Placing value, price on new drugs: The challenge facing new UK policy, say Hopkins bioethicists

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The United States should pay close attention to how the United Kingdom carries out plans to assess a new drug's worth using factors that go beyond clinical and cost effectiveness, according to researchers at the Johns Hopkins Berman Institute of Bioethics.

In a commentary to appear in the April 7 issue of the New England Journal of Medicine, the bioethicists detail and discuss a new, "value-based pricing" policy proposed by the British government. Up to now, companies have been able to price their drugs freely. But if the new policy is implemented, the U.K. will start negotiating drug prices.

The authors point out that key to the policy is the requirement that Britain's national health-care system factor in some difficult-to-measure criteria, as well as more conventional ones, when deciding how much to pay for a new drug.

The nontraditional criteria include the extent of therapeutic innovation, the "burden of illness" that the drug aims to treat, and the prospect of "wider societal benefits." The NEJM commentary quotes statements from Britain's Department of Health that promise value-based pricing will better reflect "all the components that contribute to a treatment's impact on health and quality of life," including "important factors that patients and society value."

In their "Perspective" piece, Berman Institute Director Ruth Faden, Ph.D., M.P.H., and visiting faculty member Kalipso Chalkidou, M.D., Ph.D., acknowledge that the U.K. and U.S. health-care systems have fundamental differences. But, with skyrocketing health-care costs on both sides of the Atlantic, each country is looking for a more comprehensive approach to pricing new drugs and medical treatments. And whether or not officials in the U.K. succeed with value-based pricing, the authors say the experience could provide valuable lessons for the crisis in America.

"As important as improving the health of the population is, we know that what makes health care valuable is more than what is captured in health-outcomes statistics," says Faden, the Philip Franklin Wagley Professor of Biomedical Ethics at Johns Hopkins University. "There is value in the security of knowing dying loved ones will be cared for, that the burden on family members of people with dementias will be lessened, and in improving prospects for disadvantaged children and communities."

As proposed, this value-based pricing policy would take effect in 2014 and change the way drugs are offered through Britain's National Health Service (NHS). Currently, an independent agency known as NICE, the National Institute for Health and Clinical Excellence, reviews all new drugs that are likely to have an impact on health or the NHS budget, Chalkidou explains.

The NHS has always been able to offer drugs turned down by NICE, but it is constitutionally required to pay for those that NICE approves, says Chalkidou, the founding and current director of NICE's international program. In that role, she helps governments develop the ability to use evidence to inform health policy.

Chalkidou says ongoing talks about the new drug-pricing approach may result in changes before the policy takes effect. "The next few months

will be key to solving the technical challenges of making drug-pricing decisions, and more importantly, addressing the political and ethical challenges of making those decisions," Chalkidou says. "There is no question that both the U.S. and the U.K. already make difficult decisions about access to health services every single day. But in the U.K., we are a bit ahead with regard to transparency and an explicit reliance on evidence."

Currently, NICE recognizes the need to incorporate social values into its decision-making and has adopted as core principles not only transparency, but also public consultation, independence and an openness to patients appealing the agency's decisions, according to the commentary.

NICE periodically conducts public-opinion surveys, and its decision-making committees include laypeople as voting members, the authors point out. In addition, the agency has a formal program in place for patient and public involvement, as well as a Citizens' Council, which generates reports that inform NICE's Social Value Judgments document.

Faden and Chalkidou also note that when the proposal was first announced in October 2010, media reports stated that NICE "was being stripped of its power." These reports were misleading, as NICE is likely to play a central role in the new pricing policies. However, the co-authors assert that it remains to be seen whether the new approach will be better, more acceptable or more comprehensive than the system that Britain has in place now.

"Arguably, NICE and the NHS have gone as far, if not further, than health agencies in other countries in attempting to elicit and incorporate the values and preferences of the public," Faden says. "But there are still many deficiencies in this regard."

In both Britain and the United States, Faden adds, it remains unclear what exactly the public's values and wishes are, especially given each population's diversity. For example, the co-authors point out that the category of "wider societal benefits" is open to much interpretation and could include everything from "narrowing health inequities" to "advancing children's life prospects" to "decreasing workforce absenteeism."

Chalkidou says the main difference between the two countries is not whether cost is considered when making decisions about drug coverage, but whether those considerations are done openly or covertly. "What would be interesting for the U.S.," she explained, "would be to use the U.K. debate to inform its own discussions on whether and how to make the system more transparent, more consultative, more contestable, more independent, and hence, more consistent and more legitimate."

Provided by Johns Hopkins Medical Institutions

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