George Petters - Central Foundation Boys' School

3. Drug formulation: a science or not a science?

There are two definitions crucial to this question, 'drug formulation' and 'science'. 'Drug formulation', can be taken to mean as "processes in which different chemical substances i.e., active chemical substances will [be] combined together to produce a medical compound i.e., medical drug" (Hassan, 2012). This essentially boils down to two things, making a stable product, which is effective and sufficiently bioavailable, and it being 'acceptable' to the patient using it, i.e. the drug being in a form which the patient will take (e.g. oral tablet).

This definition may also include references to R&D, marketing and drug design and development in the pharmaceutical industry as a whole, although those are not the main focus of 'drug formulation'.

Perhaps the more difficult word to define here is 'science'. The UK charity, The Science Council, defines 'science' as "the pursuit and application of knowledge and understanding of the natural and social world following a systematic methodology based on evidence" (The Science Council, 2019). They also give a clear outline of what constitutes as 'scientific methodology':

- "Objective observation: Measurement and data (possibly although not necessarily using mathematics as a tool)
- Evidence
- Experiment and/or observation as benchmarks for testing hypotheses
- Induction: reasoning to establish general rules or conclusions drawn from facts or examples
- Repetition
- Critical analysis
- Verification and testing: critical exposure to scrutiny, peer review and assessment"

I would argue that the points outlined here do give a clear and well-rounded idea as to the meaning of 'scientific methodology', and by extension 'science'.

One aspect not mentioned here is 'falsifiability'. Karl Popper, "regarded as one of the greatest philosophers of science of the 20th century" (Thornton, 2013), suggested that "a theory which is not refutable by any conceivable event is non-scientific" (Popper, 1963). While this is an indispensable factor of 'science', it will not be discussed in great detail as a pharmaceutical product can easily be established as not stable; it *can* be proven to be *unstable*.

It could also be argued that theories where quantitative measurements are able to be taken are more 'exact' and 'scientific'. This is not necessarily the case, yet it may allow conclusions

to be drawn more confidently as quantitative evidence may *seem* to yield more reliable results. Qualitative evidence is *as* scientific as quantitative evidence, it may just be harder to reduce bias in qualitative experiments due to human description and the vast array of factors that affect this.

Drug formulation studies typically focus on factors such as particle size, pH, polymorphism and solubility, to see whether any will affect the bioavailability of the drug (Hassan, 2012). The basic example in Figure 1 below, which measures the solubility of different polymorphs of the nonsteroidal anti-inflammatory drug (NSAID) Phenylbutazone in different solvent systems, includes most of the points outlined in 'scientific methodology' above:

- Measurements and data are taken, which itself can be taken as the evidence
- This experiment was used to test a hypothesis, that 'different polymorphs do have an effect on the solubility of the drug'
- A conclusion was drawn from the data with reasoning (Form I exhibits the lowest solubility in all three solvent systems, demonstrating the lowest free energy and indicating that Form I is the most thermodynamically stable polymorph at room temperature)
- Repetition is not explicitly demonstrated here, however it is assumed that this data, as with all other well-respected data, has been repeated to ensure accuracy (data shown in Figure 1 is possibly mean data collected over a variety of repeats)
- Critical analysis, verification and testing are not demonstrated here, however the experiment undertaken is *open to* scrutiny, peer review and assessment. The pharmaceutical industry is heavily monitored and regulated (McGuire, 2007), and it is therefore implied that this, and any other data obtained with regards to drug formulation, is subjected to the final three points which define 'scientific methodology'

Solvent system	Solubility (mg/mL)				
	I	II	IV	V	III
pH 7.5 Phosphate buffer	4.80	5.10	5.15	5.35	5.9
Above buffer with 0.05% Tween 80	4.50	4.85	4.95	5.10	5.52
Above buffer with 2.25% PEG 300	3.52	5.77	5.85	6.15	6.72

Note: The polymorphs are listed in order of increasing free energy at ambient temperature.

FIGURE 1: Equilibrium Solubility of Phenylbutazone Polymorphs, at Ambient Temperature in Different Solvent Systems (Brittain, 2009)

As seen above, drug formulation could constitute as a science according to the definition given by The Science Council. In fact, according to this definition, *literally anything* can be considered a science, as long as it as it "follow[s] a systematic methodology based on evidence". This can include anything from astrology, to Feng Shui, to the Myers–Briggs Type Indicator (MBTI), to homeopathy. While some of these ideas fall under fire due to their 'unfalsifiability', many of them do have theories which are able to be refuted (e.g. MBTI). In

that case, what differentiates these ‘pseudosciences’ from hard, empirical science, and as such why is drug formulation not considered a pseudoscience?

