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HealthSense

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HealthSense Newsletter

for Science and Integrity in Healthcare

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News

"Designed to fail": HealthSense talks to *BMJ* on govt's consultation on doctors' interests

At last, the UK government is getting around to considering legislation to force manufacturers and commercial suppliers of drugs and medical devices to report what they are paying to health care professionals. But is their proposal any good? The *British Medical Journal* asked HealthSense what we thought of the government's public consultation, and we didn't hold back.

In *The BMJ*'s 7 September issue, news reporter Jacqui Wise reported: "Roger Fisken, chair of HealthSense, a UK charity that promotes evidence and integrity in healthcare, said he was disappointed that it had taken more than three years since the Cumberlege review to get to a public consultation and that the plan as described was 'designed to fail.'"

"Instead of a central GMC register, as called for by the Independent Medicines and Medical Devices Safety Review, the government's proposal is for individual healthcare units to publish their own. We believe this will be difficult for patients to navigate and impossible to regulate," he told *The BMJ*. "We are also concerned that there seems to be no mention of the relevant professional bodies, such as the GMC, having any responsibility to record or oversee the payments that have been made to individual practitioners.

"This is really important. There is clear evidence that payments from the pharma and medical device industries influence health professionals, which is why companies do it. Patients need to know their treatment is based on best evidence and not on who is paying their doctor."

Reference

1. Wise J. Government consults on legislation to disclose industry payments to doctors. BMJ 2023; 382: p2049

News in brief

Our News in Brief section features latest achievements and news from our brilliant volunteers, and opportunities to get involved. Let us know what you are doing to promote good science and integrity in healthcare by emailing newsletter@healthsense-uk.org

Fertility regulator addresses concerns with new ratings system

Fertility clinics must now give clear information on costs and success rates of "add-on" treatments, says the fertility regulator HFEA, which has acted decisively on concerns over clinics offering unproven treatments costing hundreds or even thousands of pounds. A new HFEA ratings system has been introduced to help those buying private fertility treatment make evidence-based decisions and avoid unnecessary costs.

Fertility treatment "add-ons" are optional, non-essential, treatments that many private clinics offer in addition to proven fertility treatments. But they don't always improve chances of having a baby. The new HFEA ratings system uses five colours – ranging from

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green to red – to indicate the amount of evidence there is that an add-on is effective at improving the chances of having a baby. None of those listed on the HFEA website earned a green rating.

We are pleased to say that HealthSense played a part in this campaign, through our contribution to the Competition and Markets Authority's consultation on the regulation of fertility clinics.

Clampdown on unproven fertility treatment add-ons. BBC News, 19 Oct 2023

Are you getting your HealthSense emails?

If you think HealthSense has been unusually quiet recently, it could be that you're not receiving our e-mails.

In recent weeks we've done some housekeeping on our mailing list to update contacts we know have changed, and remove duplicates and ones that bounce.

If you are not getting our emails – such as the ones we sent on 5 and 14 of October – please first check your spam folder. If you are definitely not receiving our news please let Alan Henness know your correct email address by writing to him on membership@healthsense-uk.org and he will make sure it is on the list.

Some members choose to opt out from getting our messages – that's fine, and if you get unwanted emails from us please contact Alan so he can put it right.

Macchiarini's two *Lancet* papers finally retracted after being assessed as "fraudulent" by misconduct board

The Lancet has retracted two contentious papers on research by the disgraced surgeon Paolo Macchiarini, who was imprisoned earlier this year for gross assault against three patients on whom he tested synthetic tracheae despite knowing that his experimental technique was problematical. All three patients died when the implants failed.

For years campaigners have called on *The Lancet* to remove Macchiarini's highly cited papers from the public record in the interests of patient safety. The journal finally took action in their 28 October issue, after Sweden's National Board for Assessment of Research Misconduct concluded an investigation that Macchiarani and his colleagues' papers published in 2008 and 2014, describing surgical transplantation of a tissue-engineered trachea, contained falsifications and fabrications.

While welcoming the news, cardiologist and campaigner Dr Peter Wilmshurst pointed out: "It has been more than five years since *The Lancet* received irrefutable evidence of the original paper's false claims. This has harmed the journal's reputation for correcting the scientific record. In the meantime, patients have died and Macchiarini's collaborators have been awarded massive grants from public funds to extend the research in this flawed technology."

