Finding the Right Price for Improving Care

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The US Food and Drug Administration (FDA) recently approved alirocumab and evolocumab, 2 monoclonal antibody PCSK9 inhibitors that reduce low-density lipoprotein cholesterol. In this edition of JAMA Internal Medicine, Tice et al1 of the Institute for Clinical and Economic Review (ICER) provide a systematic review of the efficacy, safety, and costs of these therapies. These drugs seem to be effective and safe; however, most included trials lasted fewer than 6 months, and none used cardiovascular events as a primary outcome. A meta-analysis of these trials estimates a 50% relative risk reduction of cardiovascular mortality; however, because of the meta-analysis’s limitations, the actual effect on mortality will not be characterized until ongoing trials conclude in 2017.

What is novel about this review is the inclusion of cost, the third rail of American medicine. Tice et al1 estimate that treatment with these $14 000-per-year drugs would cost $300 000 per quality-adjusted life-year gained—well above traditional cost-effectiveness limits. Assuming that only 25% of patients with an FDA-approved indication receive these drugs, the cost to the American health care system would be $107 billion over 5 years. This price tag is alarming considering that the United States already has the most expensive health care in the world and is struggling to contain cost growth while improving patient care. The United States is among a minority of developed nations that does not consider cost when determining national drug reimbursement policy.2 Tice et al1 calculate that to become cost-effective, the PCSK9 inhibitors would have to be discounted by 42% to 78%.

Research similar to ICER's to “right-price” drugs could help improve high-value patient care. However, to definitively determine the value of these new drugs and conduct comparative effectiveness studies, stronger clinical outcomes data are needed.

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