Strangely enough, the word ‘empirical’ answers that question for us. Evidence is one of the underlying and perhaps most important aspect of the ‘scientific methodology’, appearing in most other interpretations of ‘science’ including those across different periods in history. (Chalmers, 2013)

More specifically, it is the *quality* of evidence obtained. In that case, behold the “Evidence-Based Medicine Pyramid”. This useful diagram gives an established and reasonably accurate *guide* for the ranking of the different forms of evidence in reference to health-related decisions, identifying what constitutes as good evidence and the limitations of different types of studies.

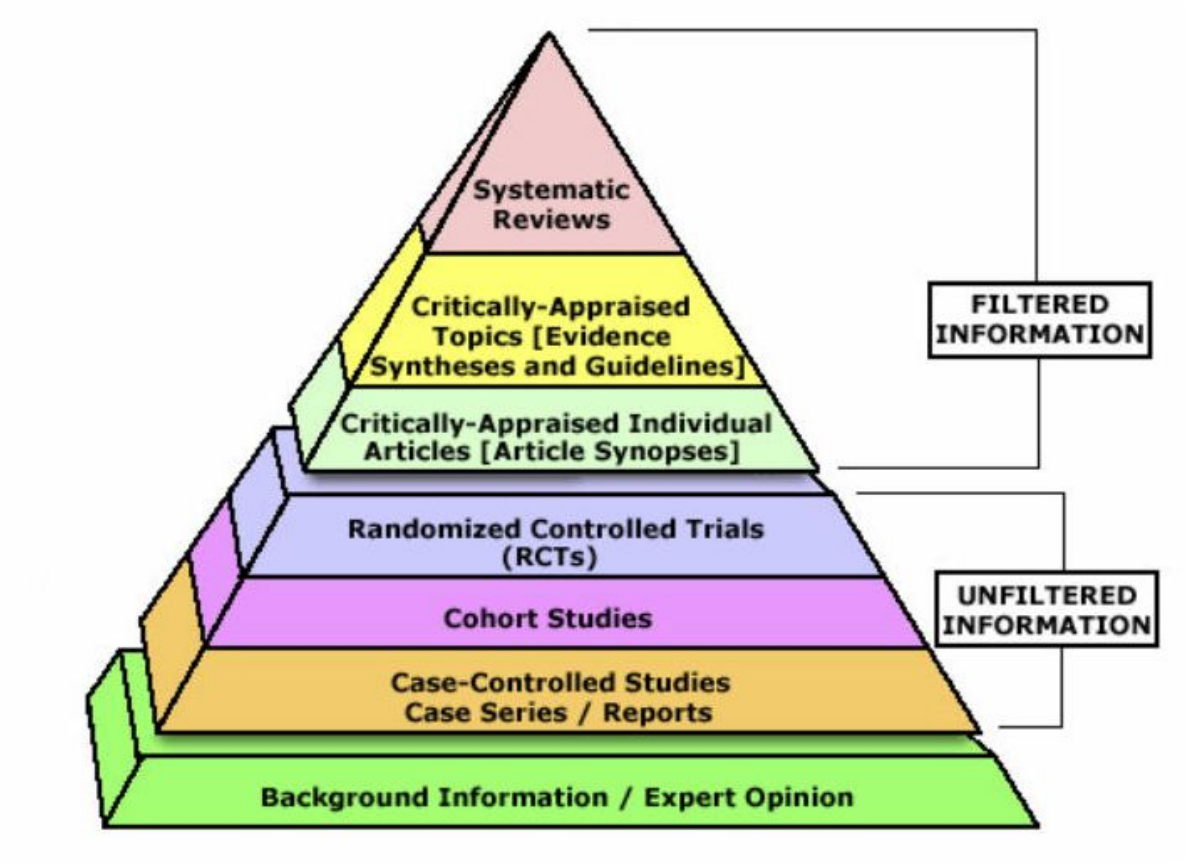

FIGURE 2: The Evidence-Based Medicine Pyramid (Minkow, 2014)

Most experts agree that the higher up the study design is positioned in the pyramid, the more rigorous the methodology and hence the more likely it is that the study design can minimise the effect of bias on the results of the study. (University of Canberra, 2018)

In the majority of these ‘evidence hierarchies’ used across the medical field, ‘expert opinion’ and ‘anecdotal evidence’ (which constitutes as the bottom level here) are at the bottom whilst ‘systematic reviews’ and ‘meta-analyses’ are at the top, giving a reliable baseline for evidence of the relatively lowest and highest quality.

