Resource paper on public involvement in commercial projects

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A brief summary of the key messages for Public Contributors is available as a free download[1].

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Introduction – the UK policy position

Working together for long-term patient benefit

Members of the Consumer Liaison Group of the National Cancer Research Institute (CLG) met with AstraZeneca executives in 2011 to discuss consumer involvement. The next year over 80 patients and carers worked with staff from AZ to review research proposals.

AZ's researchers found this so positive that the company asked if the CLG could set up a standing reference panel of experienced consumers. Terms of Reference were negotiated and agreed with lawyers and regulators; volunteers were recruited and trained.

Numerous pieces of work have been completed since then, including work on AZ's consent templates, outcome measures and training for AZ's global medical research managers. The AZ-CLG Panel helps to ensure that AZ research projects will benefit patients in the long-term[2].

In 2014, the UK spent £8.5 billion on 17,000 health research projects[3] and more and more of these projects are complying with a clear policy direction to coproduce their activities with patients and the public. Similar efforts are being made in innovation, service delivery, evaluation and quality assurance activities. This means that patients who live with the condition are frequently involved in the whole innovation pathway – setting priorities, designing research proposals, approving bids, recruiting staff, conducting interviews, interpreting and disseminating findings, implementing recommendations, delivering services and evaluating impacts.

Not all of these things happen in every project, but the exceptional is gradually becoming commonplace, supported by the NHS commitment to increase co-design of its activities[4] as set out in the *Health and Social Care Act 2012* and reinforced by a recent publication from NHS England that seeks *A new relationship with people and communities*[5] to help with the implementation of the *Five Year Forward View for the NHS*.

Back in 2011, the UK Government of the day published *Innovation, Health and Wealth* which set out the case for the convergence of interests between health innovators, healthcare providers, government and commercial interests[6]. Closer collaboration between all these stakeholders - and with Public Contributors - was expected to improve healthcare delivery and help to drive the UK powerhouse of wealth creation, which in turn was anticipated to raise the standard of living and contribute to the public health agenda by lifting people out of poverty.

Charity and Industry working together

Myeloma UK is a charity that aims to 'make myeloma history'. Seven research studies have been supported by the charity's Clinical Trials Network, each one in partnership with a pharmaceutical company[7]. The charity has a Patient and Carer Research Panel in its Health Services Research Programme[8].

In October 2016, these messages were refreshed in the *Accelerated Access Review*:

> *"Patients should be involved in horizon scanning and prioritisation, and this involvement should continue along the whole innovation pathway…. Patients' strong interest in the development and availability of new innovations means that their involvement, either directly or through charities, is critical, from influencing innovators to develop the products they need, participating in research, championing the uptake of innovations into the NHS to holding the NHS to account for the adoption and spread of the best innovations. This means that meaningful dialogue with patients has never been more important."*[9]

Academic Health Science Networks (AHSNs) were recognised for their role in linking innovators and patients to accelerate the diffusion of innovation:

> *…allow effective innovations of all types to be badged with an 'NHS warrant', recognised by commissioners and procurement teams across the NHS, and be diffused across the system via the national AHSN network and with patient input. The AHSNs should act as innovation exchanges, working with their local health economies to understand local areas of unmet*

> *clinical need and then working with innovators to meet those needs, providing advice and support throughout product development*[10].

The Review suggested that innovation in the NHS could be tracked and managed via a Scorecard:

> *We propose that, in future, the Innovation Scorecard should be the single source of information on the use of innovation in the NHS. It should be owned by NICE and used by the rest of the Accelerated Access Partnership, particularly NHS England and NHS Improvement, to hold the system to account and assess the progress of local areas. Patients and clinicians, as well as NICE, the Department of Health and NHS England, should help to define the products and outcomes that are included, and there should be an emphasis on NICE-approved technologies. This information should be accessible to patients and the public.*[11]

Lest there be any misunderstanding:

> *Patients, carers and charities provide crucial advice on what innovations are needed, their value to patients and how best to pull them into use. Integrating the patient voice at all points in the pathway will be essential.*[12]

However, when thinking about Public Contributors and Commerce, it cannot be assumed that there will always be this convergence of interests. This is illustrated by the response to the *Accelerated Access Review* published by the life sciences industry[13], that gives a clear place to medical charities as sources of funding and makes vague statements about 'local partners' in its proposed governance arrangements, but otherwise makes no reference to the involvement of patients in strategy development and governance.

So, we need to acknowledge that making the most of the opportunity for Public Contribution will require an honest acknowledgement that interests sometimes diverge or even conflict, and so a proper consideration of risks and protective factors is needed. This is what is attempted in this paper. It does not focus on the essentials common to all kinds of public involvement, as these are addressed elsewhere[14], but simply addresses the distinctive factors that arise when there are opportunities for Public Contributors to shape the activities of commercial organisations.

A word about language and purpose

This paper will use the term Public Contributor to refer to the people that others may call patients, clients, service users, survivors, experts by experience, carers or members of the public. One study found almost 200 different definitions[15] of this sort of work which in the UK is sometimes called Patient and Public Involvement or PPI. Such individuals generally stand outside the clinical and academic workforce[16] and offer their distinctive perspective and constructive challenge to the research and development team. Innovation is co-produced through a collaborative process which blends the best ideas from lived experience with academic and clinical perspectives, overseen by research ethics and governance processes.

In this paper, the term 'commercial' refers to the whole range of industry, from self-employed individuals trying to build a new business, through community interest companies and other business forms that are designed to deliver social benefits, and all the way on to vast international companies that are owned by shareholders and quoted on the stock market.

There have been instances where a patient advocacy organisation has received funding from a pharmaceutical company and then promoted a particular treatment which favours the commercial interests of the donor organisation and may even lack evidence of clinical efficacy[17]. In this situation, a conflict of interest has arisen, in which the primary purpose of the patient organisation has been eclipsed by a secondary concern, that of maximising income or showing gratitude to the funder[18]. Rather than engage in a detailed discussion of the ethics of this issue, we will confine ourselves to the single point that Public Contributors are not ambassadors working on behalf of the marketing division of the for-profit industry, but rather citizens who wish to influence the activities of commercial industry so that it produces more respectful and effective healthcare interventions for patients.

We note that the UK commercial sector in general is highly regulated, and that there are special rules for pharmaceutical companies, medical device companies and market research organisations. Some of these regulatory bodies and their rules are quoted here because they have isolated a specific ethical principle or particular behaviour that is of general value and could be applied across the whole commercial sector. This paper does not qualify, interpret or amend any law or guidance[19], but simply draws on them as a source of assistance in clarifying the issues to be considered in this document. Later versions may be easier to follow if such references are removed, but at this stage, sources are cited to show what work has been done to date.

How might Public Contributors overlap with Commercial interests?

Public Contributors get involved with commercial interests when:

- They are advising an NHS organisation which then links with commercial interests[20].
- They are asked to advise on a project that is funded by industry rather than the Government or a charity, or when the project is financed by a blend of public and private funding[21].
- A university is working in partnership with a commercial business on a project or in a 'spin-out' company which is launched by the university and then floated off into the market place. Early involvement by Public Contributors will affect the whole lifecourse of an innovation, including its ultimate commercial value.
- A private business commissions a market research company to find out what the public think about a product or service and that market research company approaches a Public Contributor.
- A charity that is engaging Public Contributors[22] accepts a donation from a commercial organisation, especially if the amount of the donation is determined by sales of the product to the public ('for every packet sold, we will donate...')
- A commercial business operates as a broker, charging a fee and making a profit out of linking Public Contributors with health organisations that wish to engage with them[23].
- Someone who runs a commercial business or works in one also gets involved as a Public Contributor and this helps their business to become more effective[24].

IXICO - an example[25] of positive collaboration between Public Contributors and Commerce

Academics at three London universities founded an ICT company called IXICO in 2004. Some years later, they linked up with the Health Innovation Network (HIN), a publicly funded body

charged with promoting evidence-based health innovation, and Innovations in Dementia, a community interest company. One result was the creation of a digital support planning tool called 'My Brain Book' was developed for use by people with dementia, their families and care staff.

The HIN created a variety of consultation processes with the public and specifically with people with dementia to determine their priorities, and the 'My Brain Book' concept emerged from these events. Innovations in Dementia then arranged some design workshops with IXICO to refine the model, working in familiar environments with paper-based materials. The next stage was some user-testing with people in their own homes or in a private room of a dementia café. The way in which each of these activities was undertaken was shaped by the preferences of participants[26].

Why is a Guide needed?

There are at least four reasons to create some guidance materials.

1. To improve patient care

The best patient care is delivered when the wisdom of Public Contributors is combined with academic and clinical insights[27]. For some Public Contributors, the focus on delivering patient benefit eclipses any worries that they might have about commerce, shareholders and profit and so they engage with industry rather than standing aloof[28]. Unfortunately, it is possible for such goodwill to be abused or lost[29]. But if we can address these legitimate worries about how Public Contributors can interact successfully with the commercial sector, then we will help to ensure that the best care reaches the greatest number of people as quickly as possible.

Working together to improve patient empowerment

The National Patient Organisation of Bulgaria has developed and coordinated a peer training programme for chronic diseases. Patient leaders, health professionals and non-governmental organisations have worked together to form the University for Patients, funded by ten pharmaceutical companies[30].

Working together to improve product quality

One organisation with an excellent track record of involving patient advisors held a workshop for one of its industry partners that created the opportunity for input by public contributors into their research study. Specifically, the industry partner wanted to show the technology that patients would be expected to use, take them through the trial regimen to see how it might be received and whether any changes might be necessary. Much feedback was given, largely around improving the patient experience – at the level of human/technology interface and also in connection with the benefits of providing participants with feedback about their treatment. Minor changes to the technology interface were made, but suggestions around providing patients with feedback were not implemented. This may be partly due to the need for rigour (i.e. not wishing to contaminate research findings by providing feedback during the trial).

2. Because healthcare is a blend of the public and private sectors

While it appears to some that healthcare is a non-profit activity, every medical device, tablet, hospital bed and sharps bin in UK healthcare is supplied by the commercial sector and so has turned a profit for someone. This means that healthcare in the NHS is, in reality, delivered by a combination of the public and the private sectors. This is illustrated by the fact that three quarters of NHS trusts support patients to participate in commercial contract research and nearly 35,000 of their patients did so in 2015/16[31]. On a broader front, some NHS organisations employ a commercial lead to 'explore opportunities with commercial partners to deliver service improvement and apply a commercial ethos and approach to maximise opportunities for NHS services.'[32]

Furthermore, commercial activity in the field of healthcare is expanding, with the number of new research studies at an all-time high[33] and the private health sector continuing to grow[34]. Within this overall growth, there are pockets of decline, such as in mental health[35], which the public may have a view about, and in consequence, a policy push to increase investment in the future.

However, the 21st century has seen some renegotiation of the relationship between the state, industry and the private individual, partly driven by austerity, with some commentators suggesting that the state intends to shrink its role as provider and make a corresponding growth in the twin roles of activator and regulator[36]. For some, combining personal responsibility and commercial interests forms the most efficient path to improved health outcomes, while for others, commerce is seen as greedy and self-serving. Such beliefs, whether in the idea that different sectors enjoy convergent goals or have divergent interests, may influence the way that individuals view Public Involvement in commercially funded activities.

Working together to solve difficult problems

The North West Coast Academic Health Science Network (AHSN) are working on The Government's Connected Health Cities project. This brings together industry, universities, patients and the public to create a healthcare system that can learn and develop. One aspect of this is the development of a 'data ark' where health information can be stored and interrogated. The Patient Panel is involved in designing the process by which consent is granted for access to the information.

Greater Manchester AHSN brought together members of the public, NHS, academic and Industry partners to explore how to enhance public involvement and engagement in helping shape and test new technology. The goal was to accelerate development so that innovations reached the market more quickly and improved outcomes for patients[37].

Working Together to run conferences and seminars

Greater Manchester AHSN and others have brought together innovators, patients and carers for a series of meetings to discuss rapid prototyping, healthcare service design and how to design products that people want to use. They also brought together NHS partners, SMEs and the public to improve patient care by exploring the development of new innovations[38].

