DRUG PROBLEMS

HOW TO PREPARE FOR THE NEXT WAVE OF PHARMACEUTICAL INNOVATION

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A SOLUTION AND A CHALLENGE

IMAGE SOURCE: GETTY IMAGES.

THE CHALLENGE

- **CHRONIC DISEASE**:
  - approximately 50% of all adults have a chronic disease[1]
  - Diabetes[2]
    - An estimated 30.3M in the US (9.4%) have diabetes in 2015 (84MM have pre-diabetes)
    - Cost of $322B in 2016 with the average cost per diabetic of $14K (2.3x > than non-diabetics)
  - In 2014, 7 of the top 10 causes of death were chronic illnesses[3]
  - Heart disease and cancer together account for nearly half of all deaths[3]

- **COMORBIDITES:**
  - Diabetes leads to cardiovascular disease, kidney failure, blindness, and amputations
  - Depression is a common complication of chronic diseases, including cardiovascular disease, cancer, Parkinson's disease, Multiple Sclerosis, chronic pain, and diabetes, with 1 in 3 experiencing depression [4]

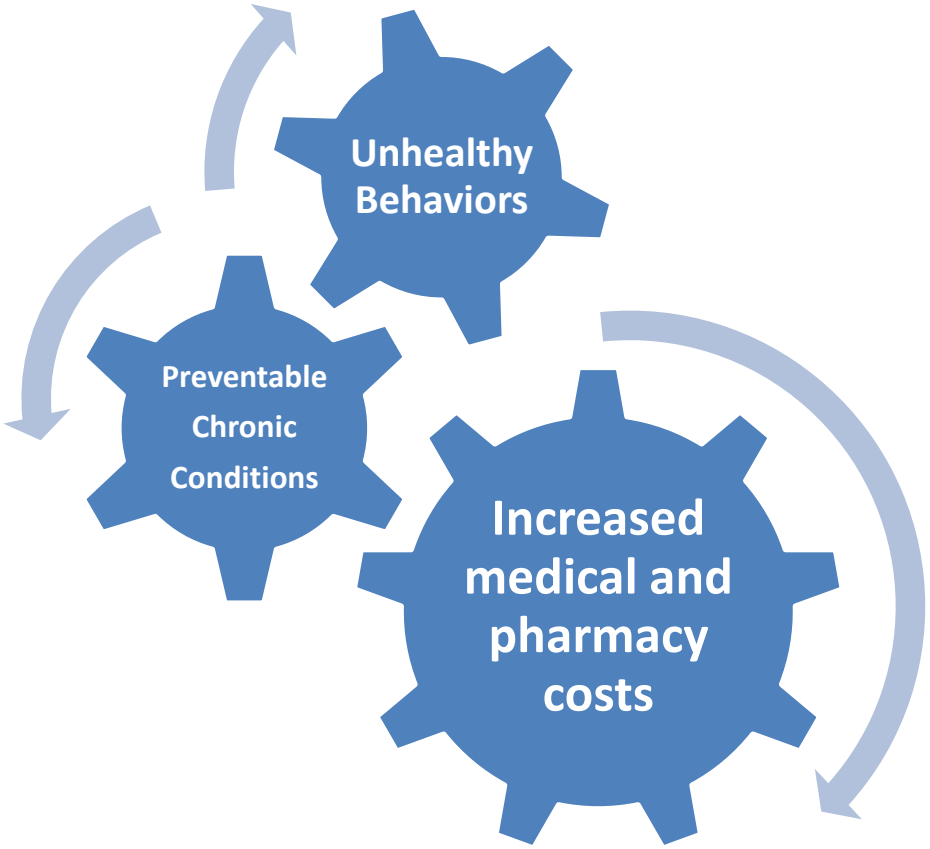
- **ESCALATING COSTS:**
  - 21% of cost--Pharmacy impact on total health care costs[5]
  - 1/3 of all drug spend is for specialty. Discovery and innovation will continue to drive more products[6]
  - 1-2% of Americans use specialty drugs and they account for 38% of total Rx costs.[7]
  - 50% Projected rise in Specialty Rx costs in next 10 years[6]
  - 40%--2020 Specialty Rx versus conventional drug spend for the average employer[8]

