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EDITORIAL

The Pharmaceutical Year That Was, 2020

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When one penetrates the cloud of COVID-19, this year has seen more than its fair share of charlatans and pharmaceutical jailbirds.

NHS England started us off by firing a new salvo at homeopathy, for which the United Kingdom (UK) taxpayer ceased paying in 2017 [1]. This time, NHS England expressed its incredulity that the Professional Standards Authority (the regulator of regulators in the UK) had recently renewed its accreditation of the Society of Homeopaths (SoH), especially when homeopaths were 'propagating misinformation about vaccines' [2]. This misinformation included unfounded therapeutic claims for 'CEASE' therapy, for which the concomitant use of homeopathic remedies helps 'clearance' of antigens and toxins, thus curing autism and replacing vaccination for infectious diseases [3, 4]. In fact, when read closely, the web pages showing the SoH position statement declare 'CEASE' therapists acceptable, although they do not actually and directly support the therapeutic claims. NHS England has now emphasised that, in particular, homeopaths should not abet the decline in uptake of pre-school vaccinations. Meanwhile, the SoH is running workshops centred on the 'three vital steps towards becoming a homeopath—belief, confidence and risk-taking' [5]!

The abuse of 'anabolic' steroids is getting much less press than that for opioids. Evidence that athletic performance is enhanced by steroids is meagre (beyond mere increase in muscle mass) [6], while there is robust evidence for endocrinological, hepatic, and psychological toxicities of these drugs [7]. A dubious record was broken this year by one Jacob Sporon-Fiedler, a Danish owner of an Indian generic drug manufacturer. He had been managing to ship approximately four tonnes of anabolic steroids each month (*sic*) into the illicit European market. In the UK alone, his revenues were about £65 million per year [8]. Importantly, this record-breaking case illustrates an international disparity in drug regulation and a legal loophole. Anabolic steroids are Schedule 3 controlled substances in the USA (i.e. possession without medical prescription is a felony). However, in England and Wales, while also being Class C drugs, *possession* of anabolic steroids is not necessarily an offence, unlike *supplying* them.[1] The loophole, therefore, is that a Londoner receiving a retail shipment from, say, India, might not commit any offence because the supplier is outside the UK jurisdiction. However, as a matter of logistical efficiency, to fulfil his large markets, Mr Sporon-Fiedler had to resort to shipping wholesale quantities into European countries, and these were then broken down into smaller shipments for local, retail distribution. In the UK, that *does* count as supplying within the jurisdiction, about which Mr Sporon-Fiedler now has plenty of time to reflect, while serving his 5 years and 4 months sentence imposed at the Old Bailey (in all likelihood, he is likely to serve about half of it before being released on licence).

A very questionable effort was started in February by the French Government to incriminate a large pharmaceutical company for failure to warn about a drug adverse event (AE). The AE in question is that sodium valproate has a low incidence of cleft palette after exposure *in utero* [10]. Rarer, and more controversial, are associations with mental retardation and spina bifida [9]. One wonders about the motivation for the charge. The information on the AE has been well known for decades [10], the hazards are in product labelling, the drug is one of the most effective anti-seizure medications ever discovered, and alternative therapies commonly have similar (if not worse) teratogenic effects [11]. Furthermore, the hazards to the foetus of untreated maternal

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[1] The Misuse of Drugs Act 1971 s.28 (3) provides the commonly used defence of ignorance that a substance is a controlled drug. A claim of taking possession to prevent a further offence by either destroying the substance or delivering it to an authorised person (e.g. 'I was going to turn it in at the Police Station on the following day') can also be used as a defence. The Misuse of Drugs Act 1971 ss.4 (1)-(3) and 5(3) for supplying, in general; The Misuse of Drugs Act (Amendment) Order 2009 (no.3209) s.2 (3)(b)(i)-(xi) for anabolic steroids, in particular.

epilepsy have been well-known since the 19th century: they are devastating and, nowadays, no placebo-controlled trial of anti-seizure medications in pregnancy would be ethical [12]. That seems to leave financial gain as the French Government's most likely motive. The legal system is inquisitorial in France, and the company has responded stoically that it will defend itself, and use this false charge as an opportunity to 'prove it has always complied with its duty to inform, and has been transparent'. The case continues.