Working Together in Decision Panels

Greater Manchester AHSN has formed a number of Boards and Panels to make decisions about funding. For example, Energise Funds support businesses to develop prototypes for a defined clinical application, while Momentum Funds are offered to accelerate the progress of innovations that are nearly ready for market. Commercial organisations may apply for these funds and their proposal is then appraised by a decision panel that includes members of the public[39].

Some projects wish to gain access to healthcare information to develop innovative responses to need. In Greater Manchester, eligible projects must be a partnership between the NHS and commercial organisations and their application for access to DataWell is assessed by a panel that includes patient representatives[40].

3. To speed up adoption of good ideas

Thirdly, it can take a very long time for research findings to start benefitting patients – indeed, one review[41] found that the average journey of the innovation from the researcher's bench to the patient's bedside took 17 years. Narrowing this translational gap demands a closer working relationship between patients and the public, research, healthcare organisations and industry.

4. To promote ethical practice

While there is potential for collaboration between Public Contributors and industry to deliver improved patient care and support a prosperous economy[42], some care is needed to ensure that relationships are positive and constructive and actually deliver this blend of innovation, health and wealth[43]. Furthermore, there are hints that where policy documents exist, such as in the pharmaceutical industry, they may not be always well understood, and folklore beliefs may have arisen about what they *might* say, rather than what they actually contain. The discussion that is stimulated by this Guide may encourage people to revisit the official guidance and check their understanding.

It has also been observed that the risk of exploitative or otherwise unethical practice is not confined to the commercial sector, but charities, academic institutions and non-profits may fall into difficulties too. Nor are these risks confined to Public Contributors – academics and clinicians face many of the same challenges as they consider with whom they wish to be aligned, whose money to accept, fair rates of remuneration and intellectual property, amongst other dilemmas.

So, the issues set out here may apply to a whole range of people and activities, and the specific example of the relationship between the Public Contributor and the for-profit sector can help by shining a light on issues of general concern.

Are current arrangements working?

1. Industry doesn't always talk to customers

The commercial sector pioneered market research approaches, such as the use of focus groups to discover customer opinions[44], but its efforts to seek out views prior to making their investments in research, product development and marketing are weak[45]. In one telling example, commercial designers created a wearable medical device that took the form of a waistcoat with wires and bulky filled pockets, and it was only at the final test that they discovered that the patient did not want to be seen in public looking like a suicide bomber! In another telling example, Grace Cordovano compiled a list of 50 excuses that the pharmaceutical industry had given her for not involving patients[46]. These anecdotes represent a broader reality – in a 2019 survey[47], patients were considerably more likely to trust and engage with a patient advocacy organisation than a pharmaceutical company, a qualitative study found that interviewees wanted to see a 'cultural mindset change' in the pharmaceutical industry[48] and there is a need to develop public trust[49].

Working together to support peer networks for patients

The pharmaceutical company UCB have supported the development of an online community for families affected by Parkinson's disease. Called 'More than Motion', the site allows patients to upload their own photos, bringing them into an active support and information group from the comfort of their own homes or wherever they may take their mobile device[50].

Probing more deeply may reveal that some for-profit businesses engage with customers as one-off informants, but do not build ongoing relationships that deliver advice throughout the product development pipeline, while others engage arms-length market research companies to work on their behalf[51]. The reputation of the pharmaceutical industry is particularly weak, with only 9% of respondents rating it as 'excellent' or 'good' at fair pricing[52]. In response, many commercial organisations are attempting to become more patient-focused[53], but experience challenges in converting this general aspiration into practical action plans[54]. Even the most recent advice makes little of the potential for patient opinion to challenge the overall practice of the pharmaceutical sector[55].

2. Commercially funded researchers don't engage very much with Public Contributors

While our brief is focused on innovation in healthcare, it is nevertheless instructive to consider what is happening in healthcare research. Between a third and a half of UK health research funding came from the commercial sector in 2012[56] and commercial research funders have a clear obligation to involve Public Contributors[57], but only around 5% of commercially funded research projects make any plans at all for involving Public Contributors, contrasting with the 40% of non-commercially funded research studies that make such plans[58]. Thus, it appears, that the vast majority of commercial organisations are not listening very carefully to patient and public voices in their research investment, and this has been recognised as an international problem[59]. We know that effective involvement of Public Contributors can enhance recruitment of research participants[60], so it is no surprise to note that commercial research studies are less successful in this[61]. The result will

surely be the development of inferior healthcare products, while a failure to engage patients in drug trials reduces the likelihood that the drug will ever be launched on the market[62]. This difficulty may, of course, be confined to the research phase of the innovation pipeline and Public Contributors may be heavily involved in service user testing and other stages of development.

It has been suggested that the for-profit sector is looking for Public Contributors who are regarded as speaking on behalf of a wide constituency, somehow representing the 'truth' about patient opinion. This viewpoint can lead them to seek contact with the official representatives of large patient organisations rather than individual Public Contributors or small, local groups. In some areas, such as health technology assessments, large patient organisations are consistently favoured over individuals[63].

3. UK Infrastructure organisations don't help much

The UK's foremost infrastructure organisation that supports Public Contribution to health research has little to say about the distinction between involvement in commercial and non-commercial research studies[64] or the potential for Public Contributors to experience a conflict of interest [65]. A search of their most recent bibliography for the word 'commercial' yielded no useful returns[66], although the organisation did commission the comparison of Public Contribution to publicly funded verses commercial research projects that was cited above. A mechanism to link commercial organisations with patient groups was developed by the Clinical Research Network and published in October 2018[67] and this procedure is attentive to the commercial interests of the business and suggests that patient groups may be engaged prior to release of any details of the company concerned. There is no hint in this procedure that patient groups may have any wish to vet and work with ethical businesses and eschew the rest.

In a recent twist, the whole of this infrastructure organisation has been moved into the private sector, and commentators are asking how Public Contribution sits with commercial interests, and whether there may be any conflicts of interest[68].

Links are being formed with various international infrastructure organisations that may lead to a joint solution. For example, some very useful recommendations[69] have been made by CTTI about collaboration between large, well-organised patient groups in the USA and pharmaceutical companies, while PFMD are forming a working group to identify and overcome barriers to collaboration[70].

Back in the UK, marketing materials[71] celebrate the number of NHS patients engaged in commercially funded studies, revealing the firm adherence to the 'activator' role of the state mentioned above and setting aside any consideration of the differences between the for-profit and the non-profit sectors. More recently, views on patient involvement with pharmaceutical companies have been surveyed[72], and a significant launch of quality standards for public involvement in March 2018 was jointly hosted by the Association of Medical Research Charities and the Association of Pharmaceutical Industries.

Where collaboration between commercial organisations and charities is discussed, it appears to pay little attention to the idea that Public Contributors might help to shape the activities of commercial organisations. For example, recent guidance from AMRC about charities working with industry[73]

explained how charities can provide funds for research[74] and organise infrastructure, such as patient registers, but neglected to give much detail of the ways that Public Contributors might influence the decision-making of for-profit companies.

For those who see Public Contributors as driven by altruism and akin to volunteers[75], it is noteworthy that the UK Institute for Volunteering Research has acknowledged the overlapping nature of charitable, community and commercial interests; the Charities Commission has reviewed the relationship between charities and the commercial sector[76]; the Local Government Association brackets social enterprises in with voluntary and charitable organisations[77]; and the Trades Union Congress has created a charter to regulate the relationship between employees and volunteers[78]. After setting out some fundamental standards for high-quality volunteering roles, this charter specifically makes three statements in respect of the relationship between employees and volunteers that are noteworthy in this discussion paper:

- The involvement of volunteers should complement and supplement the work of paid staff, and should not be used to displace paid staff or undercut their pay and conditions of service
- There should be recognised machinery for the resolution of any problems between organisations and volunteers or between paid staff and volunteers
- In the interests of harmonious relations between volunteers and paid staff, volunteers should not be used to undertake the work of paid staff during industrial disputes.

Some volunteer centres do not support any placements in 'for profit' settings and instead concentrate their volunteer resources entirely on charitable or community projects[79], while others blur the distinction as their unpaid volunteers work alongside 'employee volunteers' sent out in worktime by commercial organisations as part of their Corporate Social Responsibility activities. To add to the confusion, knowledge transfer partnerships create secondment opportunities between commercial and charitable organisations and social enterprises arise in the marketplace. Occasionally, a volunteer centre will offer placements in a commercial setting because they see this as the best place for the person to enjoy the experience they seek or gain the skills they need[80]. There is a parallel here, as Public Contributors may choose to engage with a commercial activity because it provides an unparalleled opportunity to learn or contribute.

From an academic point of view, the majority of theoretical work in both the sociology of work and the sociology of volunteering operates on the assumption of a binary division between paid work and unpaid domestic or leisure activities and thus neglects the myriad of hybrids that have grown up between these two stark positions[81]. There is a small but distinct literature on collaboration between the for-profit and the non-profit sectors[82]. A local example might be a small nursing home that is technically a for-profit business, but where volunteers prioritise the value of their contact with residents, rather than allowing their concern about the status of the company as a for-profit enterprise to deprive the residents of their input. Others have no ethical difficulties with stepping over to help the for-profit sector, but simply manage their burgeoning workload by using the line as a convenient exclusion criterion.

This symbolic boundary line between the non-profit and for-profit sectors is crossed in the other direction too, as volunteer agencies encourage employers to support their staff to give worktime to

community and charitable volunteering activities[83]. So, in conclusion, neither a blunt prohibition nor a binary division helps us think through how one might be appropriately involved with industry.

4. Local policies don't often guide work with the commercial sector

Some Public Contributors have business interests too and want to gain trade opportunities or intellectual property that will deliver commercial benefits – so they might be subject to a conflict of interest. This could perhaps be managed by the use of a policy[84] that addressed gifts and hospitality, declarations of interest and bribery, but such policies seem comparatively rare[85] and are inadequate on their own. Mandeville et al examined 53 patient organisations and found only 30% of them had a written policy on pharmaceutical industry funding[86]. It is also worth noting that declaring a conflict of interest can have a perverse effect[87].

The Association of British Pharmaceutical Industries and the International Alliance of Patients' Organisations[88] have protocols in relation to their working relationship with patients and patient groups. This is to prevent risk and harm, such as patients being influenced to ask for particular proprietary forms of a particular drug. While such guidance may effectively regulate activity in respect of ingested medication, it does not say much about the broader arena of other commercial activities or how Public Contributors might influence commercially funded research. Where a joint working advisory group operates, there may be roles for Public Contributors to be involved in oversight of collaborative projects.

Working together to set strategic direction for industry

The pharmaceutical company Novartis made a Patient Declaration in 2015 which changed their internal processes at global, regional and country level. The declaration was informed by substantial input from patient organisation and leading patient advocates[89] and participants are currently meeting to revise the declaration.

Taken together, these four concerns underscore the need for some simple principles which might help Public Contributors to decide whether to engage with the commercial sector and organisations such as the Academic Health Science Networks to support ethical participation. Some places to start are set out in the paragraphs below.

Avoid harm and maximise benefit

Collaboration between for-profit healthcare companies and healthcare providers has the potential to benefit patients and accelerate innovation[90]. This Guide suggests that this potential for benefit will be further enhanced if for-profit businesses in the healthcare sector and beyond take proper account of the views of Public Contributors. Brilliant ideas that arise in the minds of patients and the public will be captured and used to benefit patients. Commercial products will be more attractive to patients and deliver better health benefits at a lower cost. As we have seen, however, there is room for further collaboration between Public Contributors and commercial industry. An active

programme of engaging Public Contributors would increase the benefit and reduce the harm that is inherent in present arrangements.

Engaging is hazardous too. At worst, Public Contributors might be financially exploited or have their ideas stolen. Instead of a hoped-for alliance that strengthens both the for-profit organisation and Public Contributors' organisations, the partnership might divert either or both organisations from their central mission and purpose. The collaboration might stifle the independence or originality of Public Contributors, damage their reputation or simply drown them in writing terms of reference and reports, rather than doing anything useful. This is why some[91] ask for a clear explanation of the 'mission-related benefit' of the collaboration with industry, augmented with a review process to ensure that this has not been adversely affected by 'mission drift'. This means that the reasons for the collaboration are clearly set out in a way that demonstrates how the goals of the charity or patient organisation will be advanced by working with the for-profit organisation.