We must also be careful to not confuse correlation with causation, as is a big problem with the study types listed in Figure 2. As emphasised by the Simpson's paradox, data is sometimes difficult to interpret, and therefore we can sometimes generate inaccurate conclusions from said data. A good example of this is shown below in Figure 3.

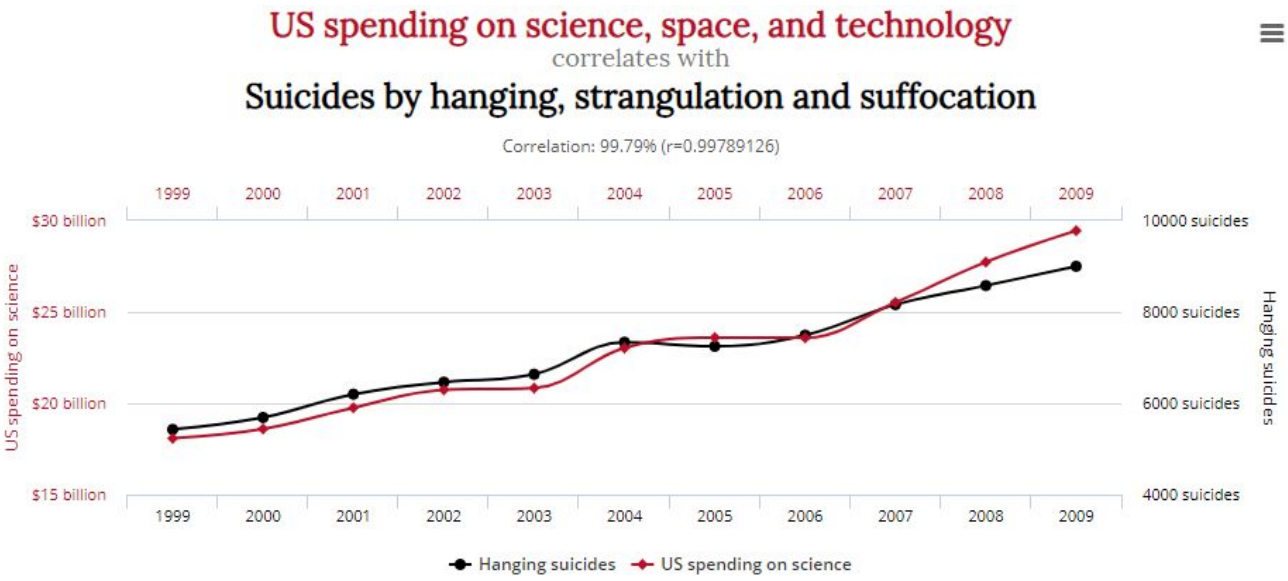

FIGURE 3 (Vigen, 2019)

The correlation of 99.79% identified is exceedingly high, but in this case the correlation is completely superficial and there is no causation. Making this judgement is more difficult when you are being presented with data that you believe fits your hypothesis, and you may end up concluding that X causes Y when there is no causation between the two at all. The evidence pyramid assists in negating many of these 'spurious correlations', as the studies at the top of the pyramid have rigorously analysed a large amount of data, although this does not mean that they are totally immune to this weakness.

Going back to the evidence pyramid, let's take the example of the Myers–Briggs Type Indicator, which is a common personality test (possibly the most widely administered) used to determine an individual's 'personality type' from 16 options, based on Jungian theories and archetypes. After taking a comprehensive assessment, the test will spit out 4 letters that inform you of your personality type (e.g. INTJ). You can then use this to discover your 'cognitive functions' (see Figure 4) and then to research ample amounts of - much of the time conflicting - information for your 'type', including generalised strengths, weaknesses, best career paths and even tips for romantic relationships.

