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Lawsuits against those legal and illegal manufacturers of narcotic drugs

Sally Ramage

Legislation

EU Directive 75/319/EEC (products for human use)

EU Directive 81/851/EEC (veterinary products)

Pharmaceutical Inspection Convention 1995

UK Medicines Act 1968

UK Misuse of Drugs Act 1971

UK Proceeds of Crime Act 2002

UK Road Traffic Act 1988

Keywords

Addiction; Certificate of Production; death; false boasting; France; GBL; GHB; lawsuit; licence; Mephedrone; misrepresentation; New Mexico; psychosis; Professional Rules and Guidance for Pharmaceutical Manufacturers; opioid; spice substances; Synthetic cannabinoids.

Abstract

This is the story of drug addiction; misrepresentation by drug companies; false boasting (or fraud) by drug companies; brazen illegal manufacture of substances; knowledgeable

persons who took advantage of pharmaceutical loopholes to create dangerous party drugs from cleaning products and what UK police can do about it.

Introduction-latest United States Action against drug addiction

The State of New Mexico on Thursday, 8th September 2017, sued eight opioid manufacturers and wholesale distributors. New Mexico is not the only state to do litigate against a pharmaceutical corporation for causing massive addiction to its population. New Mexico issued litigation papers to five pharmaceutical manufacturers for their deceptive practices. The pharma manufacturers sued are

- * Purdue Pharma LP;**
- *Johnson & Johnson Inc.;**
- * Allergan plc;**
- * Endo International Plc;**
- * Teva Pharmaceuticals Industries Ltd.**

The State of New Mexico in the United States also sued three opioid wholesale distributors, namely:

- * McKesson Corp;**
- * Cardinal Health Inc; and**
- * AmerisourceBergen Corp.**

New Mexico's filed lawsuits

The State of New Mexico sued the three wholesale distributors for knowing how addictive opioids are but encouraged the public to use opioids through deceptive

practices and deceptive marketing methods, in breach of their legal duties to monitor, detect and report obvious suspicious orders of prescription opioids.

There has been a crisis of opioid addiction spread across the State of New Mexico, resulting in the destruction of thousands of lives and at the same time, billions of dollars of profits for the manufacturers and distributors.

Other similar lawsuits are from the States of:

***Oklahoma;**

*** Mississippi;**

*** Ohio;**

*** Missouri;**

*** New Hampshire;**

*** South Carolina;**

*** California's cities;**

*** Illinois's cities;**

*** New York's cities; and**

*** West Virginia**

Risks of addiction; misrepresentation of drugs; false boasting or fraud

New Mexico's lawsuit was filed in the First Judicial District Court in Santa Fe County.

Their case stated that the drug manufacturers did not acknowledge risks of addiction to prescription opioids and where the manufacturers stated any risks, these were

downplayed. These drug manufacturers misrepresented the drugs and falsely boasted

about the benefits of the long-term use of opioids. New Mexico State also accused the

wholesale distributors of violating their duties by selling large amounts of painkillers

that were then diverted for illicit uses, helping to contribute to the opioid epidemic. The

lawsuit seeks damages, including for the costs New Mexico has incurred responding to the epidemic. The companies have in similar cases denied wrongdoing. The drug manufacturers have claimed that they had acted responsibly in marketing the opioid drugs, which carry warning risks on approved labels issued by the United States Food and Drugs Administration. One drug manufacturers, Purdue (which manufactured the notorious drug OxyContin) stated that:

‘While we vigorously deny the allegations, we share public officials’ concerns about the opioid crisis and we are committed to working collaboratively to find solutions’.

One of the three opioid wholesale distributors being sued by the State of New Mexico stated:

‘This lawsuit is misguided and was launched in haste and without any factual investigation to support it.’

The United Kingdom should follow suit

The UK should follow suit because there is nothing that criminal hate as the confiscation of assets as per the Proceeds of Crime Act. Apart from increasing heroin addiction in the United Kingdom (“UK”) and much misuse of prescription drugs (which prompted the amendment of the UK Road Traffic Act in recent years)¹ there is the increasingly worrying use of a drug colloquially called “spice” which is destroying many lives in the UK.

