PERSPECTIVES FROM WASHINGTON

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UNITED STATES ATTORNEY’S OFFICE
SOUTHERN DISTRICT OF TEXAS

- 7th Largest Office in the United States
- Prosecute more cases against more defendants than any other office
- 43 counties / 8.3 million / 44,000 square miles
CIVIL DIVISION

- Represent the United States in state and federal court
- Defensive and Affirmative litigation
- Health Care
  - Fraud (False Claims Act)
  - Drug diversion
  - Food, Drug, and Cosmetic
  - Medicare appeals / suits
  - Bankruptcy
  - Medical malpractice
HEALTH CARE SPENDING

CHRONIC ILLNESS
As of 2014, 60 percent of American adults had at least one chronic condition, and 42 percent had more than one chronic condition.

Figure 1.1. Percentage of U.S. Adults with Chronic Conditions, by Number of Chronic Conditions (2014)
Hypertension and high cholesterol were the most common chronic conditions in 2014.

Figure 1.5. Prevalence of Top Chronic Conditions, 2014

- Hypertension: 27.0%
- Lipid disorders (e.g., high cholesterol): 21.6%
- Mood disorders (e.g., depression, bipolar disorder): 11.9%
- Diabetes mellitus: 10.4%
- Anxiety disorders (e.g., anxiety, panic disorders, stress): 9.7%
- Other upper respiratory disorders (e.g., chronic laryngitis, chronic sinusitis): 7.4%
- Inflammatory joint disorders (other than arthritis): 7.4%
- Osteoarthritis: 6.5%
- Asthma: 6.3%
- Coronary atherosclerosis and other heart disease: 4.8%

Heavy on heart disease
One in four U.S. adults has hypertension, and about one in five has high cholesterol.
Health service use and spending is higher for those with chronic conditions than for those who are healthy.

The more chronic conditions people have, the more they use services of all types. As one example, those with five or more chronic conditions use twice as many drugs on average per year, compared with those with three or four conditions. As another, people with five or more conditions averaged 20 doctor visits per year, compared with 12 visits for those with three or four conditions.

Figure 2.1. Annual Service Utilization by Number of Chronic Conditions (2014)

NOTES: Average utilization is presented; not everyone uses a particular service in a given year, especially inpatient stays and ED visits. The number of prescriptions represents the total number of fills, including refills, not necessarily unique active ingredients, such as acetaminophen or ibuprofen.
People with chronic conditions have higher health care spending.

Those with five or more chronic conditions spend twice as much on average as those with three or four conditions, with the majority of that additional spending going to office visits, inpatient visits, and prescriptions.

Figure 2.3: Health Care Spending by Number of Chronic Conditions (2014)
HEALTH CARE SPENDING

PRESCRIPTION DRUGS
PRESCRIPTION DRUGS

- U.S. spent $341 billion in retail prescription drugs (2016)
- 10% of total national health care spending of $3.4 trillion
- U.S. will spend $597 billion in retail prescription drugs (2025)
- 11% of total national health care spending of $5.55 trillion (2025)
PRESCRIPTION DRUGS

• Drug Mix
  ○ New innovative drugs / specialty drugs (cancer, diabetes, hepatitis C, heart disease)
    ▪ Expensive (33% of total U.S. prescription drug spending in 2014)
    ▪ Need special handling or administration (infused / injected)
    ▪ Limited distribution
    ▪ Narrow group of chronic diseases
    ▪ Biologics
    ▪ Orphan drugs
  ○ Discontinued older generic drugs
  ○ Biologics (12 years exclusivity)
    ▪ Focus of pharmaceutical firms (22% sales in 2013)
PRESCRIPTION DRUGS

- Orphan Drugs (7 years exclusivity)
  - Often biologics
  - Targeted at rare disease or condition
  - Affect fewer than 200K persons or more than 200k persons (sales less than cost)
  - 41% of FDA approvals (2014)
  - Off-label use / blockbuster drugs with sales of $1 billion + per year

