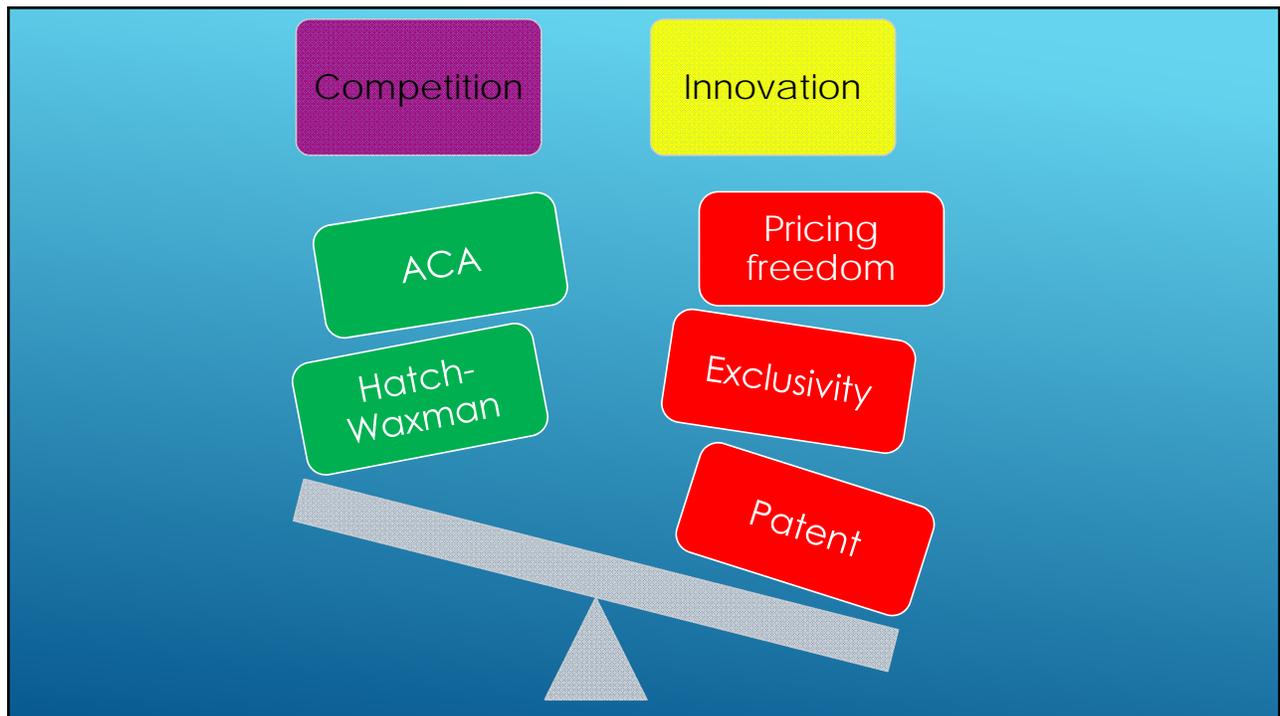


WHAT PRICE SHOULD WE PAY FOR SPECIALTY DRUGS?

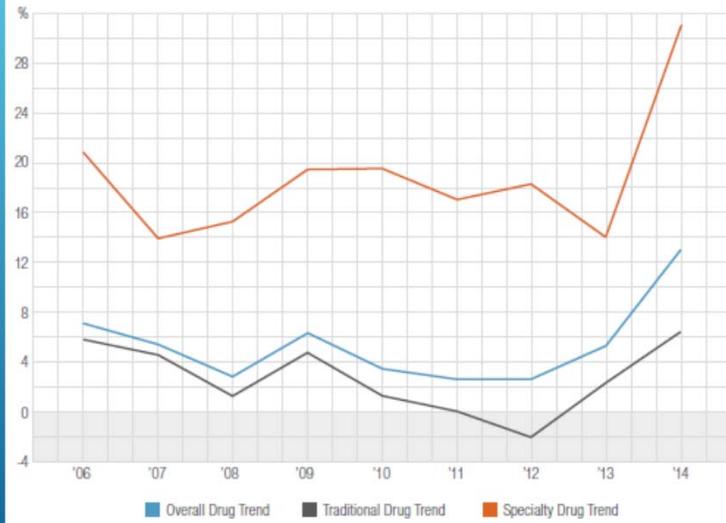
Len M. Nichols, Ph.D.
George Mason University