Editors of The Lancet. Retractions. Lancet 2023; 402(10412): 1510

Drugmaker tactics: talking with "Sick Money" author

Scandalous revelations on drug pricing were the topic of a recent seminar from our partner organisation Consilium Scientific. The interviewee on 19 October was Billy Kenber, an investigative journalist for *The Times*. His 2021 book "Sick Money: The Truth About the Global Pharmaceutical Industry" was the result of ten years of meticulous investigation. It is a white-knuckle ride through a series of shocking stories about the pricing tactics of the drug industry. The one-hour Consilium seminar is titled "High prices and dirty tricks: The evolution of the pharmaceutical industry". Find links to recordings, slides and transcripts of Consilium's latest recordings here, and for a taster of Kenber's book, read Till Bruckner's review for our last winter's newsletter, (no.121).

Prize-winning journalists collaborate to fact-check ZOE

At £24.99 a month, plus a whopping £299.99 for the "intro kit", is the highly-promoted new ZOE nutrition system worth the money? Or is it just an expensive way to be reminded to eat more fruit and veg? Medical reporter Deborah Cohen and GP broadcaster Margaret McCartney, both past HealthSense Award winners, have looked into the evidence for the online publication *UnHerd*.

Devised by genetic epidemiologist Tim Spector of Kings College London, ZOE uses blood glucose monitors and gut microbiome analysis from stool samples to create a personalised nutrition plan, claimed to boost energy levels, improve sleep, and help weight control. But in "We need to talk about ZOE", Cohen and McCartney explain why they are not convinced by evidence that ZOE's personalised plans could be any better than standard diet and lifestyle advice. Their half-hour UnHerd documentary, "Special Investigation: How scientific is the Zoe app?" is free to watch on YouTube.

Cohen D, McCartney M. We need to talk about ZOE. UnHerd, 12 Oct 2023 (subscription needed, introductory offer available)

WHO's "potentially disastrous" move on alternative medicines

In our summer issue we reported that the World Health Organization has been criticized for its moves to help countries integrate alternative therapies into their health systems (see under News in Brief, issue 123). Now subscribers to *New Scientist* can read science writer Clare Wilson explain her concerns over the potential for harm.

While agreeing that citizens should be able to use such therapies if they wish, she argues: "they should be able to make fully informed decisions that are based on genuine evidence about the risks and benefits of any therapy. The problem is that those who profit from complementary medicines generally haven't carried out the research to provide such evidence." While

welcoming the WHO's stated commitment to developing the scientific base to support the use of such therapies, she says: "the WHO's messaging so far doesn't inspire confidence that this will be done in an appropriately impartial way."

Wilson's article includes a quote from past HealthSense Award winner Edzard Ernst, who calls WHO's position an "odd and potentially disastrous" move.

Wilson C. We need evidence about the risks and benefits of alternative medicines. 6 Sept 2023 (subscription required)

New documentary series: psychiatry, drugs and vaccines

A new independent series of online documentaries examines the current crises in our medical and scientific publishing systems.

Our 2016 HealthSense Award Winner, emeritus professor Peter C Gøtzsche, is the host of "Broken Medical Science", a series from the Institute for Scientific Freedom, which he founded. In each programme Gøtzsche interviews researchers, science journalists, consumer advocates on topics including psychiatric drugs, facemask mandates, and the complexity of vaccine science. The professionally-filmed one-hour programmes are free to view, carry no ads, and are funded by the programme makers and supporters' donations.

Call for action over unreliable private online hormone tests

A large private laboratory is still processing finger prick tests for oestrogen levels, which are sold by private retailers online for up to £180, despite warnings they are unreliable, according to a *BMJ* investigation.

Test results that are misinterpreted or misleading could have long-term implications for women's life choices and decision making if they are led to believe that they are more or less fertile. There is also potential for a knock-on effect on overstretched NHS services.

The report raises questions about the validation and regulation of online tests and laboratories. There is currently no system for robustly assessing whether new tests, or new instances of existing tests, work. Similarly, the UK has no regulator of laboratories, whether private or NHS. The field of home testing kits is progressing rapidly but it appears the regulation of online tests and laboratories is lagging well behind.

Wilkinson E. Investigation: Call for action over unreliable private online hormone tests. BMJ 2023; 382: p1898

Workshop on corruption and conflicts of interest in healthcare

Corruption and lobbying divert limited resources from healthcare, and that impacts patients' welfare. A three-day workshop in London this January will discuss issues such as pharma lobbying, transparency, anti-corruption measures and how to measure corruption and its effects.

Early-career researchers in fields ranging from economics and political science to public health and sociology will discuss their work in a constructive and informal setting. Organised by the Young Scholars Initiative, the workshop will be held at the London School of Economics, 12-14 January 2024. Apply here.

Popular decongestant doesn't work, says US FDA

Phenylephrine, an ingredient used in hundreds of over-the-counter cold, flu and allergy remedies, is ineffective for the relief of nasal congestion, says a committee of the US Food and Drug Administration (FDA).

