing body of case studies, which make it clear that the emotional blunting SSRIs produce, the fear reduction, can proceed too far and become an abnormal absence of fear that has consequences for behavior. In addition to the above in their phase 1 healthy volunteer studies, company monitors have regularly recorded the occurrence of mood change on SSRIs, and coded this to emotional lability. Discontinuing treatment rapidly leads to a restoration to normal.

The significance of this is that such an effect can be expected to make an individual less sensitive to the consequences of their actions than they would be in the normal course of events – making it possible to act without fear of the consequences, or not to be inhibited by any moral consideration of the consequences of an action.

C) Psychotic Decompensation.

Since the first administration of imipramine to patients, it was also noted that patients at risk of psychotic decompensation became worse on this drug[5]. This has been a regular feature of the testing of SSRIs, with for example in the case of Prozac, numerous early reports from hospital studies of patients with schizoaffective type disorders becoming markedly worse on this drug at what was probably a greater rate than for other drugs or patients[6]. Having reviewed trials from the clinical trial databases of Prozac, Seroxat and Lustral/Zoloft, I can state that at present all SSRIs that I have reviewed have caused psychotic decompensation in some patients. This happens at a higher rate with SSRIs than occurs on placebo. This data has not been published. This problem clears up on discontinuation of the SSRI.

These drug-induced states often resolve once the medication is removed. However, the full dimensions of treatment-induced psychotic or manic reactions have yet to be mapped[7]. It has recently been estimated that these drug-induced manic or psychotic states may account for up to 8% of admissions to psychiatric facilities[8].

The development of a psychotic episode or of command hallucinations has traditionally been

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[5] Healy D (1997). The Antidepressant Era. Harvard University Press, Cambridge, Ma.

[6] Fluoxetine Project Team Meeting Minutes August 1978. Exhibit 30 in Forsyth Vs Eli Lilly; Fluoxetine Project Team Meeting Minutes July 23rd 1979

[7] Wilens TE, Biederman J, Kwon A, Chase R, Greenberg L, Mick E, Spencer TJ (2003) A systematic chart review of the nature of psychiatric adverse events in children and adolescents treated with selective serotonin reuptake inhibitors. J Child & Adolescent Psychopharmacology 13: 143-152.

[8] Preda A, MacLean RW, Mazure CM, Bowers MB (2001) Antidepressant associated mania and psychosis resulting in psychiatric admission. J Clinical Psychiatry 62: 30-33. Nakra BR, Szwabo P, Grossberg GT (1989) Mania induced by fluoxetine. Am J Psychiatry 146: 1515-1516. Hersh, CB, Sokol, MS, Pfeffer C (1991) Transient psychosis with fluoxetine. J Am Acad Child Adolesc Psychiatry 30: 851-2; Stoll AL, Mayer PV, Kolbrener M, Goldstein E, Suplit B, Lucier J, Cohen BM, Tohen M (1994) Antidepressant-associated mania: a controlled comparison with spontaneous mania. Am J Psychiatry 151: 1642-5. Narayan, M, Meckler L, Nelson JC (1995) Fluoxetine-induced delusions in psychotic depression. J Clin Psychiatry 56: 329.

linked to both violence and suicide. The labels for most SSRIs now concede a causal relationship to psychosis, and to hallucinations.

A proportion of these cases with superficially manic or psychotic reactions and unrecognised confusion may be delirious states reflecting organic brain disturbances rather than a functional psychosis or mania. Delirium has traditionally been an absolute defence against murder, where psychosis and mania may not be.

In Samuel Morgan's case it is highly likely that he developed akathisia on citalopram and possible that he showed some signs of psychotic decompensation/delirium.

Dr Adams and Citalopram

Stunned at the death of their son and reaching out for explanations for what had happened, the Morgan family found that NICE Guidelines for this drug recommend a review after a week.

They raised this apparent recommendation and issues about whether they should have been informed their son had been put on this drug at their meeting with Drs Adams and Evans.

Dr Adams responses to their questions and approach to Samuel's care seems to me to have been blameless. There is blame to be allocated but not to him, in my opinion.

There may be issues about Samuel that Dr Adams knows about and no-one else at present does that may explain his use of the word confidentiality in his discussions with the family. Otherwise, the term confidentiality in the sense of keeping the medical issues of a 25-year-old private from all others unless expressly agreed with that individual appears an appropriate word for an ordinarily appropriate action.

The general thrust of Black Box Warnings in the United States was that any SSRIs would come with medication guides that embraced the idea of letting others in your immediate circle know you were on one of these drugs and what the risks might be and what should be monitored. That is not the situation in the UK but that is not Dr Adams' fault.

The NICE Guidelines do indeed suggest that it might be good practice to monitor a person after a week of treatment but without saying clearly that these drugs can cause healthy volunteers to commit suicide. NICE are complicit with a culture that has been attempting to deny all risks in that their guidelines are based entirely on a ghostwritten literature that hypes benefits and denies risks. Without stating these drugs can cause suicide, even in healthy volunteers, NICE's recommendations are a recipe for disaster. They leave open the possibility and indeed have consistently given a steer toward the notion that if a person becomes suicidal it will be their depression that is the cause of the problem.