1. Ward,BW, Schiller JS, goodman RA. Multiple chronic conditions among US adults: a 2012 update. *Prev Chronis Dis.* 2014;11:E62.
2. CDC 2017 Diabetes Report
3. CDC. Leading causes of death and numbers of deaths by sex, race, and Hispanic origin: US,, 1980 and 2014. *Health, United States,* 2015.
4. WebMD Medical Reference, Reviewed by J. Goldberg, MD on Feb 08, 2014, WebMD, LLC. All rights reserved
5. Cigna book of business national analytics, 2013 - 2014
6. Herr, J. "Employers Becoming More Savvy About Specialty Pharmacy, but Need More Cost Controls." Midwest Business Group on Health. February 2013.
7. PEW Charitable Trusts report, December 2016
8. IMS Health: whitepaper Succeeding in the Rapidly Changing U.S. Specialty Market, 2014.

RISK FACTORS FOR PREVENTABLE CHRONIC DISEASES

A 2016 white paper from the Partnership to Fight Chronic Disease says the "growing burden of chronic disease is unsustainable" and it advocates increased coordination, continuity of care and care management.

http://www.fightchronicdisease.org/

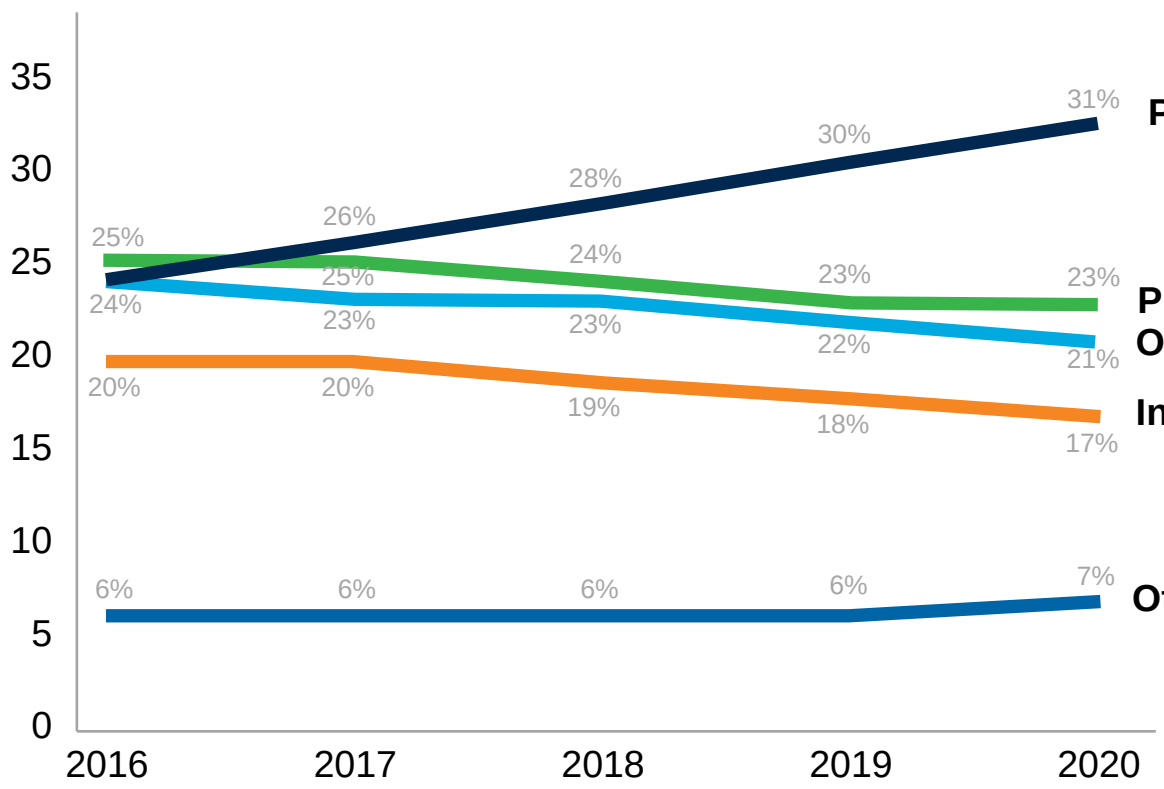


BEHAVIORAL RISK FACTORS AND CHRONIC DISEASE

- High Blood Pressure
- Tobacco
- Obesity (BMI)
- Physical Inactivity
- Excessive Alcohol Intake
- Poor Dietary Choices
- Poor Oral Hygiene
- Sun Exposure’
- Stress Management

TRENDS: HYPER-INFLATED. UNSUSTAINABLE.