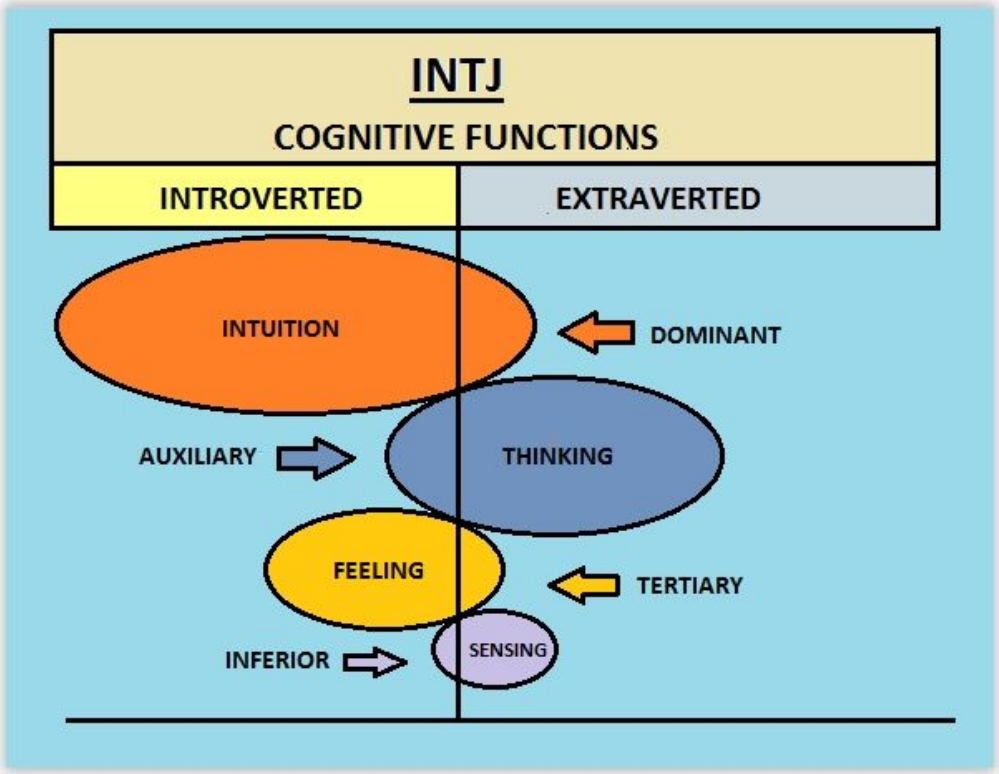

FIGURE 4: MBTI Cognitive Functions for the Personality Type 'INTJ' (Jaceris, 2016)

Conceptually, the idea of being able to research your personality extensively, and perhaps even discover things you didn't know about yourself, sounds incredible. Except when you realise that the MBTI tries to whittle down the 7.6 billion unique personalities spread across the planet into 16 measly categories. Is it possible that everybody in the world fits into these 16 distinct 'types'? As with drug formulation, we have a hypothesis, now in accordance with the scientific methodology evidence must be collected.

Although the aforementioned evidence pyramid is primarily used across the medical field, it can easily be translated into the world of psychology as the studies for collecting and collating evidence are essentially the same. Alternatively, personality typing could be considered as *directly* health-related, as it has been hypothesised that certain personality types are prone to destructive behaviours and mental illnesses (Storm, 2015). This allows us to directly compare the evidence collection for MBTI to drug formulation in order to determine the difference between the two.

There are countless meta-analyses and systematic reviews for studies around drug formulation merely a Google-search away, let alone hidden behind the obscurity of the industry. Whereas for MBTI, only one large meta-analysis has ever been undertaken (Capraro and Capraro, 2002), which while moderately successful, doesn't negate the fact that the overwhelmingly majority of evidence for MBTI is anecdotal. Not only is the idea of condensing all personalities into 16 categories counterintuitive, but also who's to say that the hundreds of MBTI tests that exist - including the 'official' one - are even accurate at *assigning* your 'personality type'.

As established by the pyramid, anecdotal evidence is the least effective at minimising bias, hence most of the conclusions made using this evidence have a high potential to be unreliable and inaccurate. Although the MBTI meta-analysis observed “variation”, it mostly followed the ‘scientific methodology’ set out at the start of this essay, and hence MBTI *could* be considered a science if studies like these continued in this field. The majority of evidence collected for drug formulation contrasts with the reliability and accuracy of the evidence collected for MBTI, highlighting a fundamental difference between the two fields of research.