The 'principles of public life' devised by Lord Nolan form a helpful plumbline against which to check that the collaboration between Public Contributors and the for-profit business are straight and true[92]. Nolan asks for accountability, which suggests that arrangements should be made public and open to scrutiny and perhaps checked from time to time against a set of expectations – perhaps even those set out in this Guide.

Work with ethical businesses

The section above on risk leads on to a consideration of the commercial business itself, as some Public Contributors may not be willing to be associated with a business that they regard as unethical[93]. An ethical business may be one that:

- operates within the law and guidance from regulatory bodies while learning from research evidence and best practice. The pharmaceutical industry has been singled out as particularly prone to corruption[94].
- manufactures items that are viewed as safe (such as evidence-based healthcare products rather than armaments or addictive items, whether tobacco, alcohol, gambling or illicit drugs)[95]
- when developing healthcare products or interventions, a plan is in place to make the intervention available to all citizens, rather than restricted to the wealthiest self-funders[96]. It is noted here that some commercial decisions prioritise people over profit[97].
- prioritises patient benefit above profit whenever possible and has a high level of customer satisfaction
- Is financially stable and has a low pay differential between the highest and lowest paid employee[98]
- is run as a community interest company or has an active approach to corporate social responsibility, perhaps accredited with the CommunityMark award from Business in the Community
- has a workforce that reflects the diversity of the community, has a flattened management structure and involves employees in shared decision-making
- takes an active approach to environmental sustainability

- if products, profits or business opportunities are moved overseas, they benefit rather than exploit people poorer than ourselves (perhaps through fair trade arrangements)[99]
- Involves Public Contributors from before the beginning to after the end, so that they can track the whole process.

One might reasonably expect that small, new businesses with small profits would demonstrate these commitments in a different way to an established global company.

While the UK's Public Services (Social Value) Act 2012 is designed to ensure that public funds are used in a way that promotes economic, social and environmental well-being, the principles of the Act have some relevance to our agenda. Indeed, it is reasonable to expect that commercial organisations that supply to public bodies will have regard to the potential that their activities can deliver a similar range of benefits, thus promoting economic, social and environmental wellbeing[100].

Finally in this section, we note that commercial interests extend beyond those who finance, carry out and benefit from the research itself. Specific activities within the research journey are also influenced by commercial interests, and so, for example, Public Contributors may have a view about where research findings should be published[101].

Protect data and honour intellectual property rights

Contact details

The for-profit organisation will not use the personal information it obtains through its relationship with Public Contributors to market its products to them or for any other commercial purpose beyond that of the involvement activity[102]. This principle should be upheld both in respect of the details, such as email and postal addresses, but also in its spirit, that engaging Public Contributors should not be used as a device to manipulate demand for a product or to increase sales.

This means that industry staff should be neutral in the way they refer to their company and avoid extolling its virtues or the values of its products. Public contributors and patient organisations retain the right to report research findings or other factual information without fear or favour, especially where they might be perceived as disadvantageous to the commercial organisation[103].

Working together to keep patients in charge of their own care

The European Cancer Patient Coalition has developed an Information Portal for patients to access so that they can learn more about treatments. The resources are designed by patients for patients, so that they are accessible and educational. Industry partners support with funding, but also check that the content is entirely non-product related and non-promotional and thereby adheres to their own compliance rules[104].

Intellectual property

The law surrounding intellectual property[105] covers written or recorded materials (copyright), inventions (patent), designs (registered designs) and marketing (trademarks). In summary, the law protects owners of intellectual property from others who may wish to misrepresent or profit from their work without permission. Thus the for-profit company will be eager that their ideas are not shared with competitors, while Public Contributors will want to retain the right to offer or withhold use of their name, logo and other identifying marks in any advertising or reporting in the public domain[106]. In order to maintain faith with their mission and members of the public, the patient advocacy organisation should not advertise or promote a product unless it is holds substantial evidence of its claims, and nor should it market products that are unrelated to its mission[107].

Conversations are not covered by the law, inventions cannot be patented if they have been shared with other people, and in a business context, rights are usually held by the company rather than individual employees. As a default position, self-employed persons usually own the intellectual property, even if the work was commissioned, so many firms and publishing houses respond by obtaining the intellectual property rights as part of their contract. All this means that, while there is a moral obligation to acknowledge the contribution of Public Contributors that is made during informal discussion and working together, it would be difficult to uphold this in a legal sense[108].

Indeed, the very nature of coproduction, as a fundamentally shared, open approach where insights emerge through creative dialogue in diverse groups, appears to be quite the opposite of the approach needed to guard one's private intellectual property. This is illustrated by another of the Nolan principles – openness – which declares that information should be restricted only when the wider public interest clearly demands. Furthermore, Public Contributors are often encouraged to establish relationships with a wider constituency of people who share their life experience, so that they can bring a broader set of perspectives beyond their own personal viewpoint.

Similarly, for-profit industry may be concerned about information that it regards as 'commercial in confidence'. At worst, commercial interests have led to the suppression of research findings beyond the point needed to file a patent[109], while Public Contributors expect research findings to benefit the patient community as quickly as possible. Effective collaboration will, from time to time, demand that commercial interests are disclosed to Public Contributors, over whom they have fewer sanctions compared to their employees. So, perhaps the industry and the Public contributor's organisation should make a mutually binding promise[110], that both parties will behave honourably with the information that they learn about the other. Such a document may strengthen the moral imperative but is unlikely to have much value in a court of law, and a piece of paper is almost worthless in the absence of trusting relationships. Advice is available on these matters[111].

Research participants are citizens first and therefore have a general right to control the data held about themselves, while the tenets of scientific inquiry suggest that anonymised datasets should be available for scrutiny and analysis by others, so that the veracity of the raw data can be established and the conclusions shown to be legitimate rather than fabricated. A lively debate is underway on whether identifiable personal healthcare data should be shared between health providers for clinical reasons and with others in a de-identified form for research purposes, and a study of 29,275 people in 2020 found that, while opinion varied, there was more reluctance to share de-identified information when for-profit commercial interests were involved in research[112]. This is often waived

in health research while the study is under way, so that participants and researchers remain blinded to the status of particular participants until the study is over. Arguments from industry about such information remaining locked in secure vaults where Public Contributors are permanently denied access under the guise of 'commercial in confidence' should be challenged.

Honest communications

Communications with Public Contributors, employees, managers, Boards and the public should be truthful, non-deceptive and clear[113].

One of the areas where the for-profit sector and Public Contributors might come together in in the development and provision of non-promotional patient information, although even such benign activity can lead to the Public Contributor's organisation losing its reputation as an independent voice[114], or weaken the wider public's engagement with the fundamental issues[115]. Nolan also indicates that healthy arrangements will involve a leadership dimension, so that the commercial business and Public Contributors let others know what they are doing, rather than keeping the work secret. Reports about the involvement of Public Contributors should appear in business news briefings as well as being reported in the patient-led sector and academic settings.

Consider the consequences for authors

Editors of professional journals that publish health research have become sceptical of the integrity of some commercial interests, especially since some sectors of the pharmaceutical industry have tried to corrupt the usual scientific process to protect their interests[116]. In consequence, some editors have insisted that anyone involved in writing an academic paper should declare any payments that they receive for doing so, fearful that the payment will distort the text in favour of the company or its profits; and that readers will discount the article, whether or not it has intrinsic merit, as indeed, they have been found to do[117].

These hazards might, in theory, be managed by ensuring that public contributors avoid the pharmaceutical industry, avoid referring to their employer's business or products, work for free, or channel payments via an organisation that protects the principle of independence. A better solution would be for professional bodies (such as WAME and ICMJE) or individual journals[118] to frame guidance that was effective in recognising, promoting and remunerating ethical public co-authorship[119]. Until then, it is likely that in practice, receiving any payment at all from a commercial organisation may confine public authors to publishing formats where academic standards are less rigorous.

Exercise power responsibly

The commercial organisation should make no attempt to influence the public contributor to use, support or endorse their products[120]. Market consultation must not be disguised product promotion[121] or clinical advice, as the industry must not usurp the role of the healthcare professional; and commercial organisations must respect the independence of patient organisations[122]. The commercial organisation should not falsely represent the views of the Public Contributor or r use strategies such as 'astroturfing' by engaging confidence tricksters to misrepresent patient views[123]. It is worth mentioning in passing that some commercial organisations have become so fearful of censure by regulatory bodies that they define 'improper influence' in an overly restrictive manner[124].

A core component of patient organisations is their independence, and it is vital that this is upheld in any collaboration with the commercial sector, so that the decisions, actions and opinions of Public Contributors remain impartial and are not unduly shaped by commercial interests[125]. In most situations, this is tested by asking whether the Public Contributors feel free of coercion, rather than by asking the commercial organisation whether they intend to exercise influence. It is also possible that funding may lead to feelings of gratitude and on to unconscious bias. Lin et al (2016) found that patient organisations that had received funding from drug manufacturers were more likely than their unfunded counterparts to oppose the introduction of guidelines on prescription[126].

To reduce the risk that independence may be compromised by an undue dependency on one organisation, the Public Contributor's group should be encouraged to seek multiple sources of funding and avoid becoming tied into a specific commercial organisation[127], but rather, be able to make alliances with competitors. Sometimes, a patient organisation that receives funding from a pharmaceutical company is accused of actively lobbying on behalf of that drug treatment and this can be unhelpful to its mission and success[128].

Working together despite disagreements

Breast Cancer Now is a UK charity that has formed a robust partnership with the pharmaceutical company Pfizer through which the company has committed $15 million to tackle breast cancer. The project will be managed by an international committee of academics that includes patients. Results will be shared as soon as they are available, and the charity has retained the right to campaign, including against Pfizer, should the need arise[129].

For-profit industry should be able to point to a growing 'You said, We did' evidence base that shows how the company has involved Public Contributors throughout its work and how this has led to change that ultimately improved patient care[130]. This does not mean that everything recommended by Public Contributors will be adopted, but it is reasonable to expect that some things will be taken up. Here is an area where supportive but robust scrutiny will be employed from time to time to check that neither the Public Contributor's views, nor the industry's adoption of recommendations, is being orchestrated by a hidden conductor.

Be clear about the money

We finally reach the question that some readers might have addressed first. The fundamental difference between government-funded and charitable activities on the one hand, and work in the for-profit sector on the other, is obviously money. In some parts of the commercial sector, shareholders are making a profit or employees are being paid a salary well above that which is offered in the public services and charity sector. Some Public Contributors think it is only right that they should be paid a consultancy fee[131], or that the operating costs of their group should be covered by the commercial interest. Meanwhile, others feel that such an arrangement would destroy their independence and compromise their distinctive voice. The following paragraphs suggest some ways forward.

Be clear about payments to individuals

First of all, there are some principles that have been adopted for drug trials[132] that might be used in a broader sense to shape our thinking about payments to individuals. These are as follows:

- where payment is envisaged, the offer is of a single payment to anyone who gets involved in the early stages of product development, rather than a proportion of the as-yet unknown future profits accruing to the manufacturer. Where a Public Contributor is involved from time to time throughout the development of a piece of research or a healthcare product, the principle should be for suitable payments to be offered for each step of involvement, rather than a share of ultimate profits[133].
- Any payments offered must not be used to coerce people into participation or staged to induce people to complete a full process of participation. In other words, Public Contributors must be free to join the project and free to leave it at any point in the process without penalty.
- The risks to participants must be minimised, rather than using payment as a compensation for enduring the risk. The section above about risk is relevant here.

Beyond these principles lie a whole set of issues that address participation and expenses payments for involvement in any kind of research, whether the funder is a non-profit or a for-profit organisation. Comprehensive guidance from this perspective is available[134]. There is also a principle of transparency – that payments and other ''transfers of value' should not be made in secret. The pharmaceutical industry has a publicly accessible database to record such transfers to healthcare professionals and transfers to Public Contributors are published annually[135].

