TIPSHEET FOR REPORTING ON DRUGS, DEVICES

AND MEDICAL TECHNOLOGIES:

Some simple questions to consider and discuss.

Many of these questions will already be familiar to reporters covering health and medicine. They are not intended as a guide to writing or producing stories, but simply as a list of some key issues to think about and, if possible, discuss with a range of sources, including independent researchers. Nor are these questions necessarily meant to be used in formal interviews. Instead, they are questions to consider and discuss when researching stories. Consideration of these questions may lead a reporter's research in unexpected directions.

- 1. What is the size of the **potential benefit** offered by the therapy, and for what types of patients is it beneficial?
- 2. What are the **potential harms** associated with the therapy?
- What are the links between your sources of information about the therapy and those promoting it?
- 4. How strong is the **evidence** to support the claims being made about the therapy, and how does it relate to other available evidence?
- 5. What is the natural **history** of the condition for which the therapy is being offered, and is there potential for what some have called "disease mongering"?
- 6. What are the **alternatives** to the therapy being offered (e.g., no action or watchful waiting, generic drugs, non-drug options, complementary therapies)?
- 7. What are the **COStS** of the therapy and are the potential benefits worth the cost?

"Getting answers to these questions can help reporters craft stories that are more likely to serve the needs of their readers, viewers and listeners. They can also help reporters identify warning signs that the enthusiasm of researchers or the promotional interests of companies and institutions may be getting ahead of the science."

> — The Association of Health Care Journalists

1

What is the size of the potential benefit offered by the therapy, and for what types of patients is it beneficial?

Rather than asking "Does this work?", it may be valuable to ask "How well does this work, and for whom?" Sometimes a new drug or other therapy will have an important benefit for a particular group of patients, but little or no benefit for others.

The way in which the size of a benefit is presented is also important. Some ways of presenting statistics, or "framing" benefits, may tend to make a therapy look better than it is.

For example, osteoporosis drugs may be said to cut the risk of hip fractures by 50 percent. In fact the drugs may reduce the risk of hip fracture from 2 percent for those not taking the drug to 1 percent for those patients who take the drug for several years. In relative terms this is a 50 percent benefit, in absolute terms the risk of fracture is cut from 2 percent to 1 percent. In other words, 100 patients would need to be taking the drug for several years, to prevent one hip fracture. If a story is only presenting benefits in relative terms, as many stories do, it could be misleading.

When discussing the potential benefits of a therapy, it may also be valuable to remember it is often uncertain which particular patients will benefit, and by how much.

2

What are the potential harms associated with the therapy?

The side effects or complications of a therapy are also important, though they are often left out in news stories. For example, many stories about the value of aspirin in preventing heart disease fail to mention the gastrointestinal side effects associated with taking the drug.

Clearly it would prove impractical to cover every potential adverse effect, so decisions need

to be made about which ones are the most serious and/or most frequent. Sometimes the rare but potentially serious side effects of a therapy will only become known after its widespread and/or long-term use. Reporters should apply caution and skepticism to claims that any therapy is free of potential harms.

Reporters also need to be wary of overstating the importance of adverse events. For example, some stories use figures showing the relative increase in the risk of adverse events associated with a therapy—which may sound very dramatic—without supplying the absolute numbers which may appear much less dramatic.

3

What are the links between your sources of information about the therapy (e.g. a doctor, a public relations company, scientific researchers, consumer groups, disease foundations, or the published evidence) and those promoting it?

It is very common for doctors, other health professionals, or researchers to have links with the manufacturers of drugs or devices. Those links might include company funding of research, travel, and/or consultancies. Scientific researchers may also have stock in the companies promoting the therapy, and/or hold honorary positions on advisory boards. Companies may also provide funding for third-party organizations like medical consumer groups or disease-specific foundations.

There is some evidence suggesting an association between company sponsorship of research and favorable study outcomes. There is also widespread acknowledgment within the scientific community that public disclosure of such links is valuable: many funding bodies, educational institutions and medical journals now routinely require such disclosure. However, many media stories currently fail to disclose these links. For example, many stories about new drugs for osteoporosis or heart disease cite studies and experts, without exploring their links to the drugs' manufacturer. Such links do not necessarily mean there is any problem with research-bias or with the therapy. But they should raise a flag, reinforcing the need for skepticism and caution.