One of the conclusions of this study was that the test-retest reliability of the MBTI assessment was between 57-81%, which while apparently is “quite good for psychometric assessments” (Thompson, 2013) (by convention a correlation of 70% is taken as a *minimum* for personality questionnaire scales), is objectively poor in terms of substantially ‘proving’ the reliability for MBTI. Nethertheless, the method used to determine this conclusion, as with the identification of the potential for refutability, would imply the study of MBTI to be considered a science, as is the same with drug formulation.

Rich Thompson, PhD, Director of Research, CPP claims that there are “thousands of peer-reviewed journals and case studies” that have been documented on the “validity and reliability” of MBTI, although it is unclear where to find all of these documents, as overall less than 90 are referenced in their “openly published information” section. A small cherry-picked sample of 10 case-controlled studies can also be found on The Myers-Briggs Company website (The Myers-Briggs Company, 2019).

It is also important to note that the view of CPP on MBTI is exceptionally simplistic and frankly wrong, as they literally do not consider ‘cognitive functions’, which are fundamental to the core principles of genuine MBTI.

This comparison of drug formulation with MBTI identifies one of the main differences between science and pseudoscience, which is merely the difference in the abundance of good quality evidence. Surely drug formulation is most definitely a science then? It fits the criteria for the scientific methodology *and* has plentiful amounts of good quality evidence. Unfortunately another question arises here; can drug formulation truly be considered a science if nutrition is not considered a science to the same degree?

This may sound ludicrous; drug formulation and *MBTI* are not interdependent, so why would the classification of drug formulation as a science depend on the classification of *nutrition* as a science? The problem lies in the fact that both of these ‘sciences’ are striving to achieve the same *overall* goal, while both following the scientific methodology with good quality evidence to support their conclusions.

The overall goal for the pharmaceutical industry is “to cure [patients], vaccinate them, or alleviate a symptom” (Bozenhardt, 2018), while in nutritional science (used here interchangeably with ‘nutrition’) focuses on “how diseases, conditions, and problems can be prevented or reduced with a healthy diet” (Nordqvist, 2017). These are essentially rephrasings for the optimisation of human health and the solving of particular health issues both before and after they arise.

There are countless misinformed articles shunning the scientific nature of nutrition, yet none whatsoever even fathoming the thought that drug formulation doesn't *at least* constitute as an applied science. There are many social, political and economic reasons why this is the case. Two of these include the constant exposure to conflicting information on nutrition which causes public distrust, and drug formulation being part of a large and heavily economically-driven pharmaceutical industry.

The global pharmaceutical industry was worth $934.8 billion in 2017 and is expected to reach around $1170 billion in 2021, growing at an annual rate of 5.8%. It is strange that, one of the largest industries in the world, relies heavily on the public's unawareness and misinformation of simple dietary interventions. It also comes down to the convenience of taking a drug over completely changing one's lifestyle, which compliments the misinformation that drugs have the ability cure everything.