¹ S4 ‘driving or being in charge , when under the influence of drink or drugs’. Note that spice substances are not drugs in terms of medicines. Section 5A, ‘driving or being in charge, with controlled drug above the specified limit’, meaning that the defendant will be guilty of this offence if the proportion of the drug in his or her blood or urine exceeds the specified limit for that drug.

What are *spice* substances?



Spice is a generic term for the hundreds of synthetic versions of cannabis that are used instead of herbal cannabis, known as synthetic cannabinoids.

Controlled human testing by government agency in 1970s

The first synthetic cannabinoids were made in the 1970s as potential medicines, but initial human testing found them to be so unpleasant and *potent* in their actions *that so no manufacturer ever marketed the drug.*

There must be someone who knows their way around patent law, who spotted this case and took advantage of it to supply wholesale narcotic drugs.

Spice consumed today

Since then synthetic cannabinoids were sold openly in ‘spice shops’ with the full knowledge of the UK government. That were treated by the authorities as legal alternatives to cannabis, and they were called *spice*. How this major misconception came about by the UK government is not yet known.

Apparent symptoms of violence, psychosis and/or sometimes psychiatric catatonia

Users of the spice substances often become psychotic and violent. Some other users of spice substances become soporific or psychiatrically catatonic. Yet people continued to use the spice substances because, additionally, spice substances are extremely addictive.

Knee-jerk UK legislations

The UK government then decided to legislate against its use. Yet, despite government legislation classifying these spice substances as Classified Drugs, these illegal substances are today still being illicitly produced and are accessible in the UK, even though the UK government has since closed down the spice retail outlets.

No manufacturing standards or quality control of *spice* substances

Unlike the manufacturing of the prescription-only drug Oxycontin in the US, spice substances are being manufactured illegally and therefore do not comply with pharmaceutical standards, hygiene standards, set formula of chemicals used to produce them, etc. and therefore there is absolutely no quality control in their production. This total lack of quality control of the production of illicit spice drugs or synthetic cannabinoids is highly worrying to law enforcement.

Manufacture of UK spice substances akin to US bootlegging of alcoholic substances

The manufacture of spice substances is an ‘underground’ activity, much like ‘bootlegging’ had been in the United States during the alcohol-prohibition decades of the past. No-one knows in any certainty the quantity of the synthetic cannabinoids in any one packet of spice substances or what level of potency each batch contains.

When illegal substances are manufactured without government compliance, the effect is as dangerous as in the bootlegging days. One US Chief of Pharmacology, Public Health Department described the results of their thorough and scientific analysis of the bootlegger’s products across all the states of the US. He wrote:

‘Home-made illegal whisky, called “moonshine” was found to have been produced in the most unscientific and insanitary conditions, fermented in barrels, in tubs and in musty cellars, causing the development of wild yeasts, unwholesome fermentations, , many showing active putrefaction, and containing high alcohols, aldehyde, fusel oil, and additional poisons, directly damaging the kidney, circulatory and nervous systems.’

Other UK illegal drug consumption

Other drug misuse in the UK includes the use of the following substances:

- (i) The illegal substance Mephedrone.**
- (ii) The illegal misuse of the chemical Gammahydroxybutrate (“GHB”) and Gammabutyrolactone (“GBL”).**

Illegally created by scientifically knowledgeable persons

Scientifically knowledgeable persons must have discovered the later two misused substances which have gripped and addicted many persons, even professionally qualified and outwardly respectable and responsible persons.

(i) Mephedrone - 2007

It is known that Mephedrone was first manufactured illegally around the year 2007. This was because, in 2007, Police in France seized some tablets which at first they thought were illegal recreational Ecstasy tablets and before making charges, they had the tablets tested and it was discovered that they were the newly created substance Mephedrone. This substance was not on their statute books as a banned substance but it did become so. By the year 2011, the Federal United States and many other countries made Mephedrone an illegal substance.



Mephedrone was initially created illegally in unauthorised laboratories and in people's kitchens. Therefore it has been under the radar of pharmaceutical compliance. It has not been tested nor approved by the UK government. Therefore the medical profession

and also the pharmaceutical industry are ignorant of its medium-term; long-term and short-term effects since it has not been through the legal procedure of controlled testing and peer reviewed published papers.