Be clear about employment status

Where Public Contributors offer advice to projects that are funded by the Government or charitable bodies, this fact may shore up the notion that such activity falls within the definition of volunteering[136]. In addition, Public Contributors involved in health research find their participation payments and reimbursement of expenses are likely to be ignored by the tax and benefit system[137], while involvement with health services or commercial enterprises is less likely to be subject to these provisions. Similarly, while it is custom and practice in health research establishments to offer

participation payments to public contributors, similar advisory roles in NHS Trusts or Clinical Commissioning Groups are usually on a strictly unpaid basis.

All this means that bringing together public contributors across the innovation pathway will expose significant differences in the terms and conditions offered in different parts of the system, which may in turn create tensions or migration from less attractive areas to more rewarding activities. Perhaps more significantly, external stakeholders, whether HMRC, Department of Work and Pensions or employers may find it more difficult to navigate this changing landscape.

Moreover, advice offered by a public contributor to a commercial organisation in exchange for payment becomes part of that world and may be subject to regulation as employment. Similarly, where Public Contributors are 'working', i.e. delivering expertise, services or productivity on a regular basis and could raise a grievance if they were not appropriately remunerated, then employment law is likely to apply[138]. The UK law is notoriously complex in this arena[139] and includes some unexpected items, such as the prohibition on people aged under 14 from volunteering for a for-profit company[140], and the obligation to follow 'right to work' rules for migrants even if the activity is judged to be unpaid work[141]. Another possible prohibition comes from a different source - the European Medicines Agency deems that a patient representative has lost their authentic voice and so is entirely disqualified from representing patient interests if they are employed on any kind of contract with a commercial organisation[142].

The stronger the likeness to employment, the more the issues in this paper dissolve into standard matters of business ethics, and the more the paymaster may wish to sell the expertise of their staff (including Public Contributors) to anyone who will pay. Cuts in public funding press even the most publicly-minded organisation, including the NHS and charities, to consider whether the group of Public Contributors it hosts might become part of its income-generating strategy.

Be clear about fair market value

A commercial organisation may contract with a Public Contributor's organisation for the provision of expert advice or speakers, but this must be established on a sound and proportionate basis[143], in which the company genuinely needs and uses the service, and that remuneration is based on fair market value, quality is assured and grievance mechanisms are to hand.

The question of what counts as fair market value and how to manage these payments well remains untidy in the United Kingdom, especially for those Public Contributors who receive means-tested welfare benefits. As a result, customs vary from one project to another, irrespective of who is funding and managing the individual project. The dilemma is amplified in respect of commercially funded projects.

One aspect of this is perhaps the scarcity of the expertise. For example, an investigation using a questionnaire in a doctor's waiting room to find out about the stress experienced by those obliged to wait a long time will find it easy to recruit, while we might guess that a similar questionnaire for the doctor asking about stress levels amongst the medical profession would need to offer a greater incentive[144] to get the medics to spend time filling in the form.

We might note in passing that such a complex marketplace in which the same person carrying out the same activity can do it for nothing in one context, expenses in another, a small participation fee

in a third place and a full consultancy fee in a fourth creates inequities and economic migrants, clouding the simple principle of fairness. Indeed, it is rather like the current arrangements for accessing medical expertise in the United Kingdom!

Be clear about who is paying for what

Commercial organisations should not provide hospitality to Public Contributors except in association with scientific or educational purposes or to obtain patient views on legitimate business questions through establishing an advisory board[145]. The ABPI sets out[146] the following requirement in which all eleven tests must be passed before a patient advisory board can be approved:

- ✓ Does the company have a legitimate unanswered business question?
- ✓ Is an advisory board the most appropriate way of obtaining the information?
- ✓ Does every participant have the relevant expertise to contribute meaningfully to the purpose and expected output of the meeting?
- ✓ Is the number of participants limited so as to allow active participation by all?
- ✓ Does the agenda allow adequate time for discussion? Is a significant majority of the time spent on feedback from the participants?
- ✓ Has the company wholly and solely determined its need for the advisory board, with no input from expected attendees?
- ✓ Is the number of delegates/meetings strictly limited to that required to answer the question?
- ✓ Does the invitation to participate clearly state the purpose of the meeting, the expected advisory role and the amount of work to be undertaken?
- ✓ Are the participants being paid no more than 'fair market value'?
- ✓ Are intended presentations to participants relevant to their role in answering the business question?
- ✓ Is this the only advisory board to address the business question at issue?
- ✓ Are the participants expected to do any preparatory work?
- ✓ Are all those involved with the meeting (staff, third parties, participants) clear on the need for and expected output from the meeting?

The choice of venue, subsistence and other costs should be at a similar level to what would be arranged if the group were paying for themselves. Honoraria may be paid[147]. If commercial organisations do pay any costs related to the meeting, this fact should be shared with all stakeholders in a written statement that also gives a description of the nature of the working relationship between the Public Contributor's organisation and the for-profit[148].

It is important that information about financial support is made public, as this can help others to judge whether there is a conflict of interest. Back in 2007, the pharmaceutical business Eli Lilly and Company gave $3.2 million to health advocacy organisations and published details of each of its 188 grants on its website, but this level of transparency was not always mirrored by the voluntary sector, as a search of the websites of the recipients found only 25% of these health advocacy organisations acknowledged Lilly's contribution[149]. The practice of patient organisations has not improved, as Mandeville et al's 2019 study of NICE technology appraisals found 72% of the patient organisations that contributed to NICE technology appraisals had recently received funding from the manufacturer

of the treatment being assessed or from a competitor, but only 21% had made this known to the decision-making committee[150]. The same research team found that 38% of those who had failed to disclose had not been asked about any conflicts of interest. Similar findings have been reported from Canada[151]. These findings reinforce the conclusions of similar studies[152] that show a common pattern of negligence regarding conflicts of interests. We can conclude that decision-making committees need to be more thorough and inquire about conflicts of interest, and patient organisations should be ethically alert and proffer that information, even when it is not requested.

Two pieces of research (one concerning the regulation of opiod use[153] and the other in tobacco control[154]) have found that patient organisations that receive funding from industry and more likely to favour the interests of that industry in their campaigning, while unfunded organisations oppose them. This may be rooted in some simple psychology through which gift recipients experience an unconscious obligation to return the favour[155].

In response, some[156] have encouraged patient organisations to disentangle themselves from industry, and Cancer Voices Australia have posted online a position statement making clear that they want to get involved with the for-profit sector, but will not accept any money for doing so, so that they maintain their independence[157]. Similarly, a few patient organisations in the UK refuse such funding[158]. Indeed, some people are so afraid that making money will distort or discredit the consultation process to such a severe extent that it is entirely invalidated, such as the Welsh Government, that has suggested that staff of public authorities should not attend or participate in any event that is chargeable, even where the event is designed as part of a public consultation process and the charges merely cover costs and are paid to a not-for-profit agency[159]. In France, all payments from commercial to patient organisations must be reported to a centralised public database[160].

In between these two extremes lies a moderate position where petty amounts are not made public, but anything substantial should be announced – for the National Health Council of America, this threshold stands at $5,000 or 2% of the voluntary health organisation's income – any more, and there is a risk of undue influence[161]. Unfortunately, psychologists have found that small gifts also affect behaviour[162]. The same organisation is concerned that a number of commercial donors may act in concert, either intentionally or unintentionally, to influence the activities, voice or reputation of the non-profit, and so ask for the overall percentage of revenue received from the for-profit sector to be made public too. Largent and team[163] would exclude any patient organisation from involvement in research if they received more than 10% of their funding from a for-profit source, and also limit the number of Public Contributors who had any affiliation with a patient organisation that received commercial funding.

One organisation[164] has recommended that any charitable donation from a commercial interest to a patient group should be unrestricted, to prevent perceived or actual 'improper influence'. Another[165] simply asks that the conditions of the funding be made public, so people can see whether the money is for a particular service or product or is an unrestricted contribution to operating costs. The manner in which the disclosure is made should be agreed between the donor and the recipient[166].

In passing, it is worth noting that some independent community groups that have allowed other organisations to 'help' them by shouldering the costs of their activities have then collapsed when the funding was withdrawn.

These standards align with the recommendation of Lord Nolan who declared that "Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interest." While those who take up a role as a Public Contributor to health research are perhaps not technically a 'holder of public office', it is reasonable to expect that people are motivated by a similar set of values relating to the public good and patient benefit. This reinforces the need for policies addressing gifts and hospitality, conflict of interests, bribery and whistleblowing.

Summary of Recommendations

1. Have an open and honest discussion about the opportunities and commercial implications of any activity undertaken by Public Contributors so that people can understand the whole developmental process, with its potential and uncertainties.
2. Check official policy documents (such as guidance for collaboration with specific industries) to ensure that understanding is accurate and complete.
3. Public Contributors to consider how they would respond to opportunities to become involved with for-profit organisations and what safeguards might be needed. It may be helpful to write a general policy document that addresses some of the issues raised in this paper and a second document that sets out the specific agreement with an individual for-profit company. This will help to avoid any misunderstandings that might arise from the different assumptions and expectations held by profit and non-profit groups. Such documents should be free of jargon and not too long[167].
4. Create a consistent, mutual and respectful approach to data protection, marketing and logos, confidential materials and intellectual property.
5. Think carefully about money, especially its impact in relation to independence, reputation and employment status. Develop a policy on gifts and hospitality, conflicts of interest and bribery.
6. Create a complaints and whistleblowing policy with independent arbitration, so that concerns can be addressed as soon as they are recognised.

Endnote: What is this document?

Most of the documents we read are finished pieces of work, carefully crafted and edited in private before being shared with anyone else. This is a different kind of paper – it was shared online here from the first day, when the initial handful of ideas were incomplete, poorly phrased and tactless. The work has been edited many times and on each occasion a revised version has replaced the earlier material online. This process is still under way, and so this paper may still be lacking crucial concepts, evidence, structure and grammar. As readers continue to provide feedback[168], further insights will be used to update it, so please contact peter.bates96@gmail.com with your contributions[169].

As an initial repository of references and ideas, it has become too long for easy digestion, so a summary version is available here that highlights the key points. It is one of a suite of documents

available here that try to open up debate[170] about how in practical terms to share decision-making in health and social care services – in research, implementation and evaluation.

This way of writing is risky, as it opens opportunities to those who may misunderstand, mistake the stopping points on the journey for the destination, and misuse or distort the material. This way of writing requires courage, as an early version can damage the reputation of the author or any of its contributors. At least, it can harm those who insist on showing only their 'best side' to the camera, who want others to believe that their insights appear fully formed, complete and beautiful in their simplicity. It can harm those who are gagged by their employer or the workplace culture, silenced lest they say something in a discussion that is not the agreed party line. It can harm those who want to profit from their writing, either financially or by having their material accepted by academic journals.

In contrast, this way of writing can engage people who are not chosen to attend the meeting or asked for their view until the power holders have agreed on the 'right message'. It can draw in unexpected perspectives, stimulate debate and crowdsource wisdom. It can provide free, leading edge resources.

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[1] Go to https://peterbates.org.uk/wp-content/uploads/2020/01/How-to-decide-whether-to-support-public-involvement-in-commercial-projects.pdf

[2] Information received from Richard Stephens (personal communication).

[3] UK Clinical Research Collaboration (2015) *UK Health Research Analysis 2014.* See here. An estimate published in 2017 suggests this has fallen to £8.3bn, made up of approximately £1bn from NIHR, £5.7bn from industry and £1.6bn from charities – see the Life Sciences Industrial Strategy. Figures are also offered by the Association of Medical Research Charities here.

[4] The 2014 Five Year Forward View, page 25, makes a clear commitment to co-designing the NHS with patients and communities. In writing this document, I have (perhaps lazily), neglected to interrogate differences in the meaning of terms like co-design, coproduction and involvement in decision-making. Using some 'shorthand' helps me to remain focused on the main discussion point of the document.

[5] NHS England (Feb 2017) *A new relationship with people and communities: Actions for delivering chapter 2 of the NHS five year forward view.* See here.

[6] The benefits of collaboration to patient groups and funders are neatly summed up by the CTTI here.