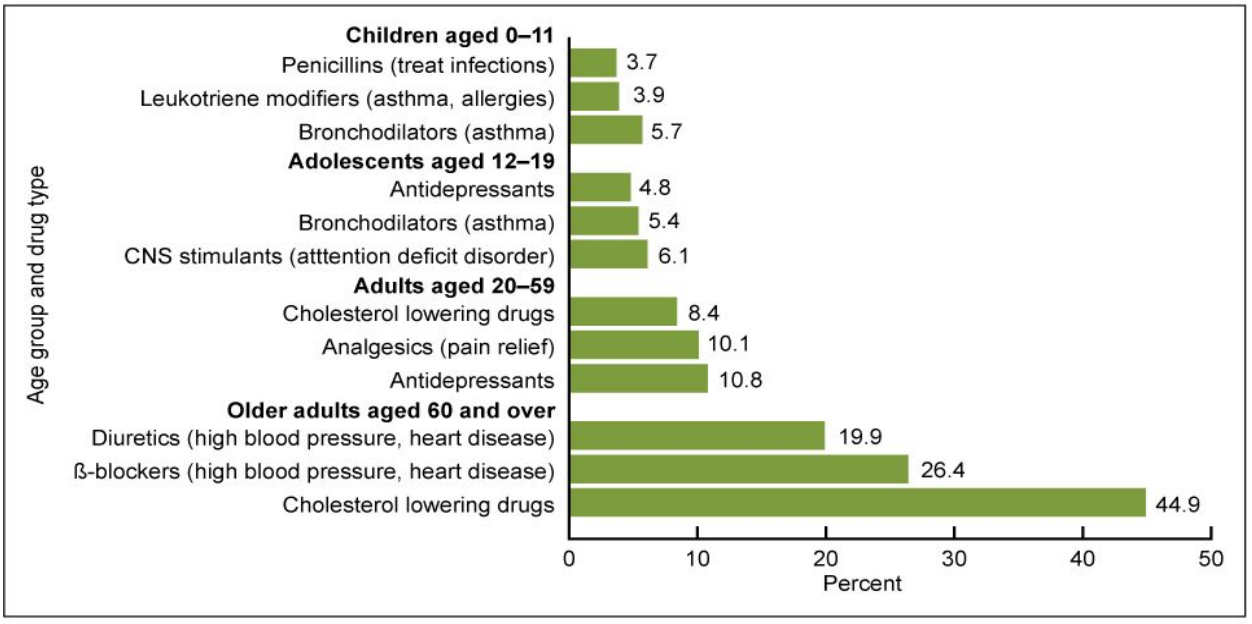

FIGURE 5: Percentage of prescription drugs used most often, by drug type and age group: United States, 2007-2008 (Gu, 2010)

Figure 5 above shows that an enormous 91.2% of adults aged 60 and over relied on drugs that treated symptoms of a poor diet and sedentary lifestyle in 2008. Although it has been proven time and time again in countless meta-analyses and systematic reviews (How Not To Die) that high cholesterol and blood pressure, especially at older ages, can be combated by sticking to a whole-food, plant-based diet and regular exercise, it seems that the drug market still has a rather tight grip on treatments for 'lifestyle-induced diseases'. It has even been speculated (rather generously) that up to 80% of chronic health issues could be reversed by improving and making changes to our lifestyles.

Dr Rhonda Patrick and Dr Michael Greger are two staunch advocates dedicated to spreading awareness on the paramount importance of diet and exercise on human health,

and both have completely accepted the idea that many diseases, especially type 2 diabetes, can be reversed with proper lifestyle interventions.

Obviously there are many chronic diseases and conditions which cannot simply be cured with a change in diet, but this does not mean that lifestyle interventions would not benefit the patient *at all*. Majoritively however, drug formulation is pivotal to the survival and improvements in quality of life for those suffering with 'non-lifestyle-induced diseases', and as such this essay is not in any way eschewing the usage and success of pharmaceuticals for this purpose. It is however, highlighting society's overdependence on drugs as a 'magic bullet', when simply paying 30 pence more for fruit and vegetables a day may reduce your all-cause mortality by 10% (Greger and Stone, 2018).