It is possible now that the FDA may remove phenylephrine from its list of drugs generally recognised as being safe and effective. This would have consequences for a vast market – annual sales of products containing phenylephedrine total $1.76bn in the US. In the UK, phenylephrine appears in preparations marketed under household names such as Benylin and Lemsip, as well as many own brand cold and flu relief remedies.

There have been questions over the drug's efficacy going back to the 1990s. It is now thought that when the drug is included in oral preparations it is mainly destroyed in the stomach.

Hopkins Tanne J. Phenylephrine: Commonly used decongestant in cold and flu remedies doesn't work, says FDA. BMJ 2023; 382: p2124

Media

Screening study triggers UK press coverage

By Mandy Payne

When a US journal published a study recently that seemed to contradict the mantra "screening saves lives", some UK newspapers seized on the story, but their message was not always clear.

An international group led by Michael Bretthauer of the Clinical Effectiveness Research Group at the University of Oslo, Norway had analysed the results of randomised controlled trials of 6 common cancer screening tests, involving 2.1 million individuals, over a 9-year period. Their study was unusual because it looked at screening outcomes in relation to deaths from *all* causes, not just from the cancer being screened for.

Their analysis, published in *JAMA Internal Medicine* this August, concluded "current evidence does not substantiate the claim that common cancer screening tests save lives by extending lifetime, except possibly for colorectal cancer screening with sigmoidoscopy."

Even though many screening tests have the potential to prevent some deaths from the cancer they screen for, they can in themselves result in early deaths from other causes, for example, from the side-effects of treatments. The balance between a screening

test's *positive* effect on reducing cancer deaths, and *negative* effect of causing other deaths, varies for different types of screening and can be delicate.

For breast cancer screening by mammography, the team reported a mean impact on life expectancy of precisely zero.

Threat to powerful stakeholders

In a linked Viewpoint article, Bretthauer and colleagues noted that discussions about cancer screening tests are a challenge because the "delicate balance of benefits and harms have become a threat to powerful stakeholders". Conflicts of interest have, they said, made it "difficult or indeed impossible to phase out screening programs, even when research has failed to document significant benefits."

The Guardian's article by Linda Geddes gave a balanced, informative report. Research leader Michael Bretthauer was quoted as saying: "I think organisations, institutions and policymakers who promote cancer screening tests as saving lives should probably be a little bit more careful with that message in future."

Unfortunately, the article on *Mail Online* presented a rather confusing message, starting from the headline: "Most cancer screenings 'do not extend someone's life expectancy' claims review of more than 2 million patients – but early testing DOES reduce risk of dying from cancer".

What is an appropriate outcome?

HealthSense's chair Roger Fisken commented, "The problem with the [*Mail*'s] report is the old one of failing to understand what constitutes an appropriate outcome: the piece says: "this doesn't mean you should cancel that mammogram or other screening appointment because other data has shown that screening does reduce the risk of dying from cancer". But drinking strychnine reduces your risk of dying from cancer because you die of the strychnine poisoning first - why is it so hard for people to understand that it's all-cause mortality and the screening-associated morbidity that matters?

Dr Fisken has written to the UK government's Department of Health and Social Care with a proposal for a system for archiving and retiring screening programmes that evidence has determined as obsolete. We'll let you know how that goes.

Mandy Payne
HealthSense Newsletter Editor, Pembroke Dock, Wales, UK

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3. Geddes L. Some cancer screening tests may not extend lifespans, study finds. The Guardian, 28 Aug 2023
4. Lardieri A. Most cancer screenings 'do not extend someone's life expectancy' claims review of more than 2 million patients – but early testing DOES reduce risk of dying from cancer. Mail Online, 28 Aug 2023

Obituary

Ronald Bradley – pioneer of evidence-based intensive care

By John Illman

Ronald Bradley, the UK's first professor of intensive care, is widely credited with developing the world's first mobile intensive care unit in the 1960s. But his then senior registrar, Dr Margaret Branthwaite, said: "It was actually a mobile intensive diagnostic unit."

Bradley's emphasis on diagnosis and underlying pathology introduced an evidence base into intensive care. The field had been largely synonymous with ventilation after the 1952 polio pandemic when patients in Copenhagen were hand-ventilated, in some cases for weeks, by hundreds of medical and dental students.

Branthwaite and Bradley were dubbed 'The Death Watch Beetles' as they trundled the unit from bedside to bedside at St Thomas Hospital, London because mortality rates among their critically-ill patients were inevitably high. The 'unit' was a vast, lumbering trolley full of equipment for catheterisation and blood gas analysis.

As a young researcher Bradley had an inspiring, visionary boss with a reputation as a talent spotter. When Professor Edward Peter Sharpey-Schafaer asked Bradley what he wanted to do, he replied that he wanted to explore the pathophysiology of circulatory collapse.

