SPECIALTY DRUGS: IT'S ABOUT HEALTH, VALUE AND PRICE

(OR, IF SPECIALTY DRUGS ARE SO COST EFFECTIVE, WHY CAN'Y WE AFFORD THEM?)

Sharon Levine MD

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What is a “specialty drug”

- Definitions vary
- Not to be confused with “specialty tier” in drug benefits
- Meets at least one of the following criteria:
- > special steps: procurement, prescribing, handling, dispensing, use, monitoring
- > unique safety and reporting issues
- > manufacturer imposed restrictions on dispensing
- > and, costs at least $600 per month
- May be oral, or administered (IV, IM) – office, hospital or at home

- Payor perspective
- Provider/clinician perspective
- Citizen perspective

Why the Focus on Specialty Drugs Now,?

- Shift in focus of industry from small molecule drugs to biologics/specialty drugs
- >50% FDA drug approvals since 2011 (not to mention new indications!); 1% of Rx's in 2013, 25% of drug spend;
- Shift in pricing strategy from "cost of development" to "the sky's the limit; because we can"
- Shift in target population from small #'s of patients (orphan drugs/drug pricing) to large populations (Hep C, hyperlipidemia, ↑ BP)
- U.S. spending on specialty prescription drugs is projected to **quadruple** rising from $87.1 billion in 2012 to $401.7 billion in 2020
- **Traditional** tools of drug use management are not up to the task of managing drug costs
- What's left: public outrage? policy interventions? campaign finance reform?

How big a problem ? Over the last 5 years ('08-'13)..

- OUTPATIENT: ↑spend 29%; ↑specialty drugs **213%**; specialty drugs from 16% of total to 39% of total
- ALL DRUGS: ↑spend 25%; ↑ specialty drugs 65%; specialty drugs from 32% to 43% (likely 60% by 2020): new drugs, new indications/"fast track" approvals (FasterCures)
- Cancer; rheumatologics; Hep C; and soon, hyperlipidemia and hypertension, MS, dementias
- Limited competition; 12 year patents; REMS/limited distribution; ≠ biosimilar pathway

How big a problem ? Over the last 5 years ('08-'13)..

- FDA: Breakthrough therapy – "…intended, alone or in combination with one or more other drugs, to treat a serious of life-threatening disease/condition, and [for which] preliminary clinical evidence indicates [they] ***may*** demonstrate substantial improvement over existing therapies…"
- Fast-track approvals –
- Based on small #'s of patients
- Over a decade, from $5000 to $10,000/month of Tx launch prices
- And now, 21st Century Cures; Precision Medicine

And the tools we have to manage specialty drugs?

- Traditional drug use management tools – of limited use: step therapy; generics; therapeutic substitution; prior authorization.
- Limited ability to force manufacturers to compete with sole-source drugs.
- No pricing relief from biosimilars in the near term

Hepatitis C DAA's: a new paradigm

- "Orphan drug" pricing for large population (3 to 5 million Americans; up to 150 million worldwide)
- Clinically superior therapy: 70% viral clearance with prior tx, to >95% viral clearance *efficacy*
- *$95,000 to $150,000 per patient* (≈ 50,000 KP pts)
- Sovaldi (sofosbuvir - the $1000 pil); Olysio (simeprivir); Harvoni (combination pill – 2 oral meds; 8 weeks vs. 12 weeks of tx) – interferon sparing, minimal side effects, superior efficacy in clinical trials – need long term tracking to determine if viral clearance= cure of liver disease

Gilead's Hep C Treatments

- $1,000 per pill
- Approved 2013
- $84,000 for 12 week course
- Some patients need 24 weeks
- $11 billion to Pharmasset for the rights to the drug
- Over $11 billion in revenue in 2014
- Once daily oral used with interferon
- Moderate to high cure rate

- $1,125 per pill
- Approved 2014
- $94,500 for 12-week course
- $63,000 for 8-week course
- One pill containing two drugs
- All oral treatment
- Fewer side effects
- High cure rate

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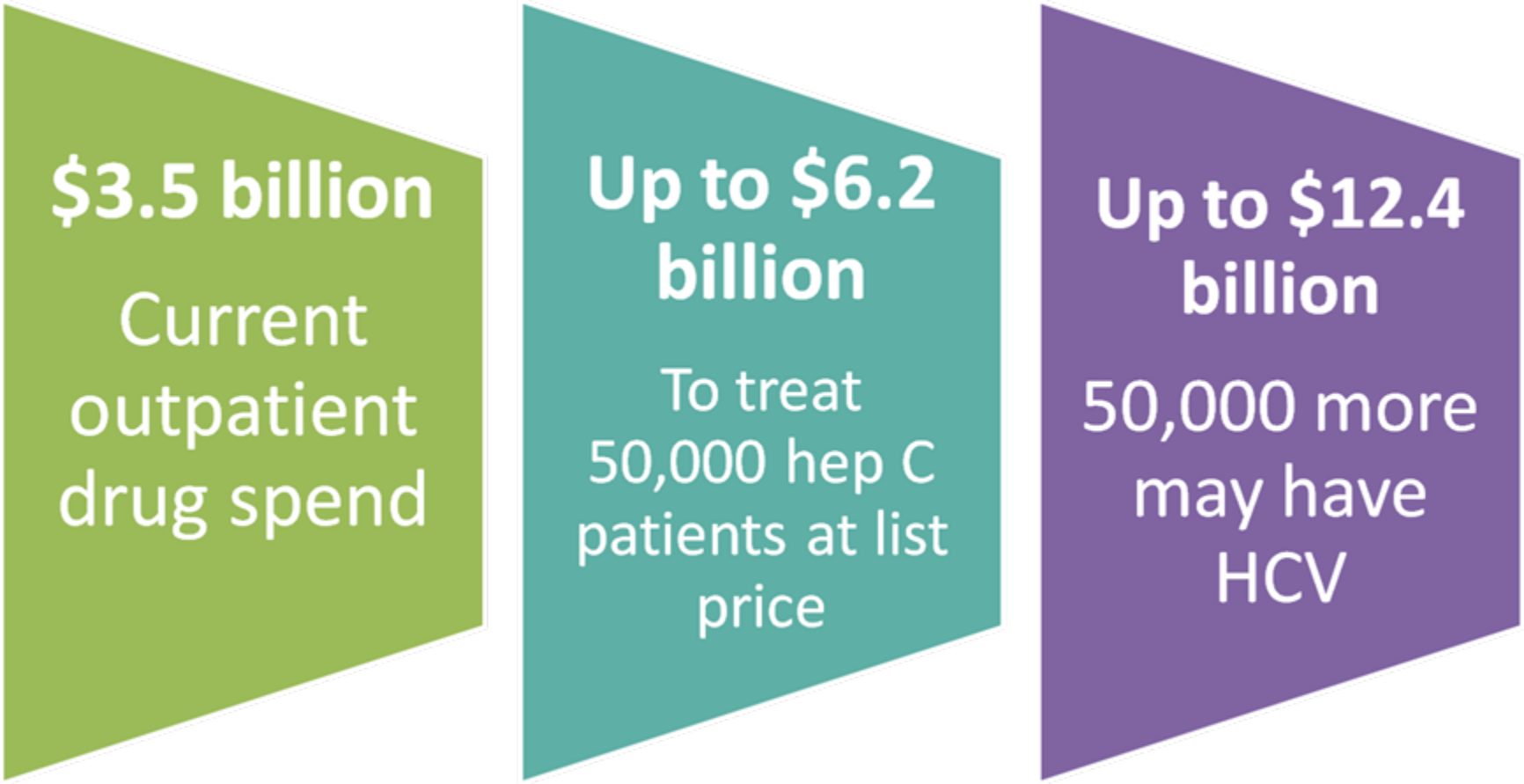
Hepatitis C DAA's: a new paradigm

- Agreement: treat Metavir stage 3 & 4 patients – fibrosis, cirrhosis, extrahepatic manifestations, transplant & post-transplant candidates; co-infected HIV/Hep C; Hep B/Hep C
- 20% of chronic Hep C infected pts (3 million) will progress to cirrhosis/cancer (600,000); 5% of the 20% (1% of total) will require transplant (30,000)
- Av. Cost of liver transplant $580,000 × 30,000≈$17 billion; tx for 3 million = >350 billion; so much for the "cost offset" argument that Hep C represents economic value for the country

And the outstanding questions…

- ? Asymptomatic pts; ? Screening of all “boomers” (b. 1950 and after); ? Emerging issue of 19 to 39 yo white suburban & rural Rx drug/cocaine users
- ? Viral clearance = end of progression of liver disease;
- ? Effectiveness vs. efficacy;
- ? Re-infection;
- **Clinical & ethical dilemma for providers**
- **Cost dilemma for payers: private, public, taxpayers**
- **Affordability dilemma for patients**
- Need for a different business model; broader, transparent conversation about distribution of “value”;