Dr. John Kapoor was the founder of Insys Therapeutics (Chandler, Arizona). While the company was filing amendments to its Chapter 11 Bankruptcy arrangements in the Spring, Dr. Kapoor was sentenced to five and a half years in prison (four of his colleagues got lesser sentences) [13]. The proximate reason for this, the courts found, was the payment of bribes to encourage greater prescribing of a fentanyl sublingual spray. The scheme involved the sales' people at Insys Therapeutics, and even a nurse practitioner in a Connecticut pain clinic. At previous companies, Dr. Kapoor had been associated with major manufacturing violations, and failure to train a low-salary salesforce motivated by large bonuses based on territory prescription volumes. In short, Dr. Kapoor is a rogue violator of everything that modern, ethical pharmaceutical marketing is meant to be. It is a pity that the press will doubtless extrapolate this to other pharmaceutical companies, and conflate it with the heightened sensitivities of the epidemic of opioid over-use in the USA.

Price-fixing usually requires collusion amongst competitors. In the UK, this is a violation of a variety of commercial laws, and is enforced by the Competition and Markets Authority. In March, four small pharma companies were found to be colluding. The miscreants conspired to carve up the market by creating monopolies for each dose size of generic nortriptyline [14]. Penalties are limited to 10% of global turnover, and therefore the fines ranged from £75,573 to £1,882,238 for what was essentially the same conduct. Three of the four companies admitted the offence, and, perhaps unjustly, the company that did not admit the offence did not get the largest fine.

An unexpected newcomer to pharmaceutical medicine this year was the Oscar-winning actress Gwyneth Paltrow. Her company ('Goop'™) has expanded into marketing 'clinically proven' products on its website [15]. Most hilarious[2] is '*High School Genes*', which are small envelopes containing a variety of six different tablets and capsules. Like Paddington Bear's marmalade sandwiches, this product provides all the vitamins and minerals a patient needs for a whole day. This grossly mis-labelled, unapproved medication is: '*formulated for women—particularly those in a perimenopausal or postmenopausal state—who feel like their metabolism might be slowing down and whose bodies are no longer responding to the exercise and diet levers that they've always pulled*.' Legs are levers.

Given the incessant press coverage of COVID-19, there's not much more that is worth writing about here. However, it was disappointing to see the *British Medical Journal* (*BMJ*) criticise the clinical trials of remdesivir, which were conducted at high quality and high speed. With superb support from the regulators, these led to expedited licenses, which allowed Gilead to commit to providing, without charge, what sounds like about as much product as they can produce for the foreseeable future. Regrettably, the *BMJ* criticised Gilead because it 'supplied the drug for the trial, one of the trial investigators was a Gilead employee, and six others declared financial ties to Gilead' [16]. The *BMJ* did not say where a preferable alternative source of drug might be found, nor did it say where else the repository of information on how to use this investigational, intravenous medicinal product might reside. While one of the clinical trials *per se* in the USA was government-funded, the rest of the development work was the result of private enterprise, and would never have found support from any government. It is a pity that the *BMJ* goes to such lengths to ensure that conflicts of interest in others' work are disclosed, but reliably manufactures opportunities to exercise its unannounced bias against the pharmaceutical industry. Overarching, however, is the question of when will dim politicians, and the general public, ever learn? (see Fig. 1).

Looking forward to next year, there is the possibility that The Cancer Act 1939 in the UK will be reviewed [17]. This venerable statute has successfully banned the advertising of cancer treatments for more than 80 years. Prosecutions continue under the Act, including, one Errol Denton; he was convicted in 2013 of nine breaches of the Act, for which he blamed the pharmaceutical industry [18]. It is unclear who he blamed for his next three convictions in 2018 [19, 20]. The punishments under the Act, in particular, need review: even notorious, multiple offenders are fined less than £20,000. More importantly, this aged Act does not anticipate modern social media, advertisements that cross international boundaries, and conduct which is not specifically an advertisement for a service or by a product provider. The cross-party review at Westminster has begun, and we must hope that they are not distracted by either COVID-19 or Brexit.