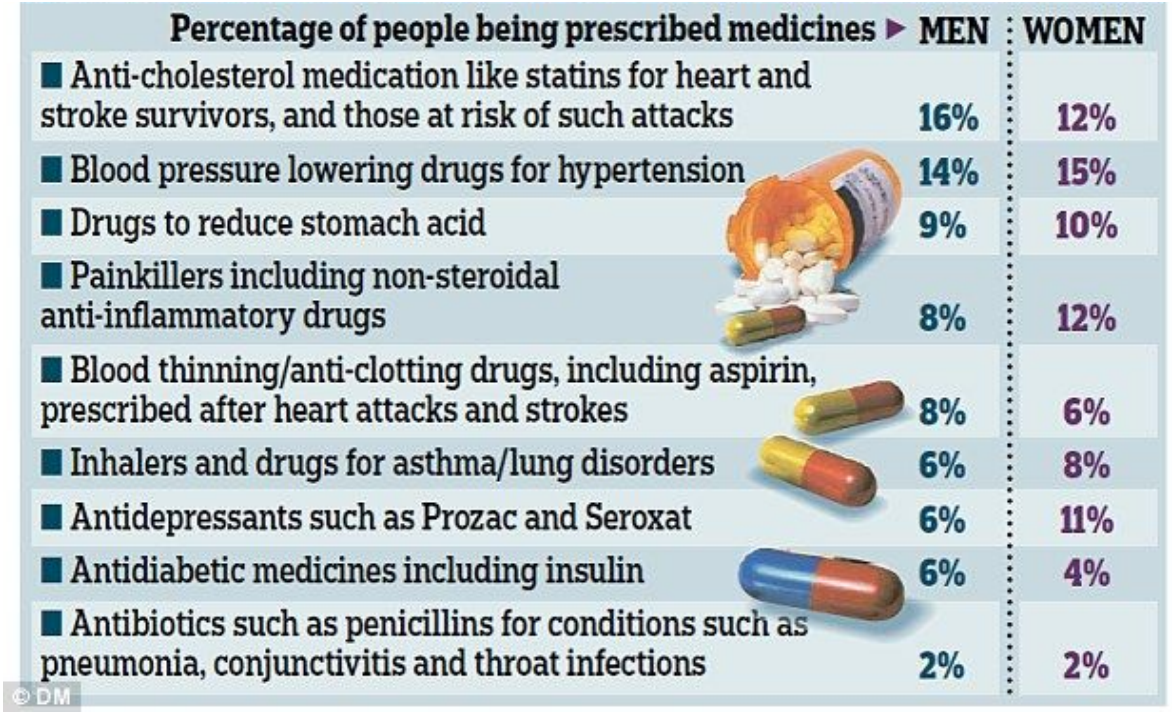

FIGURE 6: Percentage of prescription drugs used most often, by gender: United Kingdom, 2013 (Hope, 2014)

This UK study above (Figure 6) further confirms this, as at least between 37-44% of all prescribed medicine was used to treat CVD in 2013. Why is it then, that with there being such large amounts of research undertaken on the importance of diet for preventing and treating CVD, are such large numbers of the population resulting to pharmaceuticals to solve these problems other than due to convenience alone?

Perhaps one reason is due to the incentivisation for companies to prioritise drug formulation and pharmaceutical development over all other types of treatments (namely nutrition). This is driven by disgustingly large profit margins on pharmaceuticals (see Figure 7 below), which are still ridiculously high even after taking into account the moderately high development costs and time spent on development. This also leads to selective research, misinformation and cherry-picking becoming tactics to maximise sales (Goldacre, 2013).

In fact, “the [US] health care system runs on a fee-for-service model in which doctors get paid for the pills and procedures they prescribe” (Greger and Stone, 2018), which when considering the effect of simple lifestyle changes, is quite a crude and obviously economically-driven rather than health-driven model. It seems that the education system is also set up to compliment this model, as only a quarter of medical schools in the US offer a single dedicated course on nutrition.

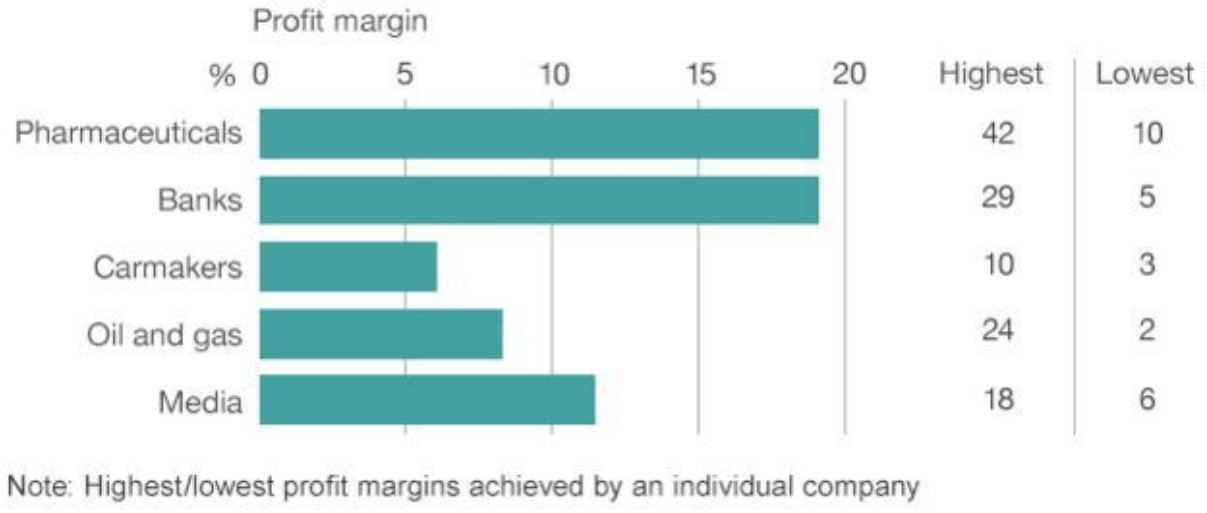

FIGURE 7: Average profit margins of five main industrial sectors, 2013 (Anderson, 2014)

Unfortunately, these ‘bad practices’ are not exclusive to the pharmaceutical industry, and even play a large role in modern nutrition and other industries. For example, CPP (the company that handles the MBTI testing) brings in roughly $20 million a year from MBTI and about 800 other products, such as coaching guides, that have developed from their ill-informed, distorted version of MBTI (Cunningham, 2012).