Unless NICE Guidance explicitly states that a patient may be suffering from SSRI toxicity rather than depression, in the current circumstances, where there is no approved treatment for SSRI toxicity and general denial that cases like Samuels are more likely to be SSRI toxicity, and doctors like Dr Adams left without any steer as to how best to handle SSRI toxicity, then such doctors are much more likely to diagnose depression and if anything increase the dose of the medicine causing a problem making a suicide even more likely.

It is not possible to return a verdict against a prescription drug. Given this, faced with a good doctor, like Dr Adams appears to me to be, rather than return a medical negligence verdict, coroners have in my experience blamed the mental illness the patient had or must have had, even to the point of all but inventing a mental illness from scraps of information, rather than blame the drug and by implication the doctor who prescribed it.

Dr Adams is not in a good position to argue as an expert on the details of the clinical trial data in this case or the origins of warnings that these drugs carry here compared with the United States but he is in a good position to agree (as he implicitly appears to have done in his meeting with Morgans) that it appears that the drug is likely the prime factor in Samuel Morgan's death and that he has problems with being put in a position where he was not able to treat his patient safely.

It is likely that Dr Adams has been deeply affected by Samuel Morgan's death. It is to be hoped that he will have the courage to implicate citalopram in what happened and also to be hoped that his union will not attempt to inhibit him from doing so.

Who to Blame?

In 2016, I wrote to Vaughan Gething advising him that the literature on these and all drugs used in healthcare is ghostwritten and the clinical trial data sequestered. My concerns were two-fold. One that this situation would inevitably lead to deaths like Samuel Morgan's. The other was this situation is responsible for bankrupting healthcare worldwide, most obviously in the US but also in the UK where it destroys the basis for an NHS. These factors were also playing a part in the Health Board in which I worked being in Special Measures.

Mr Gething's responses suggested either he, or more likely members of his department, did not understand the issues or did not wish to grapple with them.

In 2018, I wrote again covering very similar ground. This letter to Mr Gething (Appendix 1) and a reply from Dr Atherton, the Chief Medical Officer in Wales (not the CMO in 2016) (Appendix 2), are attached. (The 2016 correspondence can be forwarded). Dr Atherton's reply concedes the key points I raised – about ghostwriting and clinical trial data sequestration – and that these factors apply in Wales and elsewhere making it difficult for someone in his position to do much to change the larger "system".

There is a certain onus on Wales to do something in that many of the healthy volunteer trials conducted in the 1980s, before the SSRIs were marketed, showing that these drugs could make healthy volunteers suicidal and wipe-out their sexual functioning, facts that enable companies to shape their medical trials to hide these very problems, were done in Cardiff.

I have also presented these issues in a lecture in the Welsh Senedd building in December 2018, with Mark Drakeford at one point standing in the background. This lecture was put online and has been viewed extensively – so a very wide public knows that Welsh politicians have been informed about what has been happening and at present have chosen to do nothing to keep patients or the NHS safe.

In addition to writing to Mr Gething (and other health ministers in England, N Ireland and Scotland), I have written to Andrew Dillon, the then CEO of NICE, David Haslam, the then Chair of NICE about these issues and had Andrew Dillon essentially concede the point also – or at least not deny it (Appendix 3).

It is perhaps worth noting that NICE guidelines are not based on science in the sense that if the data on which a claim is based are not available for scrutiny the claim is not a scientific one. If I were to announce a treatment and refuse to make the data available, I would be struck off by the GMC.

A medicine is a combination of a chemical and information. We take a risk on poisoning people with the chemical in the hope or averting or circumventing greater risks from some condition. A full set of information about the prior administration of these chemicals in people is essential to inform physicians about when to use them and what poisonous effects to look out for. The chemicals are irredeemably risky - they always have been and always will be dangerous. The

medicines are much riskier than they were 20 or 30 years ago because their informational component has been seriously degraded.

Samuel Morgan

Based on the facts available to me, I can say with some confidence that Samuel Morgan would be alive today had he not been put on an SSRI or related antidepressant, in this case citalopram.

His death is not appropriately regarded as a suicide, or even death by his own hand, in that he did not intend to commit suicide. He was not doing the intending at the time of his death, any more than a person under the influence of LSD who steps out of a 55th floor window, thinking perhaps they can fly, intends to commit suicide.

I enclose an inquest report on Shane Clancy, a 23-year-old man put on citalopram in 2009, who shortly afterwards killed himself and another person, and wounded two more (Appendix 4). In this inquest, a jury primarily comprised of farming/townspeople were invited to consider whether this young man intended to kill himself and others and returned a verdict that in their opinion he didn't. The family of the dead man made efforts to have the verdict overturned but failed.

This was not a death by misadventure. The circumstances that led to Samuel's death were known about by Vaughan Gething and others who appear to have chosen to do nothing about them.

An open verdict does not appear to me to be an appropriate verdict in that it is clear what killed Samuel.

Coroners are not however able to return a verdict implicating a prescription drug. They can draw the case to the attention of a Minister of Health or other responsible party but there is little else they have been able to do. Samuel Morgan's case may offer some scope to bring about a more general, desperately needed change.

Yours sincerely

David Healy MD FRCPsych

Professor of Psychiatry