[7] See https://www.myeloma.org.uk/what-we-do/research/clinical-trial-network/ctn-trials/

[8] See https://www.myeloma.org.uk/what-we-do/research/health-services-research/

[9] Accelerated Access Review 2016, paragraph 1.5.1.

[10] Accelerated Access Review 2016, paragraph 3.5.3.

[11] Accelerated Access Review 2016, paragraph 5.7.2.

[12] Accelerated Access Review 2016, paragraph 7.2.6.

[13] See Life Sciences Industrial Strategy – A report to the Government from the life sciences sector, published 30 August 2017.

[14] See resources from NIHR Involve here, the Consultation Institute here, the NHS England Involvement Hub here, and elsewhere.

[15] See Milken Institute (2016) *Expanding the science of patient input: The power of language* here for a report that deconstructs the thinking behind terms such as patient centricity, patient engagement, patient preferences and patient perspectives. The following paper uses a Delphi approach to isolate the essential and desirable components of a definition - Baines RL, Regan de Bere S. Optimizing patient and public involvement (PPI): Identifying its "essential" and "desirable" principles using a systematic review and modified Delphi methodology. Health Expect. 2018;21:327– 335. https://doi.org/10.1111/hex.12618.

[16] Such divisions are never tidy, and some people can be considered as dually qualified, in that they bring both lived experience *and* academic or clinical expertise to the table. Our focus in this paper is to ensure that the coproduction approach includes people who have lived experience and stand outside the academic and clinical staff community.

[17] Hughes D, Williams-Jones B (2013) Coalition Priorité Cancer and the pharmaceutical industry in Quebec: conflicts of interest in the reimbursement of expensive cancer drugs? *Healthc Policy*. 9(1): 52–64.

[18] See the paper by Susannah L Rose here and results from a survey in the USA here and Europe here.

[19] If formal advice is required, readers should seek advice from the appropriate competent body or legal department.

[20] A conference on NHS/commercial/third sector partnerships is planned for February 2018 – see here.

[21] As an example, see here the 2017 call from the European Commission for research into standards for patient involvement, which is funded by a public-private partnership (PPP). EPEC is the branch of the European Investment Bank that promotes the use of public-private partnerships across Europe. They have no robust way to track the popularity of PPP as a funding mechanism as this is confounded by many other variables. However, the UK is understood to be a pioneer and world leader in the use of PPP – see here – and the 2016 Accelerated Access Review recommended catalyst funding bringing together public and private funds to stimulate promising small companies and digital healthcare solutions.

[22] Many medical and health charities actively promote public involvement in the research activities that they commission or deliver directly, as seen by the Charity Involvement Directory at http://www.invo.org.uk/charity-involvement-directory/

[23] An international example is WeGo – see http://www.wegohealthsolutions.com/

[24] The following is not an example from the perspective of Public Contributors, but it is notable that David Behan, who is the CEO of HC-One, a commercial provider of care homes, has a senior role in HEE and sitts on the board of NHSE.

[25] For more examples of commercial organisations that have responded to their customers, search the City Business Library or The Business and Intellectual Property Centre at the British Library.

[26] More details here.

[27] See an example from Carter et al here.

[28] See for example, Taylor J, Denegri S. Industry links with patient organisations. *BMJ* 2017;356:j1251.

[29] The commercial aspect could be downplayed in a ploy to win support from altruistic Public Contributors, while in contrast, I was told of a research participant who promptly withdrew from the study as soon as she found out it was commercially funded. Research by Kim et al Smith found potential research participants were less willing to engage when they heard that a commercial organisation was involved – see Kim, S. Y. H., R. W. Millard, et al. (2004). "Potential research participants' views regarding researcher and institutional financial conflicts of interest." J Med Ethics 30(1): 73-79. Available at http://jme.bmjjournals.com/cgi/content/full/30/1/73.

[30] See the EFPIA *Health Collaboration Guide 2016* available here.

[31] See data on commercial research studies from NIHR here. In addition, some organisations within the UK health service are establishing active partnership working with commercial organisations, such as the collaboration between NIHR Clinical Research Network Greater Manchester and Sanofi, described at http://www.nihr.ac.uk/news/crn-greater-manchester-named-sanofi-uk-premier-site/7943

[32] Quote taken from an advert in the NHS Improvement bulletin on 29 May 2019, inviting commercial leads to attend a networking meeting for commercial leads working in the NHS. See https://improvement.nhs.uk/news-alerts/provider-bulletin-29-may-2019/?utm_source=The%20King%27s%20Fund%20newsletters%20%28main%20account%29&utm_medium=email&utm_campaign=10589906_NEWSL_HMP%202019-05-31&dm_i=21A8,6AZ82,QZXL6D,OWZRE,1

[33] See here.

[34] See here.

[35] Drugs used in treating mental health conditions take longer to develop and have a higher failure rate, so some sectors of industry has responded by withdrawing from the field. See http://www.nature.com/news/2011/110614/full/news.2011.367.html. In response, the UK Department of Health has set a goal of increasing engagement with the pharmaceutical industry over the next decade – see DH (2017) *A Framework for mental health research,* page 28.

[36] For an example of the shift from state funding to voluntary effort, See Rosol M (2012) Community Volunteering as Neoliberal Strategy? Green Space Production in Berlin. *Antipode*, 44(1), pp. 239-257. Available here.

[37] This event was titled "Gizmos, Gadget and Widget – Public Involvement in the Development of New Technologies".

[38] These were called 'Mobilise the NHS' meetings.

[39] Greater Manchester AHSN also offers the Ignite Fund that is intended to support clinicians and academics working on early stage projects to develop solutions to unmet healthcare needs. Members of the public sit on the decision panel for this fund. Elsewhere in Greater Manchester AHSN members of the public sit on the decision panel to select industry partners for joint work with the Pharmaceutical Industry.

[40] This is the DataWell Accelerator Board. More information on Datawell is here.

[41] See Morris ZS, Wooding S & Grant J (2011) The answer is 17 years, what is the question: understanding time lags in translational research *Journal of the Royal Society of Medicine* Dec; 104(12): 510–520.

doi: 10.1258/jrsm.2011.110180. See here.

[42] "The pharmaceutical industry considers that, provided the requirements of the Code of Practice are met, working with patients and patient organisations can bring significant public health benefits. The requirements of the Code also apply to working with all user groups, such as disability associations, relative and carer associations and consumer associations." ABPI (2016) Code of Practice for the Pharmaceutical Industry, page 4. Available at http://www.pmcpa.org.uk/thecode/Documents/Code%20of%20Practice%202016%20.pdf

[43] Department of Health (2011) *Innovation, health and wealth: accelerating adoption and diffusion in the NHS.* See here. For an example of the breakdown of collaboration between the public and commercial interests, see Pam Carter, Graeme T. Laurie, and Mary Dixon-Woods. "The social licence for research: why care. data ran into trouble." *Journal of medical ethics* (2015): medethics-2014. See here.

[44] Ernest Dichter (1907-1991) is credited with developing the term 'focus group' and using the approach in his research on marketing methods.

[45] The James Lind Alliance runs Priority Setting Partnerships (PSPs), where patients are supported to identify the most important unanswered questions that researchers might address in their field. The recommendations from these PSPs are in the public domain here and could be used by the commercial sector to shape their own

research agenda, but the James Lind Alliance are not aware of any instances where this has happened (personal communication from JLA, May 2017). Weak and poorly funded patient engagement activities are a feature of the sector, as reported in 2018 survey by SCORR Marketing and Applied Clinical Trials – see https://pharmaphorum.com/patients/survey-patient-engagement-low-priority-clinical-trials/.

[46] See https://www.enlighteningresults.com/blog-index/2018/3/2/pharmas-50-shades-of-gray-including-patients-in-the-clinical-trial-life-cycle.

[47] See https://www.accenture.com/us-en/insights/life-sciences/better-together-patient-services-survey.

[48] Hansen MB, Nørgaard LS, Hallgreen CE (2019) How and Why to Involve Patients in Drug Development: Perspectives From the Pharmaceutical Industry, Regulatory Authorities, and Patient Organizations *Therapeutic Innovation and Regulatory Science* First Published August 7. https://doi.org/10.1177/2168479019864294

[49] See Consumers Health Forum of Australia and Medicines Australia (2015) *Working Together: A guide to relationships between health consumer organisations & pharmaceutical companies.* Available at https://www.chf.org.au/sites/default/files/working-together-brochure-2015.pdf

[50] See http://www.ucb.com/patients/magazine/article/Parkinson%E2%80%99s-Disease-website-More-than-Motion.

[51] It may be worth exploring the differences between market research and coproduction with the public. As a start, market researchers collect anonymised data from a large number of respondents, while public involvement tends to be more identifiable and personal in style. For regulated companies, such as the pharmaceutical industry, the anonymity of data and arms-length nature of the market research work are two mechanisms for safeguarding against accusations of exerting undue influence on patients.

[52] PatientView (2017) *The Corporate Reputation of Pharma Companies, 2016: from the Perspective of 94 UK Patient Groups (5th edition).* This report costs £2,500, but a press release is available here.

[53] There are a number of networking groups seeking to encourage collaboration between commercial healthcare and pharmaceutical industries and to encourage a patient-centred focus. They include Transcelerate, Share4Rare, IMI PARADIGM and PFMD. In August 2019, Sara Heath asserted that 85% of pharmaceutical companies are planning to ramp up their patient engagement activities in the next 18 months. See https://patientengagementhit.com/news/pharma-patient-advocacy-partnership-may-drive-patient-engagement

[54] At one pharmaceutical company a variety of things are being explored by the Patient Office. One of the more unusual is for some teams to seat a doll at the committee table to represent the patient - staff are required to 'explain it to Oscar' from time to time. Sanofi has made some progress towards their goal of becoming a 'patient-centric' organisation, and Amgen, GSK Healthcare, Roche and UCB are active participants in the PFMD discussions, along with other commercial members including AstraZeneca, Janssen, MSD and Pfizer. Meanwhile, the UK is using live patients to help select candidates for nurse training (see here), as the patients can detect real respect and compassion in contrast to lip service, but this is not a part of staff recruitment in the commercial sector. (from discussions at the PFMD workshop 27 April 2017.

[55] See ABPI (2019) *Working with patients and patient organisations.* London: ABPI. Available at http://www.abpi.org.uk/media/6948/abpi_workingwithpatients_webbrochure_v5.pdf. It is notable that this document provides a definition of expert patient that almost entirely ignores the recovery movement's own definition of expert, that is the patient who knows more than anyone else about how to successfully live their own life with their own symptoms.

[56] UKCRC data for 2014, shown at Table 2 here indicates the for-profit sector contributes 48%, while the Clinical Research Network here shows that 33% of the portfolio is funded by the life science industry. These may be subtly different parameters, but together they show that a substantial proportion of the overall activity is funded by the commercial sector.

[57] See Health Research Authority (2017) *UK policy framework for health and social care research* para 9.10 here.

[58] See Tarpey M and Bite S (2014) *Public involvement in research applications to the National Research Ethics Service: Comparative analysis of 2010 and 2012 data* Southampton: NIHR Involve and the Health Research Authority. See the report here.

[59] See the international overview of patient participation in medicines development here.

[60] See Staley 2012, available here.

[61] 65% of commercial studies achieved recruitment to time and target in 2015-16,compared to 76% of non-commercial studies – see here. Since then, recruitment has improved, but commercial studies continue to lag. With support from NIHR CRN, in 2019-20, 87% of non-commercial studies recruited to time and target while only 70% of commercial studies did so – see https://www.nihr.ac.uk/news/a-team-effort-performance-figures-for-the-clinical-research-network/25172.

[62] See https://druginnovation.eiu.com/patient-centric-trials/summary/patient-centric-trials-summary/. Drugs developed using patient-centric designs had an 87% chance of being launched, while the figure for the control group was 68%.

[63] Whitty JA. An international survey of the public engagement practices of health technology assessment organizations. *Value Health* 2013;16:155-63. Doi:10.1016/j.jval.2012.09.011. Also Kreis J, Schmidt H. Public engagement in health technology assessment and coverage decisions: a study of experiences in France, Germany, and the United Kingdom. *J Health Polit Policy Law* 2013;38:89-122. Doi:10.1215/03616878-1898812.