Alliance for Health Reform
Washington, DC
September 18, 2015



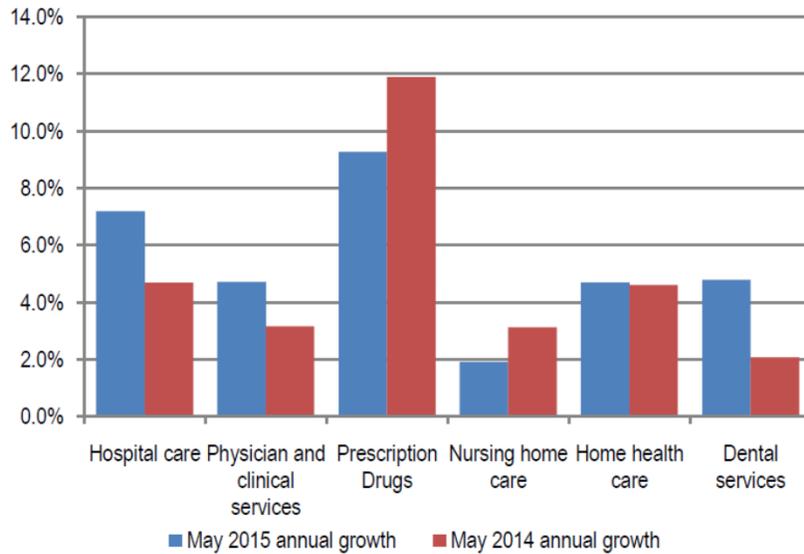
TRADITIONAL, SPECIALTY AND OVERALL TREND

2006 TO 2014



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Exhibit 4. Health Spending Year-over-Year Growth for Selected Categories



Source: Altarum monthly national health spending estimates.

63% Increase in N of patients with more than \$50,000 in drug spend from 2013-2014

MAJOR COST DRIVERS

The estimated number of Americans with drug costs exceeding \$50,000 increased 63% in 2014, from 352,000 to 576,000. The estimated size of the population at the highest end of this spectrum – where annual medication costs exceed \$100,000 per patient – jumped 193%, from an estimated 47,388 to 138,722 Americans. This population now represents 6.5% of total U.S. drug spend (up from 2.5% in 2013).

As noted in Table 1 below, the 0.2% of patients with annual spending at or above \$50,000 accounted for 16% of total spend, while the costliest 5% of patients accounted for 61% of the country's total medication spend.

TABLE 1: DISTRIBUTION OF PATIENTS

BY COST CATEGORY

COST CATEGORY	% TOTAL PATIENTS		% TOTAL COST	
	% TOTAL	CUMUL. %	% TOTAL	CUMUL. %
≥\$100,000	0.05%	0.05%	6.5%	6.5%
\$50,000 - \$99,999	0.17%	0.22%	9.2%	15.7%
\$10,000 - \$49,999	1.8%	2.0%	27.6%	43.2%
\$5,000 - \$9,999	3.1%	5.1%	17.8%	61.0%
\$1,000 - \$4,999	15.6%	20.7%	29.6%	90.7%
<\$1,000	48.2%	68.9%	9.3%	100.0%
NON-UTILIZERS	31.1%	100.0%		
TOTAL	100.0%		100.0%	

193% Increase in N of patients with more than \$100,000 in drug spend from 2013-2014

- ▶ Part B drugs require 20% coinsurance, there is no OOP cap
 - ▶ Average annual income of elderly \$23,000
- ▶ Part D increasingly using coinsurance, there is a cap, but \$7000 (Sovaldi)
- ▶ Marketplace and employer plans now use coinsurance for tiers 3 and 4: average for Silver and Bronze is 40%, some as high as 60%
- ▶ Even with OOP cap under ACA plans, limit would still be \$6,600/\$13,200
- ▶ ERISA plans have no OOP cap, 20-30% coinsurance => 20-30k in liability
- ▶ One survey (JMCP) found most have 25% coinsurance or more for oral cancer drugs
 - ▶ Delays and discontinuation due to cost, especially early in treatment, common:

SOME PATIENT COST-SHARING FACTS

- ▶ Accept status quo, cave to complexity
- ▶ Impose Price Controls
- ▶ Let Medicare bargain with manufacturers for Part B drugs
- ▶ Sanders-Cummings' recent legislation would:
 - ▶ Allow importation from Canada
 - ▶ Require Medicare to negotiate under Part D
 - ▶ Require disclosure of transaction prices and profits earned in other countries, as well as
 - ▶ HOW they set prices, R&D costs, US tax credits received
 - ▶ Outlaw "pay to delay" deals between brand and generic/biosimilar companies
- ▶ Replace private capital with public capital
- ▶ Use fast access and diagnostics for better matches
- ▶ Just say no to low-value drugs; use indication specific pricing
- ▶ Binding arbitration for truly unique drugs
- ▶ Tie exclusivity grant to launch price level (the best new idea in a while)

POLICY OPTIONS

- ▶ This is America, you can price where you want
- ▶ But, IF you set launch price "too high", you will not get exclusivities and we will fast track competitors to market
- ▶ How high is too high? P that allows earnings more than 20-50% higher than cost of capital

A MODEST, RE-BALANCING PROPOSAL