POLICY FORUM: HEALTH CARE POLICY

The Courts—A Challenge to Health Technology Assessment

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Health technology assessment (HTA) draws together information from a variety of sources to provide an evidence-based appraisal of technology. The results of HTA can help to optimize clinical practice as well as to inform health policy and administration on such issues as coverage decisions and regulations.

In the past, litigation has been used to challenge clinical practice and health-related administrative decisions, especially in the United States. Court suits brought by industry against researchers constitute a relatively new method to dispute findings and block dissemination of results. Recent developments suggest that this practice may spread internationally to affect assessors of health technologies. Here we describe illustrative cases and relevant international agreements, and suggest approaches to preserve objective and meaningful HTA.

Cholesterol-lowering drugs, Canada

The pharmaceutical company Bristol-Myers-Squibb Canada Inc. (BMS) sought to prevent release by the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) of a summary report on statins, drugs that lower blood cholesterol. Pharmaceutical companies whose products were analyzed had been given the opportunity to review and comment on the draft assessment report; the final version was released in October 1997 (*1*). In an executive summary meant for policymakers, CCOHTA took the position that all drugs in the class of statins provided benefit (a "class effect"). In its lawsuit, BMS stated that the summary was "negligently misleading" for stating that there was a class effect, as there were adequate clinical trials with only two statin drugs (*2*). The court refused to grant an injunction on release of the report, and a higher court denied an appeal of the decision by BMS.

Two features of this case raise concerns for the ability of assessors to provide neutral advice. First, although the report was technically competent and reflected the available literature, BMS wanted to prevent conclusions of the research from being made public. Despite suggestions to the contrary in a press release by BMS, such legal action and fear of litigation can impede the free exchange of scientific information (*2*).

The second disquieting feature is the cost and administrative impact on an HTA agency with limited resources. The money spent by CCOHTA on lawyers to defend its right to publish amounted to 13% of its annual budget (*2*). There was also a drain on the limited human resources at CCOHTA. Overall, the case may have substantially impaired other HTA activities at the agency.

In a similar case, a drug company (Merck) tried through court proceedings to stop distribution of a newsletter from the Norwegian Medicines Control Authority containing a critical evaluation of Fosamax, an osteoporosis drug (*3*). Although the judge was critical of the newsletter's content, he felt that the Authority should be free to publish its view.

Licensing documentation for a contraceptive, Finland

Norplant is a contraceptive method based on slow-release levonorgesterel capsules. Norplant had been controversial because of doubts concerning its safety and its suitability for developing countries (*4*). Two Finnish researchers wanted to study the documentation for Norplant's licensing in Finland in 1983. Licensing data were made available for research through special permission by the Finnish Ministry of Social Affairs and Health (MOH) and a report was written by 1996. The study showed that the 1983 release of Norplant was premature by current standards; the evidence now usually required for licensing new drugs was not then available (*5, 6*). However, most of these results have remained unpublished because of legal action taken by Leiras, the producer of the drug (*5*).

After seeing the manuscript (provided by MOH), Leiras sued MOH for having released confidential data. It took 2 years for the Supreme Administrative Court of Finland to decide that the case did not have legal merit.

Before taking the case to court, the drug company advised MOH that, if the article were to be published, MOH and the researchers would be "responsible for economic harm resulting to the company" (*7*). A salary-based researcher could not pay compensation even for a small decline in the sales of Norplant. Either compensation would have been paid by the employer, or the financial threat was intended only to make researchers give up publication of their research. The legal challenge may affect future decisions of the MOH on whether to release confidential information for research.

International treaties and future legal challenges to HTA

Our examples of court cases were related to action based on national laws. The nature of recent international treaties on trade and investment (see the table) leads us to believe that in the future, industry may be in a stronger position to challenge HTA and its findings. These treaties will mainly have indirect effects: what kind of HTA is requested and which results are considered useful. However, secrecy issues will have a direct impact on HTA by impeding acquisition of data.

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The General Agreement on Tariffs and Trade (GATT) of the World Trade Organization (WTO) requires that if national regulations on human, animal, or plant life and health are stricter than existing international standards, the country imposing such measures must prove that they are based on risk assessment and do not represent a technical barrier to trade. Well-known examples of environmental con-

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flicts are the hormone-beef case and the asbestos case in which stricter standards set by the European Union (EU) have been challenged (*8, 9*). In both cases, those wanting to adopt the stricter measures had to prove that they were based on scientific risk assessment. For HTA and policies based on HTA, the usual paradigm is that products should be shown to be safe and effective before they are widely used. The EU lost the hormone-beef case in the WTO dispute panel, because it could not provide scientific evidence satisfactory to the panel; the asbestos case is still pending.

