The World of Drug Regulation Meets the Biotech Wunderkind

Hatchard Report

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The World of Drug Regulation Meets the Biotech Wunderkind

A large number of recent articles and studies raise crucial questions about the standards being applied to drug assessment and regulation.

Are the regulators facilitating drug approval by failing to require adequate long term testing and assessment of adverse effects? In other words, are the general public now firmly established as legitimate subjects for experimentation? We look at three examples among the many causing growing public concern:

Weight Loss Drugs

Weight loss is one the highest earning drug sectors. An article in the Daily Mail entitled "How the new weight-loss drugs may work BETTER than Ozempic and other jabs. So will they really be free of the grim side-effects which mean so many give up within a year or two?" illustrates how the merry go round of drug approval works—short term testing, miracle promises, lax drug approval, adoption by the medical profession, widespread use among the public, adverse effects come to light, then new drugs are offered as replacements with promises that this time….

A very profitable business for all concerned except Joe Public who invariably has to bear the burden of pain, disappointment, and disability.

Weight loss drugs Wegovy and Ozempic have been wildly popular market winners with celebrity endorsement and reportedly amazing results, which a few years ago, before their introduction, seemed an impossible dream. All of the weight loss drugs, including a soon-to-be-released new generation of drugs, work by mimicking GLP-1, a hormone made naturally in the body that helps slow the passage of food through the stomach — which makes people feel less hungry and rapidly lose weight.

It's not difficult to understand why drug companies are pouring into this field. Analysts at Barclays forecast that sales of weight-loss drugs will top £19billion globally this year, with the market growing to £110billion by 2030.

Nor is it difficult to realise why manufacturers are *'promising'* new versions of the weight loss drugs with *'fewer side effects'*.

The long term side effects of the weekly injections have started to bite. Mounting evidence suggests that in the real world, the drugs' side-effects such as vomiting, diarrhoea, nausea, constipation and tiredness are proving so common and overwhelming that it makes the current versions impractical for most patients to stay on for very long.

Less common complications of GLP-1 medications are gallstones, increased heart rate, kidney damage, and pancreatitis — a condition where the pancreas rapidly becomes painfully inflamed.

Another serious concern is gastroparesis, a severe disorder where the stomach muscles become effectively paralysed and the stomach does not empty. Sufferers vomit days-old food. For some patients, the only remedy for gastroparesis may be a gastric bypass. Around 10,000 patients in the U.S. are now suing Ozempic's maker, Novo Nordisk, and Mounjaro's manufacturer, Eli Lilly, for medical-injury damages.

A study in the journal BMJ Open Diabetes Research & Care in 2022, entitled "Real-world weight change, adherence, and discontinuation among patients with type 2 diabetes initiating glucagon-like peptide-1 receptor agonists in the UK" looked at health records of 589 Britons who had been prescribed GLP-1 medications for type 2 diabetes. It reported the patient drop-out rates were a staggering 45 per cent after one year and 65 per cent at two years.

The researchers warned that their study results ***'suggest the real-world benefit of these agents on weight loss may be lower than that observed in clinical trials'.***

Prime Therapeutics, in an analysis of data from over 4,000 US patients prescribed GLP-1 drugs, found that more than two-thirds of patients stopped taking them within a year.

Other studies show once a patient drops out of the regimen, most of their weight returns, along with related risks for heart disease and type 2 diabetes, such as obesity, chronic body-wide inflammation and problems with insulin control. Meanwhile, longer-term side-effects are also emerging. One concern is muscle loss: trials of GLP-1 drugs show roughly 40 percent of the weight loss is muscle mass rather than fat.

The Daily Mail article goes on to describe efforts to develop alternative weight loss drugs, all of which appear to already have known side effects as serious as GLP-1 inhibitors. Yet this doesn't seem to stop drug companies from promising that side effect-free weight loss drugs are just around the corner.

Ahmed Ahmed, a consultant bariatric surgeon at Imperial College Healthcare NHS Trust in London, strikes a note of warning:

"Unrealistic expectations of a weight-loss cure have been driven by social media, not science or medicine, and by marketing rather than public health….

"These drugs are still quite new and we only have three or four years' worth of evidence. I worry that after ten years of taking the drugs people may develop very serious physical side-effects. We just don't know yet. As for other types of new drugs that speed the metabolism, we just don't know whether they will work and there is certainly a risk of serious side-effects such as heart damage here."

If you want to dive deeper into the murky world of weight loss drugs, watch "The effects of Ozempic and other weight loss injections | 60 Minutes Australia". The video features reports of deaths following Ozempic use. It asks questions of drug regulators, doctors, and researchers which reveal ***an elaborate system of evasion, passing the buck, blaming others, and dismissing deaths as the price of health.***

NSAIDs

You may not be taking weight loss drugs, but most of the public are now fully conditioned by their doctor to take non-steroidal anti-inflammatory drugs (NSAIDs) like ibuprofen to relieve acute inflammation. New research suggests this might not be a good idea. An article entitled Anti-Inflammatory Drug Might Lead to Chronic Pain, While Inflammation Could Heal: Experts in Epoch Health explains more. It asks: *does short-term relief—and interfering with the body's natural healing process—come at the cost of chronic pain?*

An article in Science Translational Medicine entitled Acute inflammatory response via neutrophil activation protects against the development of chronic pain reported mouse studies where early treatment with a steroid or non-steroidal anti-inflammatory drug (NSAID) also led to prolonged pain despite being analgesic in the short term. Analysis of pain trajectories of human subjects reporting acute back pain in the UK Biobank identified elevated risk of pain persistence for subjects taking NSAIDs.

