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First person

The price of independence

Joe Collier

Career pressure and a focus on payment by results are making the critical and impartial thinker an endangered species. Society must take steps to protect this invaluable resource

My professional life has been dominated by a drive to ensure that every opinion or piece of advice I give is independent and seen as such. Independence first became an issue for me in 1969 when I edited my first article for *Drug and Therapeutics Bulletin*.[1] The then editor, Andrew Herxheimer, made my responsibilities clear: I was to scrutinise all the relevant published data, read and note all of the comments made by article reviewers, and use all this information to prepare the article for publication, ensuring clarity, reliability, and impartiality. The published article must reflect the scientific knowledge available and distinguish what was known about the product from what was derived from conjecture, bias, or the uncritical position of the establishment. Moreover, there would be no place for my own (preconceived) biases. Readers were to be given information they could trust and be confident that the advice given had no hidden agenda no ulterior motive.

Four decades on, and I am still discovering the full implications of these ideals. Their meaning became more pertinent when I was appointed the bulletin's deputy editor in 1972, then its editor in 1992, and a year later when it coined the strapline, "The independent review for doctors." Perhaps, more importantly, the ideals have taken on new dimensions as they have shaped my career as teacher, researcher, physician, administrator, writer, broadcaster, and adviser.

What is independence and does it matter?

In the context of this article, independence relates to intellectual function, the way our minds process information to make decisions; ultimately, it is the way we make up our minds and, as advisers, give our opinions.

What has emerged over the years is that my views have needed to be much more than independent. To be of real value, they have needed to be delivered in a way that the message was clear, pertinent, honest, and unambiguous. Advice that can be misinterpreted or leaves room for misunderstanding is often unusable and may be dangerous. In my experience, people who have conflicts of interest often find giving clear advice (or opinions) particularly difficult.

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Advice also needs to target the recipients' needs and respond to their concern or question, whether the recipient is a patient, a government minister, a committee, or one of millions of people listening to a broadcast or reading an article. How advice or opinion is couched and delivered will depend on the particular circumstances. Sometimes it will be signalled simply by the act of raising your hand to vote at a meeting, sometimes be spoken as part of the rapid deliberations of the busy committee, sometimes be more measured (as when presenting a report), and sometimes argued in detail (as in an article in a medical journal). Whatever the method, the responsibilities of the independent adviser remain the same.

Sources of bias

So what influences might undermine impartiality? In advice relating to medicines, drug companies are

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always depicted as the key distorter. The drug industry works hard, and with great success, to persuade people of the advantages of their products, so the allegation that companies will introduce bias is hardly surprising. However, other classic distorters include the views of peers, colleagues, opinion leaders, and those (such as a line manager, employer, or minister) who could bestow or deny privileges. Further distortion can arise when the adviser does not understand exactly what the recipient wants. In this instance, the advice will be formulated in terms of the giver's incorrect understanding of the problem rather than that faced by the recipient.

Independence in itself does not make the advice right, and, conversely, partisan advice is not necessarily wrong. Similarly, an adviser's bias will not necessarily colour all of their judgments adversely. A chief executive of a large drug company could give unbiased and invaluable guidance on how to increase business success. But the same executive's advice on the best drug for headache is unlikely to be helpful. What independence does is to improve clarity.

How close can you get to independence?

Full independence and the capacity to give totally impartial advice are not achievable. It would, for example, be impossible for me to prove in a court of law that my advice had not contained bias in one form or another. The issue then arises as to the extent to which any potentially biasing influence could have affected my advice. Might there be a way of assessing possible bias and determining its relevance in a particular case?

The European Medicines Evaluation Agency tries to do this by using the concept of proportionality in its policy on conflicts of interest.[2] When dealing with their expert advisers' involvement with drug companies, the agency adopts different levels of concern depending on the nature of the relationship. So, for instance, there are three risk levels for those experts advising the agency on a licensing application who have declared institutional conflict of interests—that is, an institutional contract with a drug company or a supervisory research interest. The risk of conflict is high if, for example, the expert "has acted in the past year as a consultant on the product's development, or was employed by the applicant in relation to the particular product." The risk is downgraded to medium if the act(s) occurred between one and three years ago, and to low if over three years ago. The level of perceived risk determines the capacity in which the expert might help. This notion of proportionality appears repeatedly in the policy and is echoed in the policies of others but not so explicitly.

I have had no such relationship with the industry since the late 1960s. I have spoken with members of the industry, given seminars and lectures, and debated with them, but in terms of proportionality my advice would seem to carry a low risk of contamination. But proportionality must also be extended to relationships with other powerful bodies, such as employers and government. Over the years, I have spoken with members of parliament, ministers, civil servants, and, of course, been in regular contact with my employers. Sometimes the discussions have been in strictest confidence, but more often they have been along the lines of openness as defined under the Chatham House rule—the content of the meeting can be referred to outside but in a non-attributable context.[3]

The key thing for me has been to establish from the start the level of confidentiality about the meeting. Moreover, if asked to offer other people advice relating to confidential areas, I have declined, usually with an explanation. To this extent, my independence is curtailed. But one should remember that any confidentiality bar should not extend to other areas. Nor should being close to a particular branch of government inhibit public criticism if this is appropriate. Having to keep secrets complicates the freedom to advise as it can functionally remove key components from your database. Minimising the secrecy surrounding government (or other's) business would simplify the lot of the independent adviser and improve advice generally.