Bradley recalled: "Schafer rubbed the side of his nose, I remember, and there was a long, long pause. At the end of it he said:'Take three years and see what you can do.'

"So I found myself sawing up lengths of steel tubing and making a scaffolding and putting wheels on the bottom of it so that we could take four pressure heads, a set of gas electrodes and an ECG and a recorder on which you could write the pressure records and everything else that came out.

"One rather important bit of the kit was a centrifuge so that you could tell what the haematocrit (erythrocyte volume fraction) was doing. All that was on wheels and we went anywhere there was trouble".

History has not always given Bradley his due credit. What should have been called the 'Bradley-Branthwaite catheter' became known as the 'Swan-Ganz catheter' — after William Ganz, the Slovakian-born American cardiologist, and Jeremy Swan, the Irish cardiologist and former president of the American College of Cardiology.

Dr Peter Wilmshurst, Bradley's senior registrar (1983-87) and recipient of HealthSense's 2003 award for his 'dogged pursuit of truth', dismissed the perception that Ganz and Swan originated flow-directed pulmonary artery catheterisation to measure pressure and cardiac output. He said: "They publicised

the value of their technique, but their intellectual contribution was minor. They combined in one catheter the idea of two other groups."

Writing in *The Lancet* in 1997, Wilmshurst, said: "Bradley was the first to use light flexible flow-directed catheters in man, through which right heart pressures could be measured and used to position the catheter tip without the need for fluoroscopy."

Along with Branthwaite, Bradley was also the first to perform thermodilution cardiac output measurements in healthy volunteers and critically-ill patients with a flow-directed thermistor-tipped catheter positioned in the pulmonary artery by observation of lumenal pressure.

Margaret Branthwaite explained the background behind the catheter's naming at a meeting about the history of intensive care in Britain at the Wellcome Trust Centre in 2010.

Recalling a meeting between Swan and Bradley in the UK, she explained: "As he left, he asked that we should send him the details of the technique. I was the scribe who typed out in immense detail on a very old manual typewriter with a very grey ribbon, how we made our own thermal dilution catheters. The letter was sent, and as far as I know it was received, but unfortunately it was never acknowledged.

"It was with some sorrow that shortly afterwards – within a year I think – we saw the publication of a notice of this spectacular new device – the Swan-Ganz catheter – which not only allowed you to measure the pulmonary artery pressure, but also allowed you to calculate and measure the cardiac output as well. Sadly credit was not given where credit was due: that is to Ron."

Bradley combined diagnostic acumen and logic with clinical observation. Braithwaite recalled how he became able to predict the likely pathophysiology of a patient without needing to make measurements.

In 1966 the purpose-built Mead Ward at St Thomas became the UK's first ICU and Bradley reputedly became the only UK intensive care professor with a bed in his office. He didn't like to leave the unit at especially critical times or in the hands of a newly arrived SHO.

Wilmshurst said: "Ron was an excellent role model as well as a fantastic teacher. He wasn't one of those people who gave out a lot of work and then cleared off at 4.30pm. He'd be there until nine and sometimes a lot later. You didn't mind working late for someone like that".

Sir Richard Thompson, former President of the Royal College of Physicians and a member of the Medical Household of Elizabeth II, said: "He was a fantastic physician — a pioneer who worked incredibly hard without due recognition. He was never a self-publicist."

Ronald Bradley (1929-2023)

John Illman
Medical journalist and author, London

Opinion

Communicating benefits and harms of anti-cancer drugs ... and the rest

By Mandy Payne, Susan Bewley and Mark Wilson

A recent *British Medical Journal* editorial: "Communicating the benefits and harms of anticancer drugs" (1) reported on the results of an important (2) study of information about new cancer drugs.

An international team led by Courtney Davis of King's College, London, had analysed the information available to patients about drugs recently authorized in Europe for the treatment of cancer.

Davis et al had found – no surprise to us – that the patient-directed information lacked important details needed to enable them to make informed decisions, including how their anticancer drug had been evaluated, key findings from research studies, and the benefits expected from treatment.

In its praise of the study, the *BMJ* editorial noted: "The trust between patients and healthcare providers remains pivotal in ensuring that patients are fully informed about benefits and harms of drugs. But regulatory agencies should pay closer attention to important gaps in information for patients, and further research should aim to determine more precisely where these gaps occur and to work with patients to fill them."

Quite right. Davis and colleagues have identified a health information gap whose persistence does not bode well for cancer patients.

But preceding the editorialists' conclusion is a stranger sentence: "Whether Davis and colleagues' findings extend to non-cancer treatments remains unclear."