In other words, the natural inflammatory response of the body to injury is part of the long term healing process. Interrupt that, and the risk of long term chronic pain is elevated. This is in addition to the previously noted risks of NSAIDS which include cardiovascular events and gastrointestinal bleeding.

NSAIDs are one of the most commonly used drug classes in the world. It is estimated that more than 30 million people use them on a daily basis, and they account for 60% of the analgesic market in the United States. ***The new findings suggest that NSAIDs may actually prolong the painful injuries they are supposed to benefit and turn them into chronic conditions.***

Puberty Blockers

On March 12th the NHS banned puberty blocker prescriptions for children under 18 in a *'landmark decision'*. MPs called for the ban to be extended to private medical practice. Dr Hilary Cass, the former president of the Royal College of Paediatrics and Child Health warned that the drugs may permanently disrupt the brain maturation of adolescents, potentially rewiring neural circuits in a way that cannot be reversed, and said there was ***a lack of long-term evidence and data collection on their safety and effectiveness.*** The article said:

"The significance of NHS England's statement that there is not enough evidence to support the safety or clinical effectiveness of puberty blockers cannot be overstated."

The American College of Pediatricians warns that puberty blockers may cause mental illness. They can cause depression and other emotional disturbances related to suicide. In fact, the package insert for Lupron, the number one prescribed puberty blocker in America, lists *"emotional instability"* as a side effect and warns prescribers to *"Monitor for development or worsening of psychiatric symptoms during treatment."*

The list goes on. We recently reported that MHRA, the drug regulator in the UK, is investigating high rates of adverse effects from blood thinners, another class of products among the world's most heavily prescribed drugs. As powerful new drugs are brought to market via biotech research projects which investigate and manipulate fundamental biomolecular pathways, doctors are grappling with significantly increased rates of serious adverse effects. This has been the background to a gradual distortion of medical ethics which now accepts medical misadventure and even death as the inevitable price of 'progress'.

mRNA vaccine technology

mRNA vaccines have been associated with the highest rates of adverse effects ever recorded in the history of vaccines. But we don't see regulators wringing their hands in concern or offering weak apologies as with the above drugs. Instead, there is still a barrage of endorsement and encouragement along with a wall of silence and denial when it comes to adverse effects. Why is that?

The answer lies in the PR dynamics of the pharmaceutical industry and the modern medical profession. mRNA interventions are the poster child of future health. The biotechnology industry is promising nothing less than freedom from disease as more and more products which manipulate the transcriptional interface of DNA with RNA inside the cell are researched and brought to market.

No disease is too insignificant to be missed, they have a long list, but the unprecedented range and rate of mRNA Covid vaccine adverse effects is a fly in the ointment of this biotechnology dream. The insiders' story is clear: *we may have got this wrong but we will eventually get it right*. The story for public consumption is a brazen lie: *Nothing to see here, it is all wonderful.* The insiders' story ignores the reality of risk: Genetic processes inside the cell control the whole physiology in a complex dance of multitasking—wide ranging mutagenic events from genetic interventions are inevitable. The public story tacitly admits that it's OK to experiment on Joe Public without letting on what is happening.

At root is a complete misunderstanding of human life, which should be obvious but is carefully hidden by a scientific paradigm that seeks to hide the essence of humanity. The whole physiology works to support our everyday experience, of knower knowing and known. The tripartite 3 in 1 structure of our awareness—the togetherness of observer, process of observation and observed. As biotechnology delves too deep and disrupts fundamental cellular processes, it is putting this structure of human life at risk.

If the risks of biotech medicine were publicly admitted, a trillion dollar industry would come crashing down and the myth of a genetically manipulated perfect future would be dispelled. There is too much money, prestige, power and hope at stake to let that happen. Voices raised with questions are cancelled and denied a platform. The public remains misinformed.

However, the writing is on the wall. The New York Times has just published an article entitled "Four Years On, the Mysteries of Covid Are Unraveling." There is no mention of the increasing evidence of a lab origin for COVID-19 and, crucially, no mention of COVID-19 vaccines. The NYT was previously leading the charge for Covid vaccines, the silence is now becoming noticeable.

Here in New Zealand concerns are not yet being released to the public or covered in the media. Without full information, the New Zealand public will remain misinformed.

ACT NOW

You can register your displeasure at www.covidinquiry.co.nz, which offers you the opportunity to agree with *The People's Terms* (Full text available at the above link) and also make a submission to the review process of the current terms of the Royal Commission. The aim is to get 100,000 signatures to demonstrate the growing level of public concern, the need for transparency, and a wide ranging revised scope for the Royal Commission of Inquiry into Covid-19.

The government inquiry is closing within a week. Please act now.

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