- Change in Drug Prices
  - Retail drug inflation 6.3% vs. general consumer inflation 2.1% (2016)
  - Increase prices for existing brand-name drugs & high initial price for new innovation brand-name drugs
  - Raise prices for existing generic drugs
PRESCRIPTION DRUGS

- **Drug Utilization**
  - Patient Protection & Affordable Care Act (ACA)
  - Expand Medicaid (31 states)
  - Commercial insurance exchanges
  - Medicare Part D

- **Consumer Out-of-Pocket Spending**
  - 1990 consumers paid 57% of U.S. retail drug spending
  - 2015 consumer paid 14% of U.S. retail drug spending
  - 2015 government paid 43% and private insurance plans paid 43%
**PRESCRIPTION DRUGS**

- **Pharmaceutical Development & Marketing**
  - Federal government focus on basic / pre-clinical research
  - Pharmaceutical industry focus on clinical trials
  - Platform technologies developed with public funds enable development of FDA approved products
  - Cost to develop a new drug: $1.2 - $2.6 billion

- **Direct to Consumer Advertising**
  - Pharmaceutical firms spent $6 billion (2015)
  - 2015 study: 10% rise in advertising = 5.4% increase in filled prescriptions
PRESCRIPTION DRUGS

- Pharmacy Benefit Managers (PBM)
  - Negotiate directly with pharmaceutical manufacturer (rebates / discounts)
  - Increase cost sharing (higher deductible / impose co-insurance)
  - Use a tier formulary
  - Mail-order services – conflict of interest

- Pharmaceutical Manufacturers Patient Assistance
  - Discount cards
  - Patient assistance programs (PAP)
Co-payment Coupons
- Help consumers reduce out-of-pocket costs
- Create demand for newly introduced drugs
- Increase consumer adherence to existing prescriptions
- Bolster market for brand-name drugs with expired patent
- 2016 – 600 coupon programs / $5 billion a year
- Return on investment: 4:1 to 7:1
- Federal health benefits: not allowed (AKS)
- 2014 HHS-OIG report
- Commercial payers bar use / drop drug from preferred formulary
- Pharmaceutical companies – debit cards / rebates
PRESCRIPTION DRUGS

• Patient Assistance Programs
  ○ Pharmaceutical manufacturers
    ▪ 7 of 10 largest U.S. grant-making foundations
    ▪ Provide drugs to uninsured or underinsured
  ○ State governments
    ▪ 19 state governments (2014)
    ▪ Uninsured or fill gap (Medicare, Medicaid, or private insurance)
  ○ Independent charities
    ▪ Financial assistance to uninsured or underinsured (premiums / cost-sharing)
  ○ 501(c)(3) non-profit organizations (drugs & money)
    ▪ Contributions are tax deductible (inventory or cash donations)
PRESCRIPTION DRUGS

- Patient Assistance Programs
  - Consumer eligibility
    - Annual income (federal poverty level (FPL) 200% - 400%)
    - Insurance status
    - Physician endorsement
    - Prescription information
    - Proof of U.S. citizenship or legal residence
  
  - 2005 HHS OIG Bulletin
    - Truly independent charities could receive cash donations from drug manufacturers
    - Drug manufacturers’ PAP could operate outside of Medicare Part D (no claims)
    - PAPs may not provide data (donated funds for donor’s drugs)
Patient Assistance Programs

- 2014 Update to HHS OIG Bulletin
  - Increase scrutiny of independent charity PAPs (establish / operate funds for narrow specific diseases or limited assistance to subset of available products)
  - General tendency to move away from broad disease funds and toward narrower funds (specific stage or complication)
  - Restrictions on drugs covered harm patients, taxpayers, and federal programs
  - Steer patients to highest-cost drugs covered by PAP rather than equally effective lower-cost alternatives (no freedom of choice)

- DOJ Subpoenas
  - Celgene relationship with independent PAPs
  - Gilead Sciences relationship with independent PAPs
• **Patient Assistance Programs**
  
  o 10 leading manufacturer PAPs’ charitable expenditures rose from $376 million (2001) to $6.1 billion (2014)

  o Contributions to five independent charity PAPs increased from $2 million (2001) to $868 million (2014)
PRESCRIPTION DRUGS