4

How strong is the evidence to support the claims being made about the therapy, and how does it relate to other available evidence?

It is valuable to know whether the "evidence" supporting a new therapy has been presented in a preliminary way at a scientific conference, published in a journal after peer-review, or simply sourced to a press release or a press conference. There are different types of scientific evidence, ranging from less reliable to more reliable. It may be valuable to discuss the different sorts of evidence, or "levels of evidence," with researchers familiar with study designs.

In brief, evidence can range from early laboratory or animal experiments to individual case studies or small trials in humans-which are not adequate for assessing whether a therapy does more good than harm-to large, long-term, randomized controlled trials, where therapies are rigorously compared against control groups or placebos. Overly optimistic news stories, which rely heavily on the results of preliminary studies, may create unrealistic expectations and raise false hopes for vulnerable sufferers.

This is a complex but important question, because the public can be misled about the effectiveness of a treatment if it is promoted on the basis of weaker scientific evidence. As an example, hormone replacement therapies (HRT) were for a long time believed to reduce the chances of heart disease, on the basis of non-randomized evidence. In recent years one randomized, controlled trial produced evidence suggesting these therapies may in fact provide no heart benefit, and may even cause harm for some women. Further randomized, controlled trials are currently under way to investigate the complicated issue of the risk and benefits of HRT.

It may also be helpful to consider the new evidence in relation to other available evidence about the same therapy or condition. Sometimes there will be conflicting results from different studies, and it may be misleading if a story relies on the results of just one study.

5

What is the natural history of the condition for which the therapy is being offered, and is there potential for what some have called "disease mongering"?*

It may be valuable to think about the condition or disease for which the therapy is being suggested. Some medical conditions will improve without the need for any therapy at all. For example, many episodes of lower back pain will pass without the need for medical intervention.

Sometimes a risk factor for an illness or adverse event is presented as an illness in itself. On other occasions aspects of human life may be "medicalized" in ways which may benefit professional or commercial interests more than those people actually labeled as suffering from the illness.

In some cases companies or professionals promoting treatments will try to overstate the prevalence or severity of a disease or condition, in order to help widen the markets for their therapy. This process has been called "disease mongering."* Conversely some companies may attempt to overplay the adverse effects of a therapy, if they have a vested interest in the magnitude of such a problem (e.g., the company is promoting a competing product).

6

What are the alternatives to the therapy being offered (e.g., no action or watchful waiting, generic drugs, non-drug options, complementary therapies)?

Often it may be valuable to be aware of potential alternatives when a new therapy is being promoted. For some people it may be the case that an older, less-expensive treatment, or no therapy at all, would be just as effective. For example, many patients with uncomplicated high blood pressure may benefit as much from changes in diet and exercise or older, cheaper therapies no longer under patent, as from newer, moreexpensive drug therapies.

7

What are the costs of the therapy and are the potential benefits worth the cost?

It is increasingly the case that new therapies are assessed to see if they offer value for money. A new therapy may give some benefit over an older therapy, but if it has a very high cost it may not give value for money. Alternatively a new therapy may be more expensive initially, but save money in the long run by more effectively preventing future illness and its associated costs.

Increasingly those paying for health care public or private insurers—are investigating whether a new therapy is cost-effective, before they decide whether or not to provide coverage for it.

Payer, Lynn. Disease Mongers: How Doctors, Drug Companies, and Insurers Are Making You Feel Sick (New York: John Wiley & Sons, 1992).

Porter, Roy (ed.). *The Cambridge Illustrated History of Medicine* (New York: Cambridge University Press, 1996), pp. 13–14.

This tipsheet was developed by Australian journalist Ray Moynihan and is based on his June 1, 2000, *New England Journal of Medicine* article "Coverage by the News Media of the Benefits and Risks of Medications." Moynihan currently writes about the business of medicine and health for the *Australian Financial Review.*

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^{*} for more information and a definition of the term "disease mongering," see: