Law and the Public's Health

This installment of *Law and the Public's Health* considers the legal dimensions and impact of comparative effectiveness research, an advance in the development of evidence on clinical effectiveness that holds major promise for improving the quality and efficiency of health care.

Sara Rosenbaum, JD
Hirsh Professor and Chair, Department of Health Policy
School of Public Health and Health Services
The George Washington University Medical Center, Washington, DC

COMPARATIVE EFFECTIVENESS RESEARCH AND HEALTH REFORM: IMPLICATIONS FOR PUBLIC HEALTH POLICY AND PRACTICE

JANE HYATT THORPE, JD

This installment of *Law and the Public's Health* focuses on comparative effectiveness research (CER) and its implications for public health policy and practice. The Patient Protection and Affordable Care Act (PPACA) anticipates the implementation of CER as a matter of formal federal policy and practice. At the same time, CER raises important issues for public health.

BACKGROUND

The quality and relevance of evidence concerning the effectiveness of health-care services is crucial to policy questions related to clinical care, payment, and, ultimately, population health. The United States has lagged behind other nations in establishing a national policy to advance the production, use, and dissemination of evidence to shape key health policy decisions. For example, the National Institute for Health and Clinical Excellence in the United Kingdom uses CER to make coverage decisions under its publicly financed health-care system.

The Institute of Medicine (IOM), whose study of CER was highly influential in crafting the CER provisions in health reform, defines CER as the study of methods, including alternative approaches, to “prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care” and inform decision-making by “consumers, clinicians, purchasers, and policy makers.”¹ The IOM definition is extremely broad and potentially encompasses not only head-to-head comparisons of different clinical treatments, but also

approaches that use community- and population-level interventions to affect clinical conditions, such as improving housing quality for children with asthma or using structured nutritional and physical exercise interventions to help treat obesity.

Whether narrowly or broadly defined, CER and the evidence it generates can play a vital role for clinicians, patients, payers, public health professionals, and policy makers.² At the same time, opponents of a national policy to advance CER raise concerns regarding its potential to limit access and curb variation and innovation in health care to the detriment of individuals with rare conditions or those whose complex health conditions and/or social risks place treatment outside clinical norms.³

The American Recovery and Reinvestment Act of 2009 (ARRA)⁴ and the PPACA⁵ significantly move the nation toward a national CER policy. In combination, the two laws expand the role of government and establish the financial and structural basis for the advancement of evidence in health care and health-care financing.⁴ Their implementation can be expected to raise many questions regarding the scope and use of CER in numerous contexts: health-care delivery, public and private health insurance, and the interaction of clinical care and public health practice.

ARRA

The ARRA appropriated funding totaling \$1.1 billion for CER and created a Federal Coordinating Council to make recommendations related to federal CER initiatives (replaced by an institute under the PPACA⁶). These funds were allocated to the U.S. Department of Health and Human Services (HHS) (\$400 million) and its agencies, the National Institutes of Health (NIH) (\$400 million) and the Agency for Healthcare Research and Quality (AHRQ) (\$300 million). Furthermore, ARRA required HHS, NIH, and AHRQ to