• Barriers to Competition
  ○ Biologics Price Competition and Innovation Act (BPCIA)
    ✷ Biosimilar and interchangeable biologic product
    ✷ Delay in guidelines from FDA (biosimilars – 2015 & interchangeable – 2019)
    ✷ 12 years exclusivity for a reference biologic
    ✷ Patent resolution mechanism
    ✷ Differentiated naming standards for biosimilars (formulary problems)
  ○ Orphan Drug Act of 1983
    ✷ > 60% are biologics
    ✷ Exclusion from 340B drug program
    ✷ Off-label use for old drugs
    ✷ Separate approval for each disease subtype (i.e. cancer/ Bevacizumb = 14)
    ✷ 7 years exclusivity
PREScription Drugs

• Barriers to Competition
  ○ First generic applicant
    ▷ 180 day period of exclusivity
    ▷ Tied up in patent litigation with brand-name drug manufacture delays 180 days
  ○ Risk Evaluation and Mitigation Strategies (REMS)
    ▷ 40% of new FDA approvals are subject to REMS
    ▷ Brand-name drug companies withhold samples from potential generic or biosimilar entrants citing to REMS
    ▷ Brand-name drug manufacturers patent REMS programs and do not share with potential generics or biosimilar entrants
PRESCRIPTION DRUGS

- **Barriers to Competition**
  - **Product hopping**
    - Brand-name drug manufacture obtains new NDA or BLA approval for variant of its product (i.e. capsules vs. tablets)
    - Release the new product, market it, and get patients to move over to new version before patent for earlier version expires
    - Hard switching: withdraw the old product and only sell the new product

- **Small Pharmaceutical Firms**
  - Portfolios of one or two drugs set higher prices
  - Overcharge for restricted products & free ride on insurance bundle
  - Daraprim: generic drug by Turing Pharmaceuticals ($13.50 to $750 per tab)
    - Used REMS to stop potential generic drug entrants
Title I: Transparency

- Section 101: Drug manufacturer reporting
  - Disclose research and development costs, manufacturing and marketing costs, acquisitions, federal investments, revenue and sales
  - By product
  - Secretary of HHS make information public

- Section 102: Determining the public and private benefit of copayment coupons and other patient assistance programs
  - Independent charity assistance programs disclose to IRS total amount of patient assistance provided to patients who are prescribed drugs manufactured by a donor
  - GAO study impact of patient assistance programs on prescription drug pricing / spending
Title II: Access and Affordability

- Section 201: Negotiating fair prices for Medicare prescription drugs
  - Allow Secretary of HHS to negotiate with drug companies to lower prescription drug prices
  - Prioritize negotiations on specialty and other high-priced drugs
  - Use VA drug prices if no agreement reached

- Section 201: Prescription drug price spikes
  - HHS-OIG monitor changes in drug prices & take steps to prevent drug manufacturers from engaging in price gouging
  - If drug company increases a drug’s price above medical inflation, will pay a graduated excise tax
  - Accelerate closing of Medicare Part D coverage gap (donut hole) by 2018
Title II: Access and Affordability

- Section 204: Importing affordable and safe drugs
  - Allows wholesalers, licensed U.S. pharmacies, and individuals to import qualified prescription drugs manufactured at FDA-inspected facilities from licensed Canadian sellers and two years later from OECD countries meeting standards like U.S.