Also Health Technology Assessment International. Good practice Health Technology Assessment International. Good practice examples of patient and public involvement in health technology assessment. 2015. https://htai.org/wp-content/uploads/2018/02/Good_Practice_Examples_Feb_2015.pdf.

[64] See, for example, the National Institute of Health Research twitter feed on its work with industry at https://twitter.com/NIHR_Industry?t=1&cn=ZmxleGlibGVfcmVjcw%3D%3D&refsrc=email&iid=41dd59e557b14d0295247a0369074d71&fl=4&uid=201621953&nid=244+290062361

[65] See Bates P (2020) *How to manage overlapping roles in public involvement in research.* Available at https://peterbates.org.uk/wp-content/uploads/2019/11/How-to-manage-overlapping-roles.pdf.

[66] The 2014 bibliography here produced for NIHR Involve runs to 205 pages.

[67] National Institute for Health Research (2018) *Patient Engagement in Clinical Development: Information sheet for life sciences organisation* Version 1.0 – 02 October 2018. Available at https://www.nihr.ac.uk/funding-and-support/documents/study-support-service/Early-contact-and-engagement/pecd/Information-Sheet-for-Life-Sciences-Organisations.pdf

[68] The contract for delivery of NIHR Involve was held by the University of Southampton from 2015 to 2020 and will then transfer to a global private company, LGC Group.

[69] See here.

[70] See the PFMD project initiation document here.

[71] For examples of marketing materials that promote participation in health research without reference to the profit component or the potential for input by Public Contributors, see here and here. The 'Dragon's Den' event here provided an excellent opportunity for the for-profit sector to seek advice from Public Contributors, but the written information makes no reference to the profit/non-profit issue.

[72] See for example, the 2018 survey by the Health and Social Care Alliance for Scotland at https://www.alliance-scotland.org.uk/blog/news/questionnaire-via-eupati-uk-gsk/

[73] Association of Medical Research Charities (2014) *An essential partnership: a guide for charities working with industry.* See here.

[74] Some companies are actively seeking funds from charitable organisations to help them pursue their research and innovation agendas – see here.

[75] This statement is highly contested. Best practice in involving experts by experience in research is usually presented as a paid-for activity, rather than volunteering, while many NHS and other health and social care services engage people in service design and evaluation and make no payment for this expertise whatsoever. For some, payment is a means of acknowledging the expertise of the Public Contributor, while for others it muzzles their voice and tames their critical independence. Even where payment is offered, the majority of Public Contributors in the UK are not employed in this role, subject to performance monitoring and disciplinary processes. For a discussion of definitions of volunteering that include for-profit settings and payments, see the report from the Institute of Volunteering Research here.

[76] See *Charities and Commercial Partners* , available here. General advice from the Charities Commission about entering into partnerships is found here.

[77] See, for example, the report here.

[78] See the charter that was agreed by the TUC and Volunteering England in 2009 here.

[79] In response to an email inquiry sent out in March 2017, 4 volunteer centres explained that they confine their work to charities and non-profits. 2 centres include social enterprises and community interest companies. 1 centre has engaged with employee-supported volunteers (ESV) from the gambling industry. 1 centre treats community interest companies on a case by case basis. 1 centre charges ESV initiatives whenever possible and reinvests any surplus in providing services. 1 centre works with non-profits and ESV. 1 centre has very occasionally placed a volunteer in a for-profit setting under carefully controlled conditions. 1 centre places people in commercial settings that meet the requirements for effective volunteer support if the unpaid work experience will improve their opportunity to gain the waged employment they desire. Before deciding how to respond to invitations from for-profit organisations, one Centre does an internet search to inform the decision about whether the company is deemed to be ethical. One centre will place volunteers in commercial care homes, but only as supernumerary roles such as reading to residents rather than catering or personal care. There are also a range of responses about how to deal with requests from statutory agencies. Despite these variations in practice, most respondents reject the suggestion that this issue is a delicate one, feeling that their own perspective is the obvious, straightforward and ethical solution.

[80] As itemised in the endnote above.

[81] The 2017 paper here challenges the validity of these 'binaries' that contrast paid with unpaid, contractual with optional and so on. There are exciting innovations, such as Experience Based Co-Design, but such developments tend to focus on how to bring people together and draw out ideas, rather than addressing the basic question of how Public Contributors view commercial industry. Similarly, legal structures such as Community Interest Companies lie between profit motivated and community focused entities, while work experience placements such as internships fall between conventional employment and volunteering. The case for development of an academic specialty to study the relationship between non-profits and commercial organisations has been made here.

[82] See, for example, Austin JE, Seitanidi MM (2012). Collaborative value creation: A review of partnering between nonprofits and businesses. Part 2: Partnership processes and outcomes. *Nonprofit and Voluntary Sector Quarterly* 41(6):929–68.

[83] See the webpage on Employer-Supported Volunteering here or this review by Pajo & Lee that found that altruism, task significance and relational components all enhance the experience.

[84] Long and detailed advice on managing these issues in a Clinical Commissioning Group has been issued here.

[85] It would be helpful to point to an example of such a policy designed for Public Contributors and commercial organisations here. Even better would be a policy that was designed to show the reciprocal responsibilities of both parties, rather than a one-sided document that merely held the Public Contributor to account. The Bribery Act (UK) or the Foreign Corrupt Practices Act (USA) may be relevant here.

[86] Mandeville KL, Barker R, Packham A, Sowerby CKielan Yarrow K & Patrick H (2019) Financial interests of patient organisations contributing to technology assessment at England's National Institute for Health and

Care Excellence: policy review *BMJ* http://dx.doi.org/10.1136/bmj.k5300. They note that the Scottish Medicines Consortium asks patient organisations to provide details of previous pharmaceutical industry funding and this information is updated annually and attached to each of their submissions. See also https://blogs.bmj.com/bmj/2019/01/16/jeremy-taylor-financial-interests-of-patient-organisations/.

[87] Cain DM, Loewenstein G, Moore DA. The Dirt on Coming Clean: Perverse Effects of Disclosing Conflicts of Interest. *J Legal Studies* 2005;34:1-25.

[88] See IAPO (2014) *Consensus Framework for Ethical Collaboration between Patients' Organisations, Healthcare Professionals and the Pharmaceutical Industry* http://iapo.org.uk/sites/default/files/files/Consensus_Framework-vF.pdf

[89] See https://www.novartis.com/news/spelling-out-what-patients-can-expect-novartis. Also https://www.novartisoncology.com/patients-and-caregivers/patient-declaration#ui-id-1=0. Further information from Šarūnas Narbutas, President of Lithuanian Cancer Patient Coalition.

[90] See Bodenheimer T. Uneasy alliance. *N Engl j Med.* 2000; 342(20):1539–44. https://doi.org/10.1056/NEJM200005183422024 PMID: 10816196. Also Tasker J, Wiseman R, Bolton P, Tipper S. Collaborating to manage polypharmacy. *Aust Health Rev.* 2001; 24(3):80–90. PMID: 11668931

[91] See the National Health Council (2017) *Standards of Excellence Certification Program for Voluntary Health Agencies* Standard 31. Available here.

[92] See here.

[93] The European Patients Forum has developed a definition of a patient centred company here, and the National Health Council offers a sample Corporate Relations Policy on pp 57-60 of its Standards of Excellence for Voluntary Health Agencies.

[94] Transparency International (2016) *Corruption in the Pharmaceutical Sector*. Available at http://www.transparency.org.uk/publications/corruption-in-the-pharmaceutical-sector/#.WmL1fqhl_IU Angel argues that the seriousness of conflict of interest between the medical profession and the pharmaceutical industry is so great that commercial organisations wishing to conduct research need to relate to medical researchers via an independent intermediary, such as a Government department. See Angell M (2008) Industry-sponsored clinical research: A broken system. *The Journal of the American Medical Association.* 300:1069–1071. The research world is affected too, as illustrated by the fact that a specific type of research bias has been named as 'Industry Sponsorship Bias', and evidence presented to show that research evidence can change to favour the funding sponsor – see https://catalogofbias.org/biases/industry-sponsorship-bias. For an example, see Bero L (2007) Factors associated with findings of published trials of drug–drug comparisons: why some statins appear more efficacious than others. *PLoS Medicine,* 4(6), e184.

[95] For comparison, the World Health Organisation explicitly rejects engagement with industries that harm public health, including specifically tobacco and armaments. See here. Similarly, the British Heart Foundation refuses any collaboration with the tobacco industry – see here.

[96] This is one of the recommendations made by the European Patients Forum here and supported by the patient campaign group Just Treatment. The UK Government has recently taken action to limit excesses through the Health Service Medical Supplies (Costs) Act 2017 – see a factsheet here. There are numerous examples of anti-patient profiteering practices by pharmaceutical companies, including (i) Activas UK charged the NHS £1.07 a pack for 20mg hydrocortisone tablets in April 2008 and had increased the price to £102.74 by March 2016. See here. (ii) After Aspen bought the rights to the leukaemia medicine Busulfan, the price was reported to increase from £5.20 to £69.02 per pack in England and Wales after Aspen threatened to withdraw supplies from the Italian market. (iii) In the USA, the drug Spinrasa costs $750,000 in the first year and patients need to be take it for life – see here. (iv) The UK Competition and Markets Authority found that Concordia charged the NHS excessive prices for its thyroid drug Liothyronine. In 2016, the NHS spent more than £34 million on the drug, an increase from around £600,000 in 2006. They charged £4.46 per pack in 2007, rising to £258.19 by July 2017 – see here. (v) From 2015 to 2019, the pharmaceutical company Vertex held the NHS to ransom regarding its cystic fibrosis drug Orkambi which can lengthen the life of patients. NICE calculated a fair

price, but Vertex asked for far more, so talks deadlocked and perhaps 200 patients died. A group of families worked with Just Treatment to form a buyer's club using an exemption in patent law that permits individuals to import generic Orkambi from Argentina at a fifth of the price. In the face of this, Vertex finally gave in and accepted the NHS offer of £500 million over 5 years. (vi) In 2020, pharmaceutical companies Amilco, Tiofarma and Aspen were convicted of breaking competition law relating to the supply of Fludrocortisone to the NHS. This is a prescription-only medicine used to treat Addison's Disease. Amilco and Tiofarma were paid by Aspen to stay out of the market so that Aspen could gain the monopoly and increase the price by up to 1800%. (vii) The drug companies Bayer and Novartis own a drug called Avastin that costs £30 per injection. It was licensed to treat cancer but has also been found effective in treating wet AMD, the commonest cause of blindness in the UK. Its competitor drugs cost around £500 per dose, so using Avastin for this purpose will save millions of pounds. Bayer and Novartis have opposed this change through the courts, finally losing their fight in November 2020. (viii) In 2022, Martin Shkreli was barred for life from the pharmaceutical industry and fined $64.6m by a US court. He was chief executive of Turing Pharmaceuticals that in 2015 hiked the price of Daraprim, a drug used to treat Aids, malaria and cancer, by more than 5,000%. Shkreli focused his venture on acquiring sole-source drugs that were the gold standard treatment option for life-threatening diseases with a small patient population and inferior alternative treatments, with the intent to raise their prices, block generic competition, and reap extraordinary profits. See Martin Shkreli barred from drug industry and fined $64.6m by US court | Martin Shkreli | The Guardian.

[97] British drugmaker AstraZeneca promised in June 2020 not to make any profit from its COVID-19 vaccine during the pandemic. Despite this, they are charging South Africa £4.32 per dose, compared with £1.78 in the UK – see https://www.theguardian.com/world/2021/jan/22/south-africa-paying-more-than-double-eu-price-for-oxford-astrazeneca-vaccine?CMP=Share_AndroidApp_Other.

[98] In 2021, Cygnet Healthcare increased the pay of its boss by £4450,000 in a year when nine of its forensic hospitals failed – see https://www.dailymail.co.uk/news/article-7832979/Boss-private-mental-health-firm-receives-445-000-pay-rise-despite-hospitals-failing.html.