Unclear? Really? The editorialists who are not oncologists might feel restrained to 'stay in lane', but they must surely have access to previous *BMJ* issues. In recent years the journal has uncovered many scandals where information that should be presented to the public regarding harms from drugs or medical interventions and devices, has been obscured or suppressed by the powers-that-be. Deborah Cohen's fearless reporting of hip implant scandals springs to mind, (3) along with the *BMJ's* news reports of Julia Cumberlege and Cyril Chantler's independent review of the grievous harms from the pregnancy test drug Primodos, epilepsy drug sodium valproate, and pelvic mesh used to treat urinary incontinence. (4)

There has been no shortage in the *BMJ* of reports of information inequalities that favour commercial interests at the expense of the public interest and welfare, and neither has the journal shied from highlighting regulatory agencies' complicity where found. (5) And on the other side of the pond concerns over an information inequality that negatively impacts

patients has been the central theme of a recent book by an American physician on US health care. (6) The issue crosses national borders and involves a wide cross section of medicine in both the UK and US that has been discussed in the *BMJ*. (5)

Readers would have been better informed about the context had the editorialists who commented on Davis and colleagues' research engaged with the history of a well-documented information inequality that has disadvantaged the public in many areas of medicine. It's important to not let an historical amnesia set in on these issues and become part of, and nourish, an unacceptable status quo.

Mandy Payne, editor, HealthSense Newsletter
Susan Bewley, emeritus professor of obstetrics and womens' health, King's College London, London, UK
Mark Wilson, bioethicist, Guelph, Ontario, Canada

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Nutrition

Ultra-processed foods – a new demon?

By David Bender

In 1992 the *Health of the Nation* report by the UK Department of Health (1) noted the high prevalence of obesity, 6-8%, and set a target to halve it within a decade. Ten years later the prevalence of obesity had *doubled*, and has continued to increase to the present 30%.

In 2016, as part of investigations into a similarly rapid increase in the prevalence of obesity in Brazil, Monteiro et al (2) published a classification of foods according to the degree of processing involved. They coined the term NOVA for the classification – this is a name, not an acronym.

What Monteiro *et al* observed was that obesity was linked to the consumption of foods high in sugar, fat and salt, all of which are highly palatable, energy dense (i.e., high in calories), relatively poor in nutrients and relatively low in satiety value, so that it is easy to eat too much of them. This was perhaps an unsurprising finding – we all know that such foods are easy to over-eat and make you put on weight. However, the Monteiro classification of foods into four groups caught the popular imagination, and the idea of ultra-processed foods as a new demon caught on.

The NOVA classification (2) is as follows:

Minimally processed foods. These may have been dried, frozen, ground, fermented (as in pickling and bread making) or pasteurised, but retain their nutrient and fibre content.

Processed culinary ingredients. These are ingredients likely to be used in domestic and restaurant food preparation that have been produced by extraction and purification from unprocessed foodstuffs; examples include oils and fats, sugar, honey, starch and salt.

Processed foods. These are produced by combining two or more food products from the previous two groups, with further processing such as cooking, smoking, non-alcoholic fermentation and packaging. (It is unclear why packaging is included here, but many, or most, foods in this group will be manufactured rather than produced at home. Of course, packaged foods will have lists of ingredients, including additives, on the label, and in many countries also front-of-package (e.g., traffic light) labelling showing if they are high in fat, sugar and salt.

Ultra-processed foods. This was the group that caught public imagination; a wide range of foods considered undesirable because of their high content of fat, sugar, salt. In addition they may contain ingredients used in industrial manufacture of foods, that are unlikely to be found in a domestic kitchen, such as preservatives, flavours, colours, hydrolysed protein, high-fructose syrup, emulsifiers, thickeners, gelling agents, etc.

Monteiro et al (2) described ultra-processed foods as:

- Industrial formulations typically with five or more and usually many ingredients (but my home-made stew probably contains more than five ingredients, and curry certainly does).
- Include substances not commonly used in home culinary preparations, and additives whose purpose is to imitate sensory qualities … or disguise undesirable sensory qualities of the final product.
- Substances only found in ultra-processed products include some directly extracted from foods, such as casein, lactose, whey, and gluten, and some derived from further processing of food constituents, such as hydrogenated or inter-esterified oils, hydrolysed proteins, soy protein isolate, maltodextrin, invert sugar and high fructose corn syrup. (Note that, apart from hydrogenated oils – a source of undesirable *trans*-fats – and the last three, none of these ingredients is in itself undesirable).
- Classes of additive said only to be found in ultra-processed products include dyes and other colours (I have some food colours in my kitchen, although I rarely use them), colour stabilisers, flavours (I have almond, orange and lemon essences, as well as spices and herbs in my kitchen, and use them as appropriate), flavour enhancers, non-sugar sweeteners

(I use stevia extract in place of sugar in some dishes), and processing aids such as carbonating (I use baking powder in some dishes, self-raising flour in others), firming, bulking and anti-bulking, de-foaming, anti-caking and glazing agents, emulsifiers, sequestrants and humectants.