Impact on Kaiser Permanente



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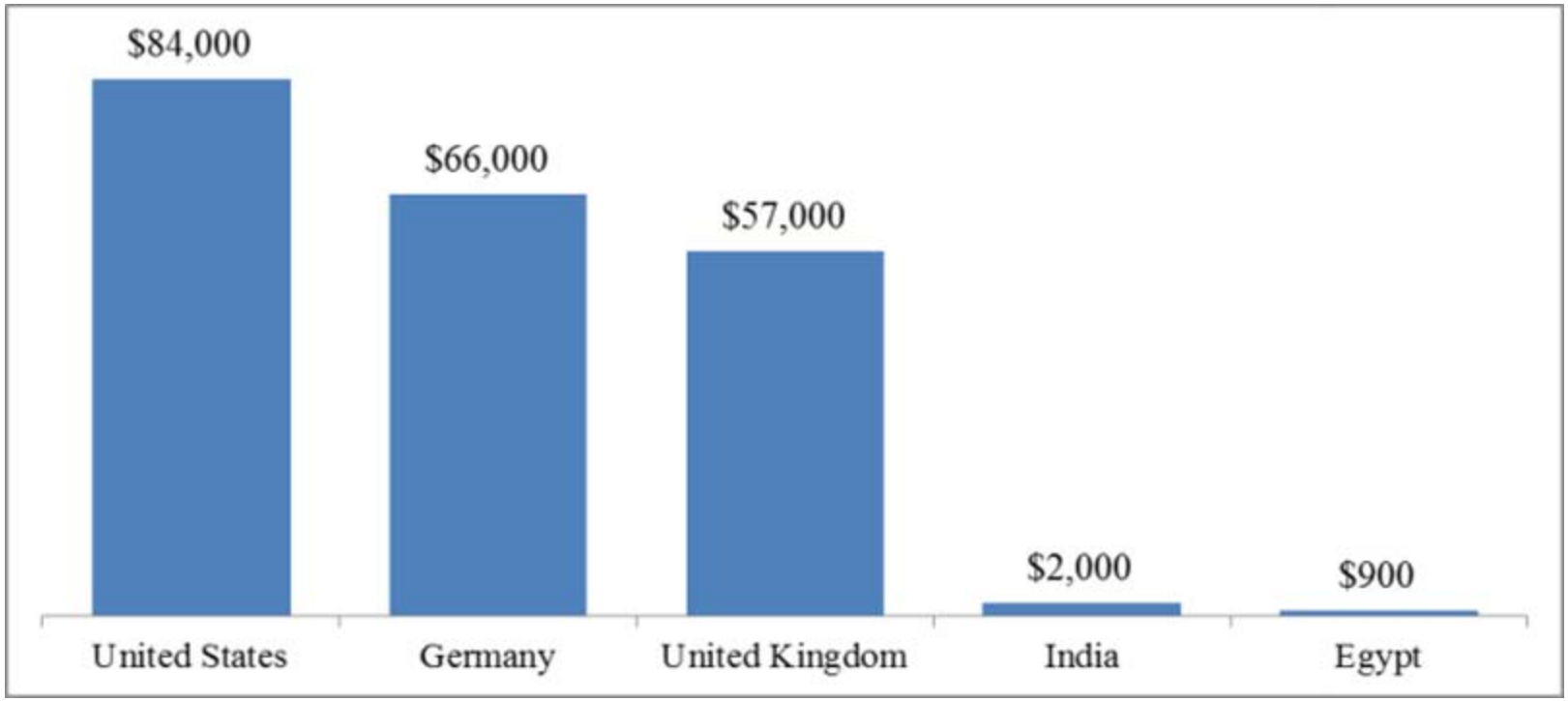
Sovaldi's pricing disparities



*Source: AARP.org and B. Berkrot and D. Beasley, "**U.S. lawmakers want Gilead to explain Sovaldi's hefty price," Reuters, March 21, 2014**.*

AT THESE PRICES, $300 BILLION TO TREAT 3 MILLION IN THE US WITH HEPATITIS C – EQUAL TO TOTAL US DRUG SPEND

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In Summary, as clinicians…

- There is no limit to the concern we feel – the only limits are the paucity of existing policy options, and the limited tools we have to manage the spend..