In the world of nutrition, the rapid growth of the dietary supplement industry has been somewhat alarming; the market is expected to reach $278.02 billion by 2024. Although 93%, 97% and 98% of Americans are deficient in Vitamin E, fibre and potassium respectively, little evidence has been shown for the effectiveness of providing vitamins and minerals *without* their whole-food counterparts. The little data that *has* been collected has also been subjected to ‘bad practices’, the main one being the application of *in vitro* and animal models to humans, irrespective of their untested real-world effects.

We require vitamins and minerals (micronutrients) in small amounts for the normal and healthy functioning of the human body, and regrettably the Western diet, especially the Standard American Diet (SAD), contains an abundance of processed foods which contain little to no micronutrient content. Three in four Americans do not even eat a *single* piece of fruit in a given day, with almost 9 out of 10 not meeting the *minimum* recommended intake of vegetables (no wonder the leading cause of death in the US is coronary heart disease). This data is easily transcribed to other Western populations including the UK, and this is where the supplement industry comes in.

Taking vitamins and minerals as supplements, especially multivitamins, has been shown to have relatively little effect, specifically in relation to eating whole-foods (i.e. unprocessed

fruits or vegetables) that contains the same amount of the desired micronutrient. This is because whole-foods are extremely complex in their molecular makeup, and contain other essential substances required for the successful absorption of specific micronutrients, which are not found in supplements. Specific supplements, such as Vitamin D_3, has been shown to improve the health of people living in areas of high latitudes, but generally it is best to obtain your micronutrients through a whole-food plant-based diet.

This is not necessarily an attack on the application of scientific methodology behind nutritional science or drug formulation, but it is a suggestion that there are alternative, perhaps cheaper and easier, interventions that can be used to improve health, which the majority of the public are scarily unaware of.

Does this truly matter though? After all, drug formulation and nutrition can equally be considered sciences according the generally universal criteria set out, the public's view on other sciences, and even ethics, should not be taken into consideration when determining simply whether something is a science or whether something is not a science.

Even if you consider the pharmaceutical industry as merely a business that exploits science and research in order to maximise profits, the fundamental data and evidence collected on drug formulation *does* follow the scientific method, and as such it *is* a science. This does not necessarily mean the conclusions made are 'good', in fact it begs the question of 'is all science impartial?'.

All in all, science comes down to the pursuit of knowledge, irrespective of how this knowledge will be used; it is irrelevant if the information gained will be used 'ethically' or not, and most of the time it can be used for both. Therefore the application of knowledge gained does not belittle what theories are defined as a 'science'.

There is one more thing that we have failed to acknowledge thus far, which is that 'drug formulation' eccompasses the ability for the drug to be taken by the patient. This means that the form in which the drug is in (i.e. solid or liquid) and the administration route (i.e. oral, topical, parenteral etc.) must be acceptable for the patient, and it therefore must be as aesthetically pleasing as possible to encourage compliance. For example, the production of a drug in liquid form would encourage the compliance of a young child to take the drug orally, while this would also be useful for those who dislike taking drugs in a solid tablet form.

Gregory Poon PhD defines 'pharmaceuticals' as "the art and applied science of dosage form design" (Poon, 2005), and the definition for drug formulation also includes this reliance on design and art. Although an interesting point, it does not detract from the scientific nature of drug formulation. In actuality, the compliance of patients, dependent on the form of the drug, could easily be subjected to the 'scientific methodology' and a study carried out on how patients responded to the different forms.

While you could argue that the difference between science and art is that they are objective and subjective respectively, it is not difficult to design the most appropriate form of drug

based on enough quality evidence obtained through scientific studies carried out in accordance with the scientific methodology.

In conclusion, ‘drug formulation’ is a science; it aims to pursue and apply knowledge for the benefit of humankind while following a systematic methodology based on evidence, and it coincides with Popper’s ideas on falsification and other generally accepted criteria of science. The ethical implications of drug formulation in the wider context of the pharmaceutical industry, while not directly associated with its definition as a science, must be cautiously observed so that they do not interfere with the authentic purpose of drug formulation.

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