- Common attributes of ultra-processed products are hyper-palatability, sophisticated and attractive packaging, multi-media and other aggressive marketing to children and adolescents, health claims, high profitability, and branding and ownership by transnational corporations (here I detect a hint of disapproval of transnational corporations that make a profit from selling food).

The UK Scientific Advisory Committee on Nutrition, SACN (3) published this summer lists ways in which ultra-processed foods (UPF) may be associated with obesity and other adverse health outcomes:

- high palatability
- high energy density
- promotion of a faster eating rate – for example, due to softer texture or other changes in the food structure or matrix
- differences in nutrient content – such as high (saturated) fat, salt or free sugars alongside low fibre content
- effects of high temperature in the production of processed foods
- effects of specific additives, including low or no calorie sweeteners
- contaminants from packaging
- higher consumption due to widespread marketing and lower cost of processed foods

The SACN report notes that "The UPF category captures a wide range of foods, including many which other approaches to dietary assessment also typically classify as less 'healthy', such as soft drinks, sweet and savoury packaged snacks, confectionery, mass-produced and/or packaged bakery items and pre-prepared meals. However, the category also captures products that other approaches to dietary assessment may classify as 'healthier' such as fortified foods, low fat yogurts, vegetable sauces and higher fibre breakfast cereals. The classification groups food and food ingredients into four categories based on their level of processing and not their energy or nutrient content. Foods typically considered 'unhealthy' are commonly classified as UPF, however, some foods typically considered 'healthier' may also fall within the UPF group."

The SACN report concluded:

"Diets high in (ultra-) processed foods are often energy dense; high in saturated fat, salt or free sugars; high in processed meat; and/or low in fruit and vegetables and fibre.

It is unclear to what extent observed associations between (ultra-) processed foods and adverse health outcomes are explained by established relationships between nutritional factors and health outcomes."

Examples given of ultra-processed foods include:

Sweetened carbonated drinks (so no tonic water with the gin?) But surely the potential for harm in such drinks depends on whether they contain sugar or high-fructose corn syrups – clearly undesirable – or non-caloric sweeteners. So-called energy drinks probably belong in this category – many are also high in caffeine; but not all contain sugar or high-fructose corn syrup.

Sweet or savoury packaged snacks, ice cream, chocolate, confectionery (what spoilsports they are! But yes, we concur that these should be limited to being occasional treats).

Mass-produced packaged breads and buns – but let's not forget that white bread in the UK is subject to mandatory, and beneficial, fortification with calcium, iron, thiamine and niacin. Also desirable is the permissive use of flour improvers for wholemeal bread. Before additives were permitted, eating wholemeal bread was a penance to be endured in the hope of improving gut health. Anti-staling agents that extend the shelf-life of bread reduce waste – surely another highly desirable aim.

Margarines and spreads – even though these can help reduce total and saturated fat intake, and some are fortified with plant sterols and stanols that proven to lower whole body cholesterol.

Cookies (biscuits), pastries, cakes, and cake mixes (again, spoilsports, but we agree it is healthier to eat less of this category too).

Breakfast cereals – while I agree that *some* are high or very high in sugar, most are not, and are a source of fibre, slowly digested starch, protein and many are fortified with vitamins and minerals. In any case, apart from the most highly sugared, the amount of sugar added at the table to non-sweetened breakfast cereals is probably similar to that in the pre-sweetened. In addition, the milk poured over them is a valuable source of nutrients.

Cereal and energy bars are often high in sugar and fat, but they can also a helpful source of fibre.

Milk drinks, fruit yoghurts and fruit drinks, cocoa drinks: here you need to read the label – some may well be high in sugar or high-fructose corn syrup, others are not.

Meat and chicken extracts and instant sauces are presumably gravy mixes; they may be high in salt, but I detect a hint of puritanism here and a degree of snobbism about people who do not make 'proper' gravy.

Infant formulas, follow-on milks, other baby products – is this puritanism too? Many will be necessary or desirable.

Health and slimming products such as powdered or fortified meal and dish substitutes; and many ready-to-heat products including pre-prepared pies and pasta and pizza dishes; poultry and fish 'nuggets' and 'sticks',

sausages, burgers, hot dogs, and other reconstituted meat products, and powdered and packaged 'instant' soups, noodles and desserts. Some are indeed higher in fat and salt than is desirable, but many are good sources of protein, vitamins and minerals. Fortified meal and dish substitutes sold as low calorie slimming aids can help with weight loss, and in any case surely this classification was concerned with foods that *promote* obesity! Again we detect the whiff of condemnation of those who do not prepare a meal from scratch every day.