It is to be noted that presently, the human consumption of Mephedrone is a criminal offence of ‘misuse of illegal substances’ in many countries, not just in the UK. So, Mephedrone has no licence or certificate of production, crucial components for quality assurance of medicines.

It is no coincidence that Mephedrone is manufactured illegally and covertly in suspicious laboratories and without pharmaceutical licence² because there are detailed and Professional Rules and Guidance for Pharmaceutical Manufacturers within the European Union (EU).

(ii) GHB and GBL

Again, some persons with scientific qualifications and knowledge much have noticed that the constituent components of an industrial cleaning fluid contain a chemical which can be used as a psychoactive drug.

The ordinal man in the street could not have known that. The author has not researched the date of first licence of the cleaning fluid compared to the date when GHB first became a known party drug. The dose required for a euphoric ‘high’ is said to be

² The UK Medicines (Standard Provisions for Licences and Certificates) Regulations have been enforced over the years by the various relevant Statutory Instruments (SI) beginning with SI 1971 No 972 in which clause 1 of Schedule 2 of the regulations states that the licence holder shall provide and maintain such staff, premises and plant (equipment) as are necessary for the carrying out in accordance with his licence and the relevant product licences of such stages of the manufacture and assembly of the medicinal products as are undertaken by him, and he shall not carry out any such manufacture or assembly *except* at the premises specified in the licence or which may be approved from time to time by the licensing authority. Clause 12 (2) of this Schedule 1 is relevant when considering the huge deception that a manufacturer of the substance GHB makes by deceiving the authorities that he is manufacturing this product as a cleaning liquid when in fact it is a *chemsex* party drug that is very dangerous and has caused very many deaths. Thus the manufacturer of the so-called liquid ‘cleaning product’ sold in quantities for litres and not grams, is continuously committing corporate manslaughter offences in English criminal law, at least, See Ashtha Nagesh, ‘Dramatic rise in deaths linked to chemsex drug *GHB*’, *Metro Newspaper*, 14 January 2017.

close to the level at which users can overdose, many times- fatally. GBL is the chemical used for industrial purposes , GBL is converted to GHB in the body, so the two are taken interchangeably and both can cause unconsciousness, coma and death. Even experienced users are at risk of death. Repeated use has been seen to cause addiction in some users, according to the participants in the 2015 documentary film *Chemsex*. In the *Chemsex* film participants spoke of people who have died after using *GHB* and *GBL*.

How to catch the criminals who initiated the GHB drug addiction in the UK

It is really astonishing that substances such as GHB³ are in use in the UK for very many years by partying crowds and that it is common knowledge that it is manufactured as cleaning products, yet one would have expected UK Police Authorities to have vigorously compiled evidence as to its *chemsex* use and face these particular manufacturers with this evidence.

First, law enforcement might wish to:

- *Enquire as to how many such companies are licensed to produce this cleaning fluid in the European Union (“EU”) including the UK?**
- * Who the directors of such companies are?**
- * Whether such directors are enjoying a living standard far beyond their stated earnings?**
- * Which directors have qualifications in chemistry?**

³ See the free *Metro* daily newspaper article: Rob Waugh, ‘What is *liquid G*? What you need to know about drug linked to George Michael’, *Metro*, 2 January 2017, A former lover has claimed that George Michael ‘was mad on’ a drug known as ‘Liquid G’ or GHB – and said that he believes he may have had it before his death. The formerly legal drug is now Class C Controlled drug in the UK. It is a clear liquid widely used on dance-floors for its euphoric effects, but is also known as a date rape drug. It is also used as a sex drug. at <http://metro.co.uk/2017/01/23/what-is-liquid-g-what-you-need-to-know-about-drug-linked-to-george-michael-6399733/#ixzz4Yx8EzFFV/>.

*** Which directors have near-relatives with qualifications in chemistry?**

Then Court Orders can be obtained to covertly survey the activities of such persons and maybe catch the criminals who first started the GHB drug addiction in the UK.

these manufacturers of these particular cleaning products, if checked and found not be linked with the wholesale supply of GHB, should then be forced to put *checks and balances* in place and keep scrupulous records to ensure that the manufacturer is absolutely certain that the product is being used by cleaning firms and that buyers are traceable.