- Section 205: Requiring drug manufacturers to provide drug rebates for drugs dispensed to low income individuals
  - Restores prescription drug rebates for seniors dual eligible Medicare / Medicaid and extends rebates to other Medicare patients in Medicare low-income-subsidy (LIS) plans

- Section 206: Cap on prescription drug cost-sharing
  - Caps prescription drug cost sharing at $250 per month (individual) and $500 a month (families) enrolled in Qualified Health Plans and employer plans (2019)
Title III: Innovation

- Section 301: Prize fund for new and more effective treatments of bacterial infections
  - Creates a $2 billion prize fund at the National Institutes of Health to fund entities that develop superior antibiotics that treat serious and life-threatening bacterial infections and to fund research that advances such treatments and is made publicly available

- In order to receive prize funds, recipients must commit to offering their products at a reasonable price, share clinical data, take steps to promote antibiotic stewardship and waive applicable exclusivity periods
Title III: Innovation

- Section 302: Public funding for clinical trials
  - Creates a Center for Clinical Research within the NIH to conduct all stages of clinical trials on drugs that may address an existing or emerging health need.
  - $10 billion in funding over 10 years.
  - If these trials support a drug that receives FDA approval, the Center for Clinical Research will execute non-exclusive licenses with drug manufacturers or enter into purchasing contracts to manufacture the approved drug.
Title III: Innovation

- Section 303: Rewarding innovative drug development
  - Modifies the New Chemical Entity (NCE) exclusivity period to allow FDA to accept a generic drug application for the branded product after three years rather than five, but maintains market exclusivity for five years
  
  - Add in a requirement that products awarded the 3-year New Clinical Investigation Exclusivity must show significant clinical benefit over existing therapies manufactured by the applicant in the 5-year period preceding the submission of the application

  - Reduces the biological product exclusivity from 12 years to 7 years

  - GAO to conduct a study on orphan drug development, awarding of exclusivities, and revenues generated from orphan drugs
Title III: Innovation

- Section 304: Improving program integrity
  - Terminate any remaining market exclusivity periods on any product found to be in violation of criminal or civil law through a federal or state fraud conviction or settlement in which the company admits fault

Title IV: Choice and Competition

- Section 401: Preserving access to affordable generics
  - Make it illegal for brand-name and generic drug manufacturers to enter into anti-competitive agreements in which the brand-name drug manufacturer pays the generic manufacturer to keep more affordable generic equivalents off the market
Title IV: Choice and Competition

- Section 402 & 403: 180-Day exclusivity period amendments regarding first applicant status and agreements to defer commercial marketing
  - Enables FDA to take away the 180-day generic drug exclusivity period from any generic company that enters into anti-competitive pay-for-delay settlements with brand-name drug manufacturers

- Section 404: Increasing generic drug competition
  - Requires the HHS Secretary to maintain a public, up-to-date list of generic drugs and their manufacturers (including distributors, labelers, and compounders) to more quickly identify drugs at risk of shortage or drugs with a limited number of competitors
  - Directs generic drug manufacturers to report a discontinuance or interruption in the production of a drug at least 180-days prior to the event or as soon as practicable
Title IV: Choice and Competition

Section 404: Increasing generic drug competition
- Authorizes the federal government to enter into purchase contracts with generic drug manufacturers if the number of manufacturers for essential medicines, as defined by the World Health Organization or another similar entity, falls below two.

Section 405: Product hopping
- Establishes a definition for the term “product hopping” and instructs the FTC to submit a report to Congress on the extent to which companies engage in these anti-competitive practices and their effects on company profits, consumer access, physician prescribing behavior, and broader economic impacts.
REPEAL AFFORDABLE CARE ACT

- Take / Pick a Bill Number
- Basic Provisions
  - Repeal individual health insurance mandates
  - Repeal all insurance coverage provisions
  - Reduction / termination of enhanced federal matching funds
  - Per capita-based cap on Medicaid payments
  - Reduce subsidies for non-group health insurance
  - Provide individual tax credits to buy health insurance ($2000 - $4000)
  - Create patient and state stability fund ($10-15 billion)
- Results
  - Reduction in federal spending $150 - $420 billion (10 yrs)
  - Reduction in enrollment: 14.2 million (2020) / 32 million (2026)
POTENTIAL IMPACTS ON PAP

- Greater oversight by HHS-OIG / FDA / FTC of PAPs
- Bar use of co-payment cards / individual debit-rebate cards
- Supported drugs dropped from insurance drug formularies
- Reduced contributions to PAPs
- Less assistance offered by PAPs