Alcohol, such as whisky, gin, rum and vodka (spoilsports again! But we already have established guidelines for appropriate levels of alcohol intake. Why are wine, beer and cider not included here? Brandy has undergone one further processing step from wine, but contains fewer ingredients!)

In conclusion, I believe the term 'ultra-processed foods' is probably unhelpful; it is a rather sloppy shorthand that does indeed include many foods that are undesirably high in sugar, fat and salt, but also many that are not 'unhealthy' and are valuable sources of nutrients.

David A Bender
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Book review

When lawyers pay scientists to join a billion-dollar fight over medical evidence

By Till Bruckner

"Toxic Exposure: The True Story behind the Monsanto Trials and the Search for Justice" by Chadhi Nabhan was published February 2023 by Johns Hopkins University Press. Hardcover £17.98

Oncologist Chadhi Nabhan's life was turned upside down when an email popped into his inbox asking him whether he'd testify as an expert in a court case against the agrochemical behemoth Monsanto. A school groundkeeper who had regularly used Roundup, the company's bestselling weedkiller, had fallen ill with cancer. Was the chemical glyphosate to blame?

In his new book *Toxic Exposure*, Nabhan recounts his role as an expert witness in three separate high profile court cases, that pitted Monsanto's legal team against lawyers representing patients who had developed non-Hodgkin's lymphoma after using the herbicide.

During pretrial discovery, evidence emerged that Monsanto had engaged in scientific ghost-writing, and had declined to investigate the possibility that its multi-billion-dollar flagship product might cause cancer. What remained unclear, however, was whether Roundup actually could cause cancer – and if so, whether it had caused cancer in the patients now taking the company to court.

The evidence was unambiguously ambiguous. Two marquee institutions, the United States Environmental Protection Agency and the World Health Organisation's International Agency for Research on Cancer, had both conducted exhaustive evidence reviews and come to opposite conclusions. Various large-scale observational studies, each of them flawed in its own ways, contradicted each other. The evidence generated by in vitro studies and animal research was disputed.

The battle of experts was on. Both teams of lawyers marshalled and coached their own crack teams of highly credentialled scientists. The ultimate aim of the game was to convince juries composed of lay people that Monsanto's herbicide either was, or was not, "a substantial factor in the causation of" the patients' cancer.

Jury members watched as the assembled professors and doctors staunchly defended studies supporting their own side's position as rock solid, while slamming studies that had reached the opposite conclusions as deeply methodologically flawed.

During cross-examination, lawyers tried to rip apart not only rival experts' arguments, but also their credentials and credibility — including those of Dr Nabhan himself. "In court, it's all about creating doubt in the minds of the jury regarding opposing experts," he writes. Again and again, the author found himself in a battle of wits against hostile lawyers, each player seeking to trip up the opponent and score a point for his team.

In the preface to the book, Dr Nabhan writes: "I'd like to tell you the tale from my ringside seat as one of the medical oncology witnesses … I invite you to see the American judicial process as I saw it." *Toxic Exposure* fully delivers on that promise.

However, maybe inevitably, the immediacy of the account leaves some broader questions unexplored.

How does getting paid $5,000 per day — which can add up to millions of dollars over the course of a career (1) — to testify for one side, influence a scientist's approach to evidence? Dr Nabhan reports having repeatedly tried to connect with the jury on an emotional level; an opposing expert presented slides prepared by Monsanto. Is a justice system where you need millions of dollars to take a powerful company to court really just? The law firms involved invested heavily in the cases, betting that they would recoup the money if they won.

Could science learn from a process that subjects key opinion leaders to protracted, hostile, well-informed cross-examination? For example, similar public grilling

of prominent scientists might have added value to scientific and policy debates about Covid restrictions.

And maybe, most importantly, does it make sense to task lay people with arbitrating complex scientific disputes — and if not, what is the alternative? Dr Nabhan praises the judges' firm grasp of the science, but how much jury members understood remains untold, and maybe unknown.

Overall, *Toxic Exposure* is well researched, well written, and provides a refreshingly personal first-hand account of a scientist's encounter with the American legal system. This book is an essential read for anyone seeking to understand how American courts navigate contested scientific evidence, and provides an excellent starting point for wider ranging debates.

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Letter to the editor

On placebos

By Colin Brewer

I cannot allow James May's claim (Summer HealthSense Newsletter, issue 123) that 'the placebo effect has itself been shown to be very largely illusory' and that 'The studies that purported to show the placebo effect are both very old and very poorly conducted' to pass unchallenged.

