

Will the Proposed Payment System Affect End-Stage Renal Disease Innovation?

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INTRODUCTION

Polio vaccine, antibiotics, coronary bypass, organ transplantation, dialysis and many other advances resulted, in part, because of government encouragement of innovation.^{1,2} Indeed, government policies may either encourage or provide disincentives for the innovation that improves healthcare, outcomes, and quality of life for citizens.

The end-stage renal disease (ESRD) Prospective Payment System (PPS), with pressure to reduce per-treatment costs is now a force in the dialysis community. One unintended consequence may be a decline in innovation by companies which develop therapeutics for ESRD patients.

¹McClellan MB. July 9, 2003. www. FDA.gov/NewsEvents/Testimony/ucm161029.htm

²Moses H & Martin JB. *New Engl J Med*. 2011;364:567-571.

METHODOLOGY

- We searched clinicaltrials.gov for clinical trials by pharmaceutical companies from 1/2005 to 12/2010.
- Search terms included CKD and ESRD, open studies, interventional, male and female, and adult and seniors. Only studies conducted in the United States and funded by industry were included.
- Included trials required ESRD patient participation. References to CKD participation were specifically reviewed to confirm ESRD.
- Pediatric trials were excluded. Trials led by individual institutions with limited participation were also excluded.

RESULTS

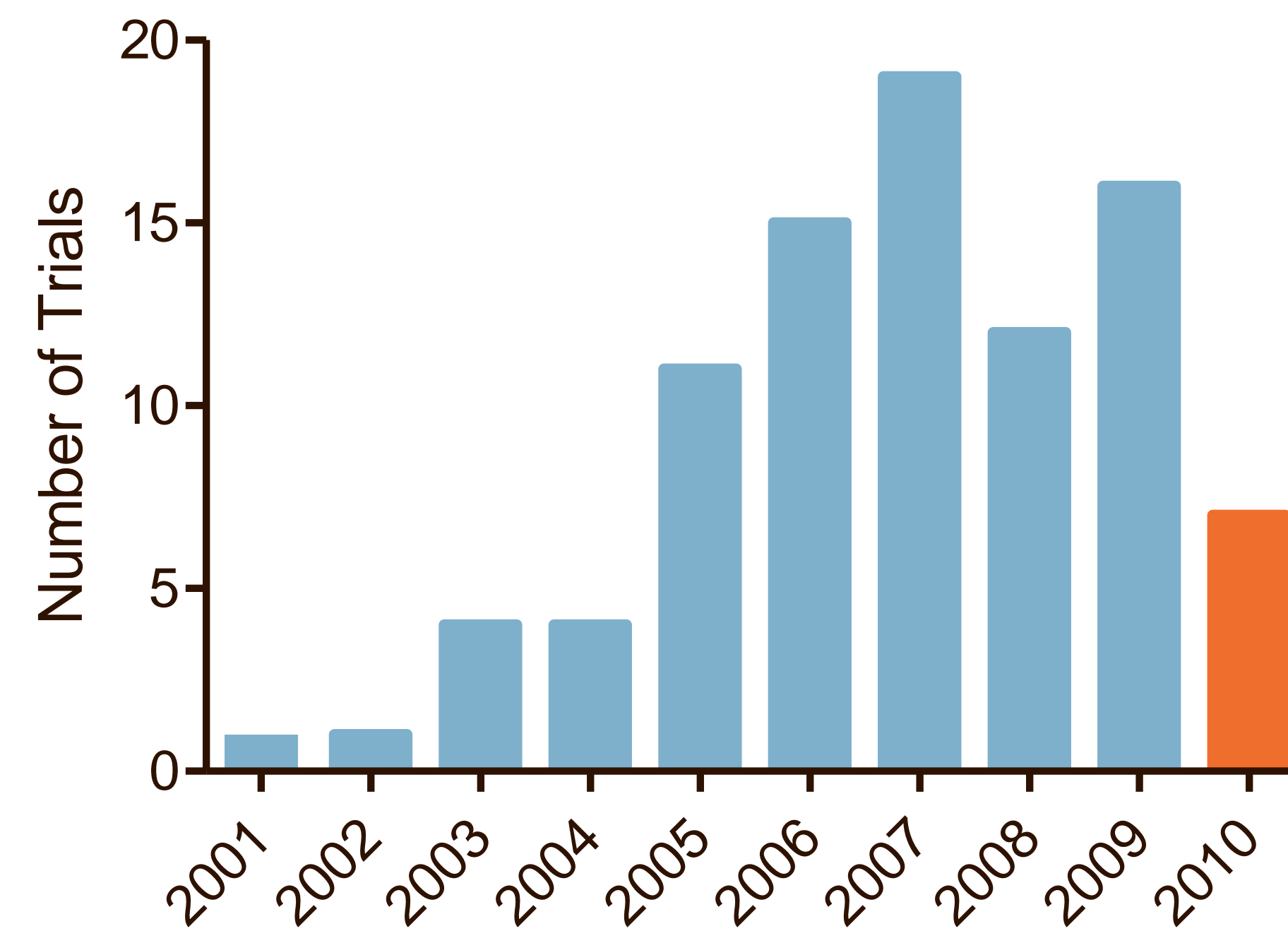


Figure 1. New ESRD Clinical Trials. Trials recruiting during that year and sponsored by industry are included.