And what about Brexit? Since the European Union (EU) departure last January, the unignited, un-sulfurated, British sky has not fallen in. All the UK medicinal product licences remain in place, as do all the EU laws that have been transposed into the UK statute books over the years. Pharmaceuticals are low on the political priority list (compared with banking, fisheries, and Northern Ireland), and

[2] Narrowly beating 'Psychic Vampire Repellent Mist', manufactured by 'Paper Crane Apothecary', whose slogan is: 'Leave your garlic in the kitchen'.

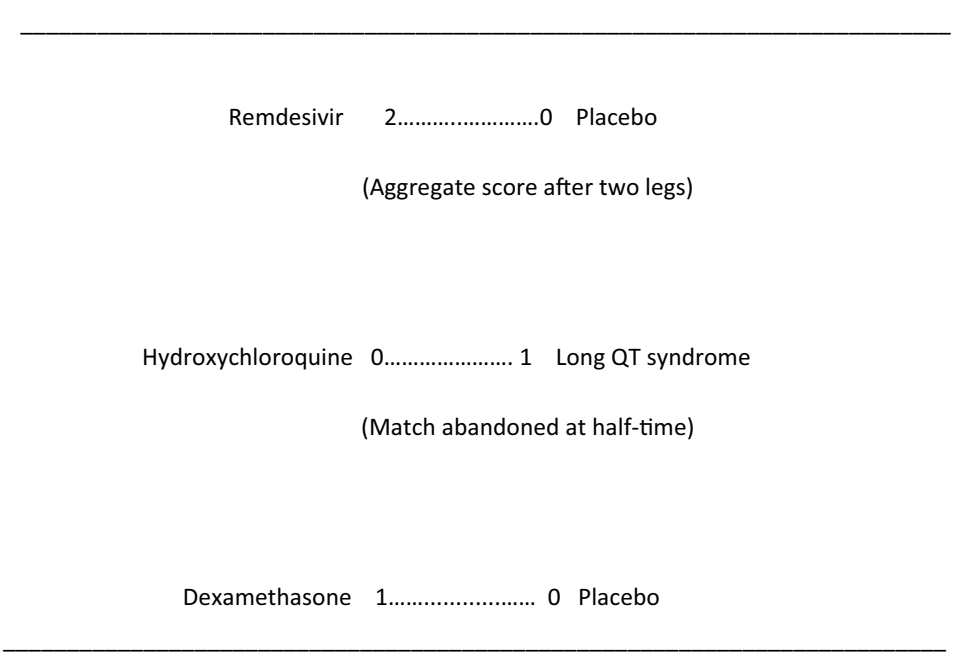

Fig. 1 Scores for treating COVID-19 in 2020: the unsurprising triumph of controlled clinical trials over anecdote, opinion and "It stands to reason". Note that swallowing disinfectant has been omitted

there is not likely to be any more negotiation over drugs before the end of the transition period (January 2021). Meanwhile, opponents of Brexit remain vocal. Their forlorn, rear-guard tactic seems to be to try to frighten the public with speculations rotating among pharmaceutical product shortages, failure of drug supply lines (inexplicably related to lines of lorries stretching from London to Dover when most drugs are imported by air), and a sale of the National Health Service to the USA! While there was a shortage of hormone replacement therapy during the Spring and Summer, that was also true within the EU, and is a source material problem. But, overall, a wafer-thin silver lining to the cloud of the tragic COVID-19 epidemic is a gratefully received respite from Brexit hysteria.

Laura Donnelly, whose elevation from Health Correspondent to Health Editor of the *Daily Telegraph* (London) more than 4 years ago, gave us one good laugh this year: she has noticed that the US has a Food and Drinks Administration! [21]. The (mashed) grain of truth is that fermented products (e.g. those produced in Kentucky) are regulated as foodstuffs by the FDA.

Lastly, congratulations are due to Sue Pochon and her team in Auckland. *Pharmaceutical Medicine* is now recognised by the principal citation authorities. Articles should be on PubMed (for example) starting from about 2 years ago.

Happy New Year !

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