Why are “risk sharing” models for pharmaceuticals so challenging to implement? In a new paper in Health Affairs, Dr. Peter Neumann and colleagues pose the question, “What values do the public want their health care systems to use in estimating productivity benefits for therapies when that information is not available from clinical trials.” Key findings include:

1. There is a lack of transparency in how companies interpret and use Section 114.
2. Section 114 of the 1997 U.S. Food and Drug Administration Modernization Act (FDAMA) has been used by companies to establish pre-existing conditions for coverage decisions.
3. Companies have used Section 114 to establish broad ranges to evaluate the conditions of future coverage decisions.
4. The lack of transparency and inconsistency can lead to confusion for patients and payers.

To read more about this topic, visit the CEVR website or contact Peter Neumann, ScD, at neumannp@tuftsmedicalcenter.org.

If you are interested in either of these positions or have any questions, please contact Amy Stern, PhD, at astern@tuftsmedicalcenter.org.

For more information, please contact Teja Thorat, M.Sc., MPH, at thorat@cearegistry.org.

**Recent Publications**

- **Improving Cost-Effectiveness Analysis (CEA) Registry**
  - CEA Registry Health Affairs 2011 December; 30(4): 2329
  - CEA Registry Radiology 2011 Dec;261(3):692
  - CEA Registry Current Medical Research Opinion. 2011 22.1018.
  - CEA Registry Friedberg, D, Neumann, PJ.
  - CEA Registry Neumann PJ.
  - CEA Registry American Medical Association 2011 May; 800 Washington Street #63, Boston, MA 02111, phone: 617.636.5705, fax: 617-7431 or by email astern@tuftsmedicalcenter.org.

**What role does risk sharing play in pharmaceuticals?**

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