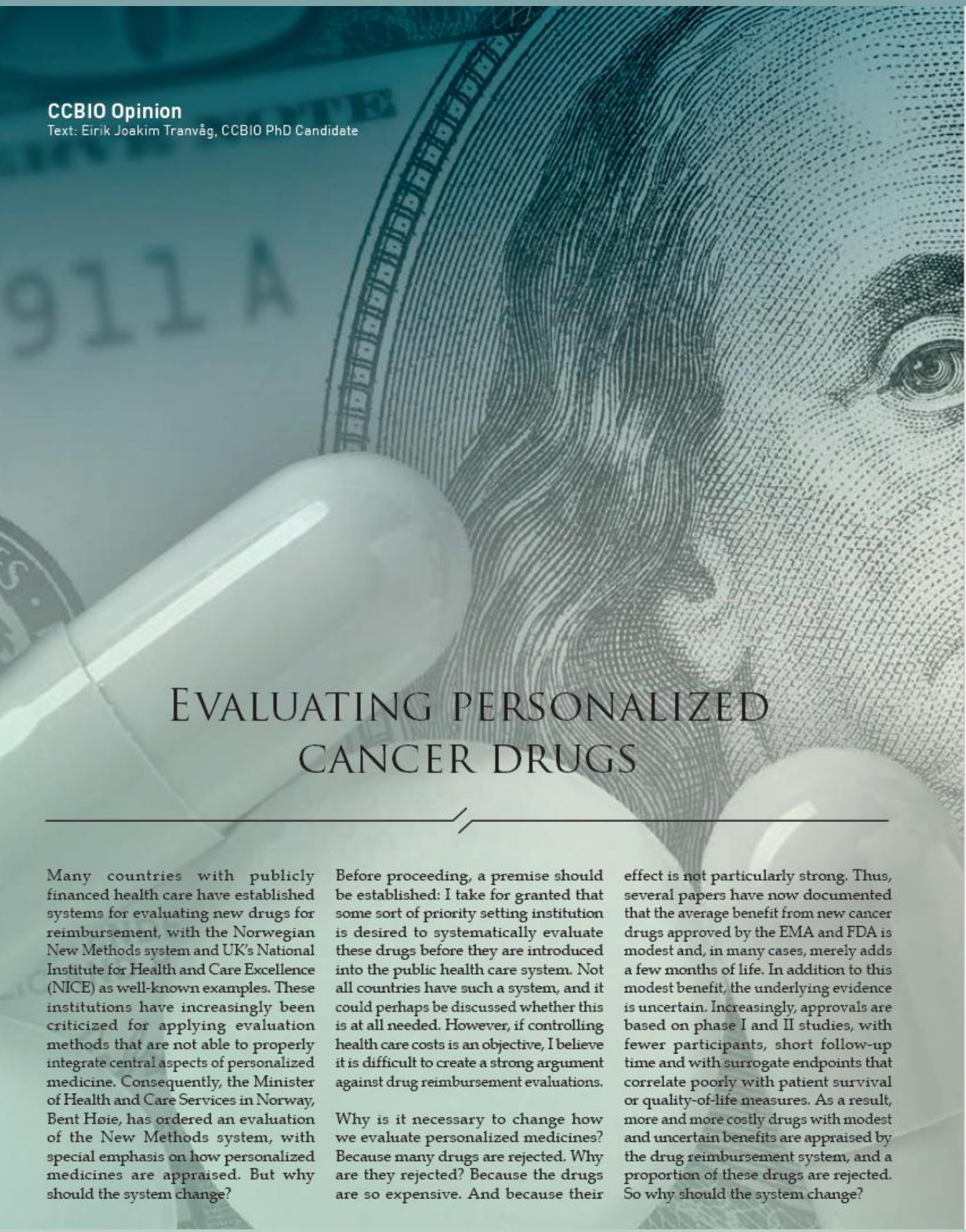

**CCBIO Opinion**

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# Evaluating personalized cancer drugs

Many countries with publicly financed health care have established systems for evaluating new drugs for reimbursement, with the Norwegian New Methods system and UK's National Institute for Health and Care Excellence (NICE) as well-known examples. These institutions have increasingly been criticized for applying evaluation methods that are not able to properly integrate central aspects of personalized medicine. Consequently, the Minister of Health and Care Services in Norway, Bent Høie, has ordered an evaluation of the New Methods system, with special emphasis on how personalized medicines are appraised. But why should the system change?

Before proceeding, a premise should be established: I take for granted that some sort of priority setting institution is desired to systematically evaluate these drugs before they are introduced into the public health care system. Not all countries have such a system, and it could perhaps be discussed whether this is at all needed. However, if controlling health care costs is an objective, I believe it is difficult to create a strong argument against drug reimbursement evaluations.

Why is it necessary to change how we evaluate personalized medicines? Because many drugs are rejected. Why are they rejected? Because the drugs are so expensive. And because their effect is not particularly strong. Thus, several papers have now documented that the average benefit from new cancer drugs approved by the EMA and FDA is modest and, in many cases, merely adds a few months of life. In addition to this modest benefit, the underlying evidence is uncertain. Increasingly, approvals are based on phase I and II studies, with fewer participants, short follow-up time and with surrogate endpoints that correlate poorly with patient survival or quality-of-life measures. As a result, more and more costly drugs with modest and uncertain benefits are appraised by the drug reimbursement system, and a proportion of these drugs are rejected. So why should the system change?

I agree that the system has to change. But not the system for reimbursement of new drugs. It is the system for research and development of new diagnostics and treatments that should change. It is unfair and unsustainable to develop new drugs with a mediocre impact on health, and price them as if they actually could cure cancer. It is unfair and unsustainable to fund basic research for drug development with public money and then having to pay for the drugs again when they enter the market. It is unfair and unsustainable that costly drugs demand increasing shares of the health care budget, with the harmful consequence that less resources are available to other needing patients.

Can universities and publicly funded research, like CCBIO, contribute to a more fair and sustainable system for research and development of new drugs? *Yes, we can.* Universities can establish guidelines and frameworks for socially responsible licensing, where affordable access to drugs built on publicly financed research is guaranteed. With such guidelines, a promising drug candidate developed by CCBIO could not be sold to big pharma without such guarantees.

And there would still be room for biomarkers. But they would need to be disconnected from new and expensive drugs. Biomarkers that predict toxicity or lack of response can prevent harmful treatment and save money by not providing treatments. Repurposing of drugs that are no longer protected by patents can be tested and tailored to new treatments for other patients. But most importantly, we as researchers must acknowledge that the current system of research and development is unfair, it has unsustainable consequences, and that the system has to change. ••