In the past two decades, placebo research has moved from regarding placebo effects as largely a tiresome but unavoidable source of confusion (and disappointment) in clinical trials to a specialty in its own right.

The Society for International Placebo Studies (SIPS) was founded in 2010 and I attended its conference in Germany last May. I've also been writing a book about placebo effects in religion and other non-therapeutic fields. However, James is right to mention the paradox that some 'alternative' therapists, both True Believers and Cynical Charlatans, are beginning to admit that their nostrums are placebos so that they can claim scientific backing for their effectiveness. (1) HealthSense will need to address this development.

Of course, there's more to placebo effects in a given situation than the placebo in question and regression to the mean can certainly be a factor. So is the therapeutic encounter between healer (orthodox or 'alternative') and patient, including its subtle symbolic meanings for both parties. These aspects are usually labeled 'non-specific effects' and they can be more important than the effects of the specific tablet, injection or procedure that constitutes the placebo but both specific and non-specific effects can be powerfully increased by appropriate sales-talk.

When James says that "Doctors can be more straightforward with their patients, not trying to 'enhance the placebo effect' by using positive spin, but sharing with patients that the medication may well not do very much, and that they are likely to feel better despite this", he is discouraging a very important facet of bedside manner.

Two recent examples of placebo research bear this out. Ted Kaptchuk heads a team at Harvard that has done many important and revealing studies. Like Edzard Ernst, who practised homoeopathy before becoming one of its main critics, Kaptchuk trained in acupuncture in China before becoming sceptical about its specific effects and developing placebo acupuncture techniques that even patients with much experience of acupuncture and faith in it could not tell from the real thing.

One study involved a trial of real and sham acupuncture in patients with irritable bowel syndrome (IBS). Some who had improved after the sham procedure and then informed that they had been in the sham wing were debriefed.(2) All were surprised to learn that they had not had real acupuncture and all reinterpreted the outcome as showing that psychological and emotional factors and natural resilience were more important than they had thought.

In the days when we could use placebos without informing patients, I once did the same with a man who had previously had ECT and wanted another course when he became depressed again many years later. I didn't think he needed ECT but he was convinced he did, so he had the anaesthetic but I didn't push the button. When he had maintained a good recovery, I told him and after some initial annoyance, he was pleased to know the truth. ECT is a very impressive procedure but probably does have some beneficial specific effects beyond its considerable placebo and non-specific ones.

Kaptchuk's team also showed that when patients in IBS trials were given 20 minutes of additional sales-talk in addition to the standard history-taking and examination, outcomes were significantly improved, both statistically and (more important) clinically. An amusing feature of this study is that the extra 20 minutes of 'augmented consultation' consisted of what Kaptchuk himself described as 'very schmaltzy care ("I'm so glad to meet you"; "I know how difficult this is for you"…"This treatment has excellent results"). Practitioners were also required to touch the hands or shoulders of members of the [augmented] group and spend at least 20 seconds lost in thoughtful silence'. Sincerity is important in medicine and having a good bedside manner means, among other things, that you've learned how to fake it convincingly.

If regression to the mean were the main factor in apparent placebo responses, how could it account for the different degrees of improvement achieved by more impressive vs less impressive placebos and by

'augmented' vs less impressive components of the non-specific effects? Placebo and non-specific effects have important similarities with hypnosis, since whatever neurophysiological processes are involved, all of them are purely psychological in origin. Suggestion, prior belief, hope and expectation are crucial factors in both cases and regression to the mean cannot possibly explain why major surgery can be carried out using only hypnotic analgesia. (3)

There's much current interest in the surprisingly powerful effect of 'open label' placebos. Numerous studies confirm a 1960s finding that patients can benefit from placebo effects even when told that what they are being given is just a 'sugar pill' with no active ingredients. (4) The psychological processes involved seem to differ from those involved when patients improve after being randomised to placebos in double-blind controlled trials. (5)

No discussion of placebos in psychiatry should fail to mention the belated but increasing recognition of the massive and inappropriate over-prescribing of antidepressants for what in most cases should be called 'understandable unhappiness'. When antidepressants are compared with 'active' placebos (drugs that have noticeable side-effects that improve blinding but no known antidepressant effects) their modest advantage over placebo becomes even more modest, sometimes to the point of invisibility. It's truly a scandal but sadly all too typical of a specialty (my own) that until not that long ago unwisely drooled over psychoanalysis.

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- Consumer protection in regard to all forms of health care
- The highest standards of education and evidence-based health care by practitioners
- Better understanding by the public and the media of the importance of application of evidence from robust clinical trials

We are against

- Misleading advertising of health products
- The sale of unproven remedies to the vulnerable and desperate
- Unethical marketing by pharmaceutical companies
- Misconduct in clinical trials
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