Besides this, police and compliance authorities should make extra special checks on the premises where these particular cleaning products are being manufactured and carry out regular ‘quality’ checks in order to find any additional suspect substances in batches of this product or changes in the constituency of the product.

If the GHB is manufactured in the EU as a cleaning substance, why was it not liable to some quality control documentation? Control documentation is generally, by way of:

- *specifications**
- *manufacturing formulae, and**
- *procedures and records**

This documentation required should provide a history of:

- *each batch of the cleaning product,**
- * its distribution, and**
- * all relevant circumstances pertinent to the quality of the final product, as per EU product manufacturing rules and guidances.**

Such manufacturers’ regulations have been in place for FORTY years

These steps could have prevented the death of dozens, perhaps hundreds of persons addicted to GHB. In many cases, post-mortems were misdiagnosed or cause of death simply stated as ‘drug overdose’.

EU Directive 75/319/EEC (products for human use) and Chapter V of EU Directive 81/851/EEC (veterinary products)

There is obligation on governments of all Member States of the EU to ensure that pharmaceutical manufacturers are authorised. This was originally stated decades ago in Chapter IV of Directive 75/319/EEC (products for human use) and Chapter V of Directive 81/851/EEC (veterinary products), these two chapters being the source of requirements for compliance with Good Manufacturing Practice (GMP); employment of Qualified Persons and repeated inspections by the regulatory authorities. The Principles and Guidelines of GMP were stated in two almost identical Directives, namely, 91/356/EEC (for medicinal purposes for human use) and 91/341/EEC (for veterinary medicinal products).

UK Medicines Act 1968 and UK Misuse of Drugs Act 1971 and Pharmaceutical Inspection Convention

The European Union (“EU”) Directives were implemented into UK law in regulations made under the *UK Medicines Act*.⁴

⁴ The UK Medicines Act defines three categories of medicine: *prescription only medicines* (POM) which are available only from a pharmacist if prescribed by an appropriate practitioner; pharmacy medicines (P), available only from a pharmacist but without a prescription; and general sales list (GSL) medicines which may be bought from any shop without a prescription. The *Medicines Act 1968* controls supply of the drugs it covers, but does not define any offence of simple possession. Possession of a prescription only drug without a prescription is only an offence if the drug is also controlled under the *Misuse of Drugs Act 1971* and possession is thus specified as an offence.

The European Communities (“EC”) guide was first issued in 1989 and adjusted in 1992 and 1993 and the UK has its own national guide, as recognised in the EC guide. Later, there was drafted the *Pharmaceutical Inspection Convention*.⁵

Police Interception –not more legislation

This prevention could have been done without a need to create new laws⁶ by ceasing it under present manufacturing laws.⁷ Vigorous police investigations⁸ would have prevented many addictions and stopped the cleaning fluid manufacture and charged and convicted those criminals who thought up the scheme of chemical conversion and wholesale supply for illegal purposes; ceased all of their assets; closed these businesses down, etc.

It has been noted hat a similar exercise could be used to investigate the legal substances that are available in the UK and the EU to catch those who supply and purchase wholesale bomb making materials since the UK has suffered several terrorist attacks during this year, the most recent occurring on Friday, 15 September 2017, a terrorism related home-made bomb, which luckily failed to detonate.

(3,000 words)

ENDS+

⁵ This Convention adopted the text of the EC guide and included other paragraphs which ensured its international harmonisation.

⁶ Smith, I.T., Thomas, G. Mead, D. (2015) *Industrial Law*, London: LexisNexis Butterworths. See also, UK Health and Safety at Work Act 1974.

⁷ See Editor, How toxic are your cleaning products? *Green Guide, Organic Consumers Association, February 2017*. Several instances have been reported of cleaning women killed by cleaning product fumes and we cannot forget that this country has a long history of health and safety regulations and one fails to understand why this product manufacture has not ceased under English law.

⁸ UK police have many powers of investigation including detention, arrest, interrogations, entry and search of premises, search of the person, taking certain samples from the person, and identification procedures by Police and Criminal Evidence Act 1984 (“PACE”) and PACE Codes.



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