[99] Between 2000 and 2011, only 4% of newly approved pharmaceutical products were for neglected diseases that affect middle and low-income countries. Most innovation was focused on profiting from chronic conditions in wealthy countries. See UCL Institute for Innovation and Public Purpose (2018) *The people's prescription: Re-imagining health innovation to deliver public value*, IIPP Policy Report, 2018-10. London: IIPP, Global Justice Now, Just Treatment, STOPAIDS. Available at: https:// www.ucl.ac.uk/bartlett/public-purpose/wp2018-10.

[100] NHS England are developing a NHS Supplier Framework for Patient and Public Participation services (contact Jonathan Leahy), and have made resources available on meeting social value requirements in all procurement activities – see here.

[101] In 2018, in a row over open-access arrangements and profit, the publishing giant Elsevier blocked German scientists from accessing its recent journal articles – see here. At least in the short-term, Elsevier demonstrated by this action that it was more interested in profit than patient benefit. Public Contributors may favour ethical publishers over those who are simply profiteering.

[102] Article 7 of the Marketing Research Association Code of Marketing Research Standards

[103] See the Genetic Alliance *Ethical Collaboration Policy* here.

[104] See the EFPIA *Health Collaboration Guide 2016* available here.

[105] For a brief introduction to intellectual property rights, see here.

[106] There is a particular concern that marketing which makes claims about the superiority of one product over others should not be endorsed by a charity or patient organisation unless they are fully convinced that they hold convincing evidence that the claims are supported by science. See the National Health Council (2017) *Standards of Excellence Certification Program for Voluntary Health Agencies* Standard 31. Available here.

[107] This position is taken in the USA by the National Health Council (2017) *Standards of Excellence Certification Program for Voluntary Health Agencies* Standard 31. Available here. Promoting any specific kind of pharmaceutical product is prohibited by the EFPIA Code of practice – see here. One set of guidelines developed by patients endorsed this approach – see Stein S, Bogard E, Boice N, Fernandez V, Field T, Gilstrap A, Kahn SR, Larkindale J, Mathieson T (2018) Principles for interactions with biopharmaceutical companies: the development of guidelines for patient advocacy organizations in the field of rare diseases. *Orphanet journal of rare diseases.* Dec 1;13(1):18.

[108] Where there is a contract between a commercial organisation and a non-profit, such as a university research department, attempts have been made to define processes that allow for academic publication and the acquisition of commercial patents (see here for an example). Such legal contracts are unlikely to be effective for small and informal patient groups or individual public contributors.

[109] Blumenthal D, Causino N, et al. (1996). Relationships between Academic Institutions and Industry in the Life Sciences -- An Industry Survey." *N Engl J Med* 334(6): 368-374.

[110] CTTI recommend that a Memorandum of Understanding be agreed between Patient Groups and the commercial organisation – see here. PFMD has developed some model agreements between commercial and patient organisations – see here. The UK Government has made available a variety of templates here, including a Mutual Non-Disclosure Agreement. The UK Government Intellectual Property Office has issued some model agreements for use when a university is planning a collaboration with business, and one of these offers a format in which "Each member of the consortium owns the intellectual property in the results that it creates. They grant each other party a non-exclusive licence to use those results for the purposes of the project only. If any member of the consortium wishes to exploit another's intellectual property they must negotiate a license or assignment with the owner of that intellectual property." See the Lambert Toolkit here that also includes some 'heads of terms' templates here that provide a framework for negotiating an agreement. Such models are designed for large organisations rather than small community groups, but nevertheless may contain some useful insights.

[111] See, for example, the work of Health Enterprise East at http://www.hee.org.uk/.

[112] In sum, opinion favoured sharing identifiable data for clinical reasons, and de-identifiable data for research purposes. When profit was introduced, net opinion shifted to an equal balance between supporters and opposers. See Jones LA, Nelder JR, Fryer JM, Alsop PH, Geary MR, Mark Prince M, Cardinal RN (preprint 2021), Public opinion on sharing data from UK health services for clinical and research purposes without explicit consent. doi: https://doi.org/10.1101/2021.07.19.21260635.

[113] Association of British Pharmaceutical Industries and National Voices (undated) *Working together, delivering for patients: A guide to collaboration between charities and pharmaceutical companies in the UK* offers four key principles: clarity of purpose, integrity, independence and transparency. See here.

[114] For an example from oncology, see here. If there is a poor fit between the values promoted by the PPI group and those promoted by the commercial organisation, then the partnership between them can lead to a loss of commitment and engagement from individuals. See the evidence here.

[115] Some industries use Cause-Related Marketing and donate a percentage of sales to a charity. One review here found that such activities could soothe the conscience of the customer and divert their attention away from structural questions. So, in this example, the American gun industry has formed a partnership with the Foundation for Suicide Prevention.

[116] Langdon-Neuner, E. (2008). Medical Ghost-Writing. *Mens Sana Monographs*, 6(1), 257–273 available here. The point is made in the following quote: 'Pressure on academics that can lead to misconduct comes from the association of academic institution with industry, such as when investigators or their institutions hold patents or shares, or they receive payments from industry, so that there is financial pressure to publish research that will be profitable for the company and to suppress "negative" findings.' This was in the evidence from Dr Peter Wilmshurst to the UK Government's Science and Technology Committee, March 2017 – see here. Similarly,

Lignou & Singh note that pressure from pharmaceutical companies can discourage contrary viewpoints and delay the release of research results. See also American Association of University Professors (2014) *Recommended Principles to Guide Academy–Industry Relationships*. Champaign, IL: University of Illinois Press, as referenced in Lignou S & Singh I (2020) Pharmaceutical industry, academia and people with experience of mental illness as partners in research: a need for ethical guidance [version 1]. *Wellcome Open Research* Downloaded from https://orcid.org/0000-0003-4497-35871 on 23/9/20. Pressure from commercial and academic interests, as well as from public contributors can delay the decision to suspend the research in response to a serious adverse incident – see WMA (2013) *Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects*. Fortaleza. When research supports the use of a particular pharmaceutical product, the manufacturer will buy large numbers of reprints from the publisher to give to commissioners and prescribers, so both the manufacturer and the publisher profit from these more than negative findings. Publishers also tend to be reluctant to publish retractions or failures to replicate, as these items cast doubt on their ability to select the best submissions.

[117] Chaudhry S, Schroter S, Smith R, Morris J. Does declaration of competing interests affect reader perceptions? A randomised trial. *BMJ*. 2002;325:1391–1392.

[118] Tessa Richards has indicated that these issues are being discussed at the BMJ (personal communication 7 May 2017). COPE has no specific guidance, simply referring to their general guidance here and discussion documents here (personal communication 7 May 2017).

[119] PatientsIncluded have no such guidance (personal communication 2 May 2017).

[120] Paragraph A30 of the 2016 ABHI Code of Practice says, "A Member Company may provide an Educational Grant to support the provision of high quality information to patients and the public about health and disease provided there is an objective patient or public need for such information and the topics covered are linked to the therapeutic areas in which the Member Company is interested and/or involved. Such disease awareness campaigns must not, however, promote the use of particular therapies, services or promote specific healthcare organisations, nor may they aim to stimulate demand by the public for specific therapies or for specific Healthcare Organisations.

[121] Clause 12.2 of the ABPI Code of Practice says, "Market research activities, clinical assessments, post-marketing surveillance and experience programmes, post-authorization studies (including those that are retrospective in nature) and the like must not be disguised promotion. They must be conducted with a primarily scientific or educational purpose."

[122] Clause 27.1 of the ABPI Code of Practice.

[123] The term 'astroturfing' refers to "the creation of a fake grassroots organization to create the perception that there is public support for an industry agenda." Sprout Pharmaceuticals financed a group called 'Even the Score' that dishonestly claimed effectiveness for a drug called Addyi. See Largent EA, Fernandez Lynch H, & McCoy MS (2018) Patient-Engaged Research: Choosing the 'Right' Patients to Avoid Pitfalls *Hastings Center Report* 48, no. 5 (2018): 26-34. DOI:10.1002/hast.898.

[124] The fear of censure is not a trivial matter – in 2014, GSK healthcare was fined $490 million for bribing doctors to promote their drugs in China. But fears of censure can lead to over-reaction. For example, some bodies (European Cancer Congress, Amsterdam 2013; ESMO14) have refused patients access to their conference or exhibition for this reason – see here. Paragraph A30 of the ABPI Code of Practice has been used to justify refusing access to any area where pharmaceutical products are being advertised, according to Martin Lodemore, and pharmaceutical companies would withdraw from exhibitions which opened to the public, thereby denying income to the organisers (personal communication, 5/6/2018). The following inquiry was sent to APBI (who forwarded it to PMCPA) 5/6/2018 '*I am seeking clarification on Clause 26 of the 2016 Code of Practice. This very helpfully prohibits advertising of particular products to the public and avoids any semblance that the pharmaceutical company is slipping into the role of prescriber. In contrast to this valuable advice we have the growing interest in patient-centric approaches across the sector, and I am wondering how the balance is achieved. I guess the sharpest example is found where a healthcare conference is held that includes an*

exhibition where pharmaceutical companies present their products. In this situation, doctors, nurses and NHS commissioners are allowed into the room, despite being members of the public, but patient organisations are sometimes excluded, despite carrying a specific role, perhaps as advisers to a research project. It seems to be that the Code of Practice cautions against any attempt to stimulate patient demand, and this is right and proper, but some pharmaceutical companies appear to me to be taking an extreme reaction to this by locking patient organisations and their representatives out of the exhibition hall or withdrawing themselves from the exhibition should they be warned that patients may be present. It seems to me that there is a more sophisticated approach to be taken than simply admitting patients who happen to have the role of healthcare professionals and banning patients who happen to be engaged with patient organisations. After all, shutting people out is a pretty ineffective way of creating partnership! I wonder if this has been discussed by ABPI or PMCPA? I'd be grateful for any thoughts or position statements you may have about this delicate balancing act!' The answer to this inquiry can be found in ABPI's 2019 publication *Working with patients and patient organisations* that endorses the exclusion of patients from anything that may be seen as promoting particular prescribed medications, whether speeches or poster presentations. Another pharmaceutical company, on hearing that a conference had been held close to a golf course, demanded previously paid and spent funding to be returned as it was now redefined as 'excessive hospitality'. (personal communication, PFMD workshop 27 April 2017).

[125] In a survey of relationships between drug companies and patient organisations in Finland found that threats to independence was a common problem. See here.

[126] Lin DH, Lucas E, Murimi IB, Kolodny A, Alexander GC. (2016) Financial conflicts of interest and the centers for disease control and prevention's 2016 guideline for prescribing opioids for chronic pain. *JAMA Intern Med* 2017;177:427-8. DOI:10.1001/jamainternmed.2016.8471.

[127] Both the Charity Commission and NCVO recommend that charities should have multiple and diverse funding streams to increase their stability should one funding stream dry up. See here, page 31. As an example, the British Heart Foundation will work with consortia such as the Association of British Healthcare Industries, but not with individual companies – see here.

[128] See https://www.gov.uk/government/publications/pain-uk-regulatory-compliance-caseconclusions/pain-uk-regulatory-compliance-case-conclusions.

[129] See more at http://breastcancernow.org/about-us/the-breast-cancer-now-catalyst-programme?deep_link=Catalyst

[130] Simply hearing recommendations from public contributors does not guarantee their adoption, so for that to take place, some other conditions need to be met. These are explained here.

[131] Nolan said that those who occupy a role in public life should not do so to gain financial or other material benefits for themselves, their family, or their friends." So we might ask, What is a reasonable remuneration and other material benefits for being involved with commercial interests? Kathy Oliver (personal communication 25 April 2017) suggested that some patient organisations expect expert patients to receive 500 euros per day. Can anyone suggest an example of gaining undue benefits for themselves their family or friends?

[132] See this 2014 guidance from the Health Research Authority.