Table 1. Summary of Industry-sponsored, Clinical Trials between 1/2005 and 12/2010

Between 1/2005-12/2010	Clinical Trials
Total Trials	152
New Trials	89

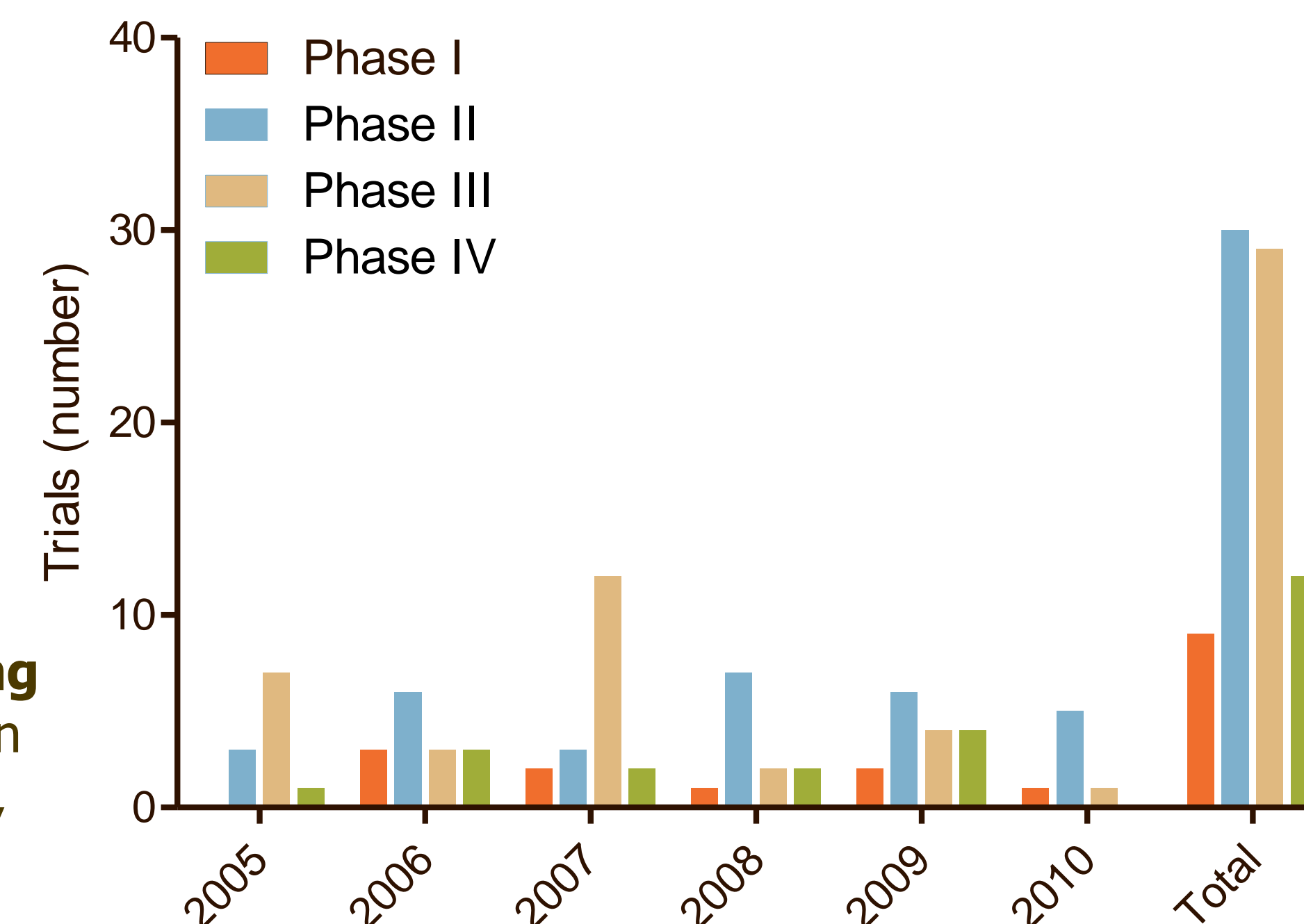


Figure 2. Currently Recruiting ESRD Trials by Phase. Trials in clinicaltrials.gov as of January 1, 2011 are included.

SUMMARY OF RESULTS

- The number of clinical trials in nephrology declined sharply in 2010 after increasing for several years (Figure 1).
- In 2007, 10 of 12 Phase III trials were for an IV product, perhaps showing a corollary effect of stifling of the PO market in ESRD (Figure 2).

KEY LEARNINGS

- ✓ 2010 signaled a decrease in ESRD clinical trials. This trend toward a decrease in registrational pharmaceutical trials as well as research leading to improvements in technology may have serious implications for the ability to improve care and outcomes in patients with ESRD.
- ✓ Innovation is costly. Industry will focus research and development in therapeutic areas with potential for investor return.
- ✓ An unintended consequence of bundled reimbursement may be a disincentive for development of new therapeutics which may improve care and outcomes for people with ESRD.

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