Principles for independence

Although proportionality offers some way of determining the risk of bias, and so conveying this to the recipient of advice, it does not provide the sort of protection that would result from personal adherence to codes of professional conduct. I attempt to live in a way that is consistent with the Nolan principles,[4] which were developed as a set of standards of behaviour for ministers, members of parliament, civil servants, and other senior public servants. But even these are incomplete and would benefit from strengthening by the addition of sections of the recently introduced *Duties of an Expert Witness* [5]:

Selflessness—No advice should be influenced by the possibility that it might result in financial gain or other material benefits for the advisers, their families, their friends, or other interested third parties.

Integrity—Independent advisers should not place themselves under any financial or other obligation to outside persons or organisations that might influence them inappropriately.

Objectivity and openness—Independent advisers must be able to explain why they have reached their conclusion and what reasoning led to their opinion.

Accountability—Independent advisers must be fully accountable for the advice they give and be prepared for their advice and their methods to be scrutinised.

Honesty—Independent advisers must declare each and every one of their competing interests that might have a bearing on the advice. It is for the recipient of the advice, not the adviser, to decide what that bearing might be.

But even these principles and the notion of proportionality are not enough. There are two additional requirements: advisers should respond if their position is challenged—silence is not a real option—and if an error has been made, the adviser is duty bound to point it out (preferably being the first to do so) and offer an apology and a correction.

The damaging power of silence cannot be underestimated. The National Institute for Health and Clinical Excellence (NICE) claims to be independent of government and so, we could assume, are its senior executives. The fact that those at the top of the organisation rarely criticise ministers, forces us to assume that such independence is compromised. Recently, the secretary of state for health undermined NICE's role as an

Summary points

- True independence is probably unachievable
- Getting close to this ideal can cause personal and professional difficulties
- Independent advice must be open, honest, objective, informed, and selfless
- Advice must be given in such a way that is clear and unambiguous
- Government and commercial secrecy compromises independence

independent authority by essentially telling it in public what to recommend about the availability of trastuzumab.[6] Privately, senior members of NICE were infuriated; publicly, they remained quiet. Speaking out might have been difficult, but remaining silent was more damaging as it dented public confidence in NICE's impartiality.

Practising independence

For me, independence has meant saying what I mean and often being seen as rude and uncaring; holding no favours; deciding on each issue on the basis of the evidence rather than blindly following the majority; risking being seen as inconsistent (a loose cannon); not necessarily being able to support friends and colleagues; giving advice that runs counter to my personal interest; and criticising employers or senior members of the establishment. Perhaps predictably, the positions I have taken have often caused me difficulties. I have lost friends, been ostracised by the establishment, and had my career advancement undermined. But the freedoms and intellectual satisfaction gained by being allowed to be an independent thinker giving unfettered advice have far outweighed these burdens. Moreover, for each of the friends I have lost, I believe I have gained professional colleagues who value and trust my judgments. My career progression is not necessarily what one would advise for someone starting out in medicine, but for those who put independence of thought high in their hierarchy of values, the stance is worthwhile and rewarding.

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The enigma

I'm a new doctor and have just arrived into the world of work. I have spent my first four months as a paediatric house officer and have been thrust into the world of hospital medicine, one, I may add, so different from that of medical school that it is scarcely worth linking the two. I am slowly coming to terms with the drudging uncertainty of many patients' diagnoses and the lack of textbook precision. Daily there is bronchiolitis, asthma, and viral induced wheeze (or was it viral exacerbation of asthma? I can't remember). Many times there is that disappointing lack of a firm diagnosis for patients, many times the phrase, "It's probably a virus," is uttered in an effort to provide vague reassurance.

Almost at the end of my job, I saw what one might term the phenomenon of the "Enigma." This is a phenomenon that breathes life back into all concerned, demonstrating the excitement and the frustrations of medicine. A 14 year old boy was admitted with neck pain, fever, and little else. Sparks didn't exactly fly. Then came the deranged liver function tests, then the squiffy international normalised ratio, and the deranged renal function. Ears began to prick up around the department. Cervical spine and chest x rays shed no light on the diagnosis, and the story was heard further afield: microbiology came knocking, radiologists were suddenly only too happy to provide magnetic resonance imaging.

Still no answer was found. Kidneys failed, liver failed, and fluid accumulated at an alarming rate. Meanwhile the investigations piled up—autoantibodies, lymphocyte subsets, serum angiotensin converting enzyme, white cell scans. Computed tomography of the abdomen showed hepatosplenomegaly and splenic infarcts, the theories flew in with yet more fervour from all corners. Every handover became a protracted discussion about the enigma, lunchtime musings and passings in the corridor descended into diagnostic pontifications worthy of anything television drama could throw at us. The enigma provided frustration and excitement in equal measure. Unfortunately, as the speculation continued, the negative results still dripped in: syphilis tests, cat scratch serology, and serum rhubarb. Reference laboratories up and down the country continued to deny us an answer.

After two weeks of deliberations and machinations, the enigma began to feel better: renal function normalised, liver function normalised, and the fever settled, his C reactive protein concentration came down, and so he slid himself off home. As for the cause of all this—we'll probably never know, but one suspects it was probably a virus.

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