[133] See Lynch HF, Darton T, Largent EA, Levy J, McCormick F, Ogbogu U, Payne R, Roth AE, Shah AJ, & Smiley T (2020) Ethical payment to participants in human infection challenge studies, with a focus on SARS-CoV-2: Report and recommendations. Downloaded from https://ascopubs.org/doi/full/10.1200/JCO.19.00250. Page 15, recommendation 19. This topic is further discussed in Beskow LM (2016) Lessons from HeLa Cells: The Ethics and Policy of Biospecimens. *Annu Rev Genom Hum Genet* 17(1):395–417.

[134] For example, see NHS England's Guide to payments here and NIHR INVOLVE's guide here.

[135] The Disclosure UK database, created by ABPI, is described here. Transfers to Patient Organisations are required to be published annually on the pharmaceutical company's website in line with the Code of Practice clause 27.7.

[136] One volunteer centre reported that 'we advise volunteers to check with DWP if unpaid work for a business will affect any benefit entitlement. We have historic cases where DWP have suspended benefit for volunteers in privately run care homes.' (personal communication, 14 March 2017). When public contributors move from advising charities to advising commercial organisations and when they move from research to implementation, they may find the HMRC remove the designation of volunteering.

[137] People who participate in clinical research are allowed to receive participation payments and reimbursement of expenses without affecting their tax liability (see here). HMRC count people who work in charities or voluntary organisations and receive no more than reimbursement of receipted expenses as volunteers rather than employees for the purposes of calculating tax credits (see here).

[138] For example, an unpaid intern was required to do the work of an employee and challenged the case with Sony, who eventually awarded him the wage he should have been paid from the outset. See here.

[139] See Government guidance from 2015 here that reinforces the definition of volunteering as a contribution to charitable, community or statutory activities in contrast to commercial undertakings. Where activities become part of the commercial world then regulation such as National Minimum Wage rules are more likely to apply. Advice about any participation payments made over and above receipted reimbursement of expenses to Public Contributors involved in research funded by Government or charities can be found here. It is important to keep in mind that a contract of employment can be implied or verbal and does not require a document to be upheld in law.

[140] See https://www.gov.uk/volunteering/when-you-can-volunteer. Sections 18(1)(a) and 18 (2) (ia) of the Children and Young Persons Act 1933 (see here) states that a person under the age of 14, or in certain circumstances, under 13, may not work. Section 30 says that a such a person who assists in a trade or occupation carried on for profit is considered as employed even though he or she may receive no payment. The UK Government Department for Children, Schools and Families considers that in today's circumstances, "any occupation where the aim is to make a surplus would be considered as a trade or occupation carried on for profit, so unpaid work at a charity shop would count as employment, but not, for example, unpaid work at a youth club." (DCSF, 2009, p4 - See here). DCSF pointed to this advice as still valid in response to an inquiry in September 2017.

[141] See here.

[142] See here.

[143] In the USA, PCORI have designed a framework that suggests that financial compensation for Public Contributors should be proportionate to contribution. See it here.

[144] Incentives are acceptable, while anything viewed as an inducement to participate is prohibited.

[145] See ABPI (2019) *Working with patients and patient organisations* page 11.

[146] See ABPI (2019) *Working with patients and patient organisations* page 14.

[147] These principles were written for pharmaceutical industries but can be reasonably adopted across the whole for-profit sector. See Clause 27.2 of the ABPI Code of Practice which says, "Pharmaceutical companies may appropriately hold or sponsor a wide range of meetings. These [include]… advisory board meetings… patient support group meetings."

[148] Clause 27.3 of the ABPI Code of Practice.

[149] Rothman SM, Raveis VH, Friedman A & Rothman DJ (2011) Health Advocacy Organizations and the Pharmaceutical Industry: An Analysis of Disclosure Practices *Am J Public Health*. 2011 Apr; 101(4): 602–609. doi: 10.2105/AJPH.2010.300027. See here. Similar findings were published in 2017, showing little had changed

see ↵Rose SL, Highland J, Karafa MT, Joffe S. Patient advocacy organizations, industry funding, and conflicts of interest. JAMA Intern Med 2017;356:344-50. doi:10.1001/jamainternmed.2016.8443 pmid:28114624. Also

McCoy MS, Carniol M, Chockley K, Urwin JW, Emanuel EJ, Schmidt H. Conflicts of interest for patient-advocacy organizations. N Engl J Med 2017;356:880-5. doi:10.1056/NEJMsr1610625 pmid:28249131.

[150] Mandeville et al op cit. Also Pike H (2019) Patient groups fail to declare financial interests during NICE assessments *BMJ*; 364 doi: https://doi.org/10.1136/bmj.l217 (Published 16 January 2019). Available at https://www.bmj.com/content/364/bmj.k5300?ijkey=2660a3aa6f8e999f0b637d11d3e271588ba8e3b5&keytype2=tf_ipsecsha

[151] Lexchin J (2022) Donations Made and Received: A Study of Disclosure Practices of Pharmaceutical Companies and Patient Groups in Canada *International Journal of Health Policy and Management*, 11(10), pp. 2046-2053. doi: 10.34172/ijhpm.2021.172.

[152] Abola MV, Prasad V (2015) Characteristics and conflicts of public speakers at meetings of the oncologic drugs advisory committee to the us food and drug administration. *JAMA Intern Med* 2016;176:389-91. doi:10.1001/jamainternmed.2015.7805. **Also** Perehudoff K, Alves TL (2010) *Patient and consumer organisations at the European Medicines Agency: Financial disclosure and transparency* Health Action International. **Also** Lin DH, Lucas E, Murimi IB, Kolodny A, Alexander GC (2017) Financial conflicts of interest and the centers for disease control and prevention's 2016 guideline for prescribing opioids for chronic pain. *JAMA Intern Med*;177:427-8. DOI:10.1001/jamainternmed.2016.8471. Also Ozieranski P, Rickard E, Mulinari S (2019) Exposing drug industry funding of UK patient organisations. *BMJ*. 365: 1806.

[153] Lin DH, Lucas E, Murimi IB, Kolodny A, Alexander GC. Financial conflicts of interest and the Centers for Disease Control and Prevention's 2016 Guideline for Prescribing Opioids for Chronic Pain. JAMA Intern Med. doi:10.1001/jamainternmed.2016.8471.

[154] Apollonio DE, Bero LA. The creation of industry front groups: the tobacco industry and "get government off our back". *Am J Public Health*. 2007 Mar; 97(3):419-27.

[155] Cialdini RB. *Influence: Science and practice.* 4th ed. Boston: Allyn & Bacon; 2001.

[156] Moynihan R, Bero L. Towards a healthier patient voice: more independence, less industry funding. JAMA Intern Med 2017;356:350-1. doi:10.1001/jamainternmed.2016.9179 pmid:28114596. Also Batt S (2017) *Health Advocacy, Inc.: How Pharmaceutical Funding Changed the Breast Cancer Movement.* Vancouver: UBC Press. Also Goldacre B. *Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients.* New York: Faber and Faber; 2012.

[157] See their position statement here.

[158] Mandeville et al op cit found two of the 53 patient organisations they studied had decided not to accept any funding from pharmaceutical or health device manufacturers.

[159] This relates to an event planned for 6 September 2017 – see here.

[160] Santos AI (2017) *The Sun Shines on Europe: Transparency of financial relationships in the healthcare sector.* Health Action International.

[161] This includes business expenses and excuses any disclosures that are prohibited by law, as well as direct payments for services, such as book sales. Rules are relaxed for small non-profit organisations. The threshold for organisation size and donation size is set by tax laws within the USA that require auditing and reporting, so a similar principle may apply in other jurisdictions. See the National Health Council (2017) *Standards of Excellence Certification Program for Voluntary Health Agencies* Standard 31. Available here. Pfizer publish information about their grants to patient organisations, and the proportion of the patient organisation's income that this grant makes up – see here.

[162] Grande D, Frosch DL, Perkins AW, Kahn BE. Effect of exposure to small pharmaceutical promotional items on treatment preferences. *Arch Intern Med* 2009;169:887-93.

[163] Largent EA, Fernandez Lynch H, & McCoy MS (2018) Patient-Engaged Research: Choosing the 'Right' Patients to Avoid Pitfalls *Hastings Center Report* 48, no. 5 (2018): 26-34. DOI:10.1002/hast.898.

[164] CTTI made this recommendation here.

[165] See the National Health Council (2017) *Standards of Excellence Certification Program for Voluntary Health Agencies* Standard 31. Available here.

[166] See the National Health Council (2017) *Standards of Excellence Certification Program for Voluntary Health Agencies* Standard 31. Available here.

[167] Gordon Oliver was involved with a survey that found most contracts between pharmaceutical companies and patient advocacy organisations were little read because they were too long, complex and incomprehensible. Contracts with patient organisations tend to be longer and more complex than those witten for use with private individuals as there is an increased risk that the pharmaceutical company will be accused of attempting to exert undue influence (personal communication, PFMD conference 25 April 2017). See https://www.mpeurope.org/legal_agreements/.

[168] Contributions and challenges to this discussion have been offered by Cara Afzal, Shahnaz Aziz, Cath Bavage, Marc Boutin, Esther Bromley, Nicholas Brooke, Nick Brown, Sarah Carr, Pam Carter, Fabian Davis, Hildegard Dumper, Carole Fogg, John Gallanders, Kelly Garrity, Paul Harvey, Elina Hemminki, Jane Hobson, Lee Hunt, Karen Inns, Rebecca Jarvis, Jessica Langton, Liz Lesquereux, Anita Mangan, Claire Nolan, Nick Ockenden, Debbie Parkinson, Helen Price, Duncan Purslow, Julie Repper, Mary Rogers, Paul Simms, Mike Slade, Jean Southey, Andrew Spong and Nicki Thomas. All the mistakes and errors of judgement are my responsibility! Requests for discussion sent in Feb 2017 to a number of PPI leads in universities, Survivor Research Network (NSUN), Simon Denegri (NIHR Involve), ABHI, BiTC, NEF, Work Foundation, UKCRC, Rebecca Taylor of the Work Futures Research Centre, CISCRP, EPF, Acres, IMI, Sue Brown from MindTech, Roslyn Schneider at Pfizer, UCB, Prof Margaret Harris (Aston), ARNOVA, Courtney Jensen (EWU), ELF, Milken Institute, National Voices, DIA, Parkinson's Disease Foundation, ACRO, Suresearch, and HRA. In June, further inquiries were sent to Alkermes, Biogen, Celgene, FasterCures (Lisa Simms), FDA (Andrea C. Furia-Helms at the Patient Engagement Advisory Committee), ICPV (Pat Fairbrother), Vertex. The following responses were received indicating that they had nothing to add to the discussion: James Munro (Patient Opinion), IAVE, Sue Ashby, Iain Upton, Irene Hardill, Stephen Jeffreys, York Volunteer Centre, Angela Stocks, Kath Evans, Terry Williams. Merck do not have an email address in the public domain, although Luther Clark is their Global Director, Scientific Medical and Patient Perspective. Inquiries sent in June 2017 to Chambers of Commerce listed here that offer an email address – no useful responses.

[169] Undated or early versions should be replaced with the most recent, available here. It is sincerely hoped that this document will soon be augmented by a more succinct version and/or superseded by a replacement from a more authoritative source.

[170] The draft document has been available online from day one of the project and over 120 people have been invited to suggest improvements, alongside any other reader who takes an interest. This attempt at coproduction has been subject to the following perceived challenges and criticisms: (i) a view that the result will be unwanted, invalid or even harmful as its development has not been entirely controlled and delivered by experts by experience; (ii) a view that another organisation or individual is the right agency to drive the development agenda and so others have no business taking this initiative; (iii) a view that staff should be prevented from participating in the discussion until they are authorised to deliver the official response of their corporate body; (iv) a view that a subgroup should carry out the first iterations prior to sharing it with a wider constituency or with patients and the public; (v) a suggestion that any challenge to the dominant view that commercial and patient interests always coincide is somehow political; (vi) a view that raising the questions found in this paper may reduce the number of patients recruited as study participants in clinical trials, so it will cause harm; (vii) a view that anyone daring to comment on the practices of pharmaceutical companies will be bewildered by the existing panoply of regulation, silenced by the force of the sector or crushed by legal challenges. It is likely that such views and perhaps others too will arise in local discussions on this topic.