In the future, the first area where HTA could be directly challenged is technologies for preventive health care, where use of normal commodities (such as tobacco, food, or alcohol) could be affected.

TREATIES ON TRADE AND INVESTMENT

WTO, GATT as amended in Marrakesh, 1994; General Agreement on Trade in Services (GATS), 1994. Agreement on TRIPS. http://www.wto.org

NAFTA, 1994. http://www.dfait-maeci.gc.ca/english/trade/nafta/table.htm

Proposal: MAI, Draft, OECD, 1998. http://www.oecd.org//daf/cmis/mai/negtext.htm

According to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), governments are responsible for ensuring the secrecy of documents used in the approval of new pharmaceutical and chemical products, unless there is a conflict with major public interests. Although industry has legitimate reasons for maintaining confidentiality on certain aspects of product development, responsibility to ensure secrecy might easily be extended to any information. There have been debates over secrecy and transparency in licensing of medicines in the EU, and over the claims of pharmaceutical companies that reports on clinical trials are commercially valuable intellectual property (*10–12*). The TRIPS agreement is especially important for the research-based transnational pharmaceutical industry, and a recent WHO resolution calling for increased WHO attention and action on TRIPS-related issues raised concern among industry groups (*13*).

Under the WTO provisions, only countries can appeal decisions. Under the North American Free Trade Agreement (NAFTA) and the draft Multilateral Agreement on Investment (MAI), commercial actors are also given rights to appeal. Dispute settlement panels treat issues brought before them in the context of trade and investment discrimination. When the Canadian government banned the use of a fuel additive, MMT, whose use is restricted in the United States by national and state legislation, the manufacturer used the NAFTA provisions to challenge the decision. The Canadian government could not prove that MMT was a health hazard, and had to lift the ban and compensate the company (*14*).

Potential impact of legal threats

In the health and social sciences, causality is difficult to prove. In analyzing findings on complex issues, researchers operate with risks and probabilities. Effects of interventions are usually conditional and vary with the characteristics of the individual, organization, and society. Because the aim of HTA is to provide a synthesis of information from different disciplines relevant for policy needs, there is often a need to use incomplete and diverse data. Thus, there is scope for varying conclusions and for attacks by legal means. Being made legally and financially responsible for research conclusions has four consequences for HTA.

First, lawsuits are to be expected from those who stand to lose financially as a result of the research. Fear of lawsuits may push researchers to consider the impact of their work on the producer of the technology. This would inevitably compromise the societal perspective.

Second, researchers, research institutions, publishers, and funding agencies may not be inclined to undertake evaluations that appear to carry legal risks. In consequence, commercial products might be evaluated mainly by the producer. Such self-evaluation is unlikely to be sufficient to aid users in making informed choices and would be a setback for evidence-based policy-making.

Third, if governments are deprived of impartial expert advice in controversial issues, it may cause them to react so as to lessen their own risks. Public-sector programs might be driven toward use of relatively arbitrary regulatory processes rather than drawing on evidence-based findings. Such a response might ultimately be disadvantageous for industry.

Fourth, well-publicized court cases may reveal the strong economic interests and forces behind individual health technologies. It may help to put into perspective decisions on adoption of health technologies, of which research and HTA findings are only one element.

What should be done?

We oppose the use of courts or international dispute panels to suppress or control HTA. They should be a last resort when other means of challenging a clearly spurious assessment are unsuccessful. Industry should be encouraged to use scientific means to challenge research results it considers unfair. Inability to make a strong case on the basis of its own research might convince a private-sector organization to put its interest and marketing efforts into other products.

Proposals made by Deyo *et al.* (*15*) to protect researchers and funding agencies from harassment by interested parties may also help in avoiding court cases. They suggest, for example, keeping research findings in a peer-review process until they are in the public domain, monitoring reviewers who have conflicts of interest, requiring evidence before charges of scientific misconduct are brought, and providing institutional support for researchers who have been attacked.

International ethical rules on health research should be formulated in the noncommercial sphere. Given the economic power of industry and existing commercial pressures, such guidelines might have limited effectiveness, but their presence would open up useful discussion and ease implementation of national legislation.

The health technology industry needs clinical and other expertise to conduct research and to market its products. Furthermore, academic input is important in innovation. If lawsuits alienate academic collaborators, industry may be less likely to use legal challenges. Making cases public and discussing them in the scientific and lay press may facilitate that process.

References and Notes

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