Total Health Care Costs*



Pharmaceuticals #1

Professional medical

Outpatient

Inpatient

Other medical services

*Cigna book of business national study 2016. Projection compares the following health care spend for medical service categories: Drugs and Biologics, Inpatient Facility, Outpatient Facility, Professional Services, Other Medical Services.

CURRENT STATE

- US drug manufacturers set their own prices
- Insurers are incentivized to prefer certain drugs
- 2 Forms of Market Protection: Patents and Market Exclusivity
  - Lengthy patent terms (20 years)
  - Duration of market exclusivity varies (granted upon FDA approval)
- Generic competition
  - Patent protection and market exclusivity system
  - FDA backlog
- Generic substitution
  - State laws: mandatory vs permissive substitution laws
  - Prescriber instructions: Dispense as Written
  - Customer preference: power of branding and marketing

OUR USE OF ALL MEDICATION TYPES IS INCREASING

- Nearly 3 in 5 American adults take a prescription drug, up markedly since 2000 because of much higher use of almost every type of medication, including antidepressants and treatments for high cholesterol and diabetes.

- In a study published in the Journal of the American Medical Association, researchers found that the prevalence of prescription drug use among people 20 and older had risen to 59 percent in 2012 from 51 percent in 2000. The percentage of people taking five or more prescription drugs nearly doubled, to 15 percent from 8 percent.

- One likely factor driving the increased use: obesity.

- Researchers noted that eight of the 10 most commonly used drugs in the United States are for hypertension, heart failure, diabetes and other elements of the “cardiometabolic syndrome.” Additionally, drugs that treat gastroesophageal reflux is a widespread condition among the overweight or obese.

JAMA. 2015;314(17):1818-1830. doi:10.1001/jama.2015.13766

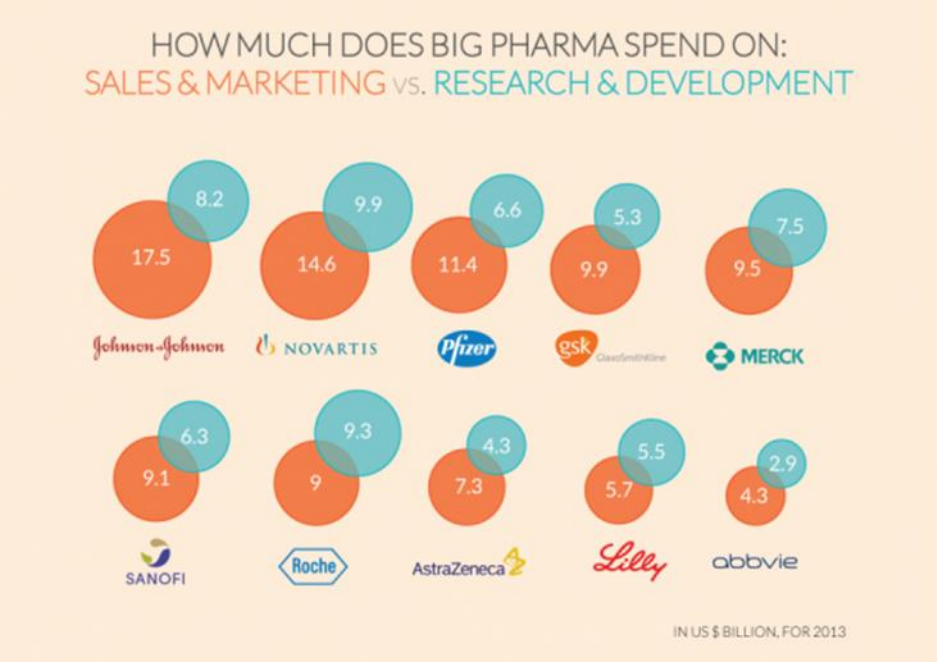
MEDICATION NON-ADHERENCE: THE OTHER SIDE OF THE COIN

- 20% to 30% prescriptions are never filled[1,2]
- 50% of doses for chronic disease are not taken as prescribed[1,2]
- Non-adherence causes
  - 125,000 deaths per year[1]
  - 10% of hospitalizations[1]
  - Significant morbidity and mortality
- $100 - $300 billion in health care costs have been attributed to non-adherence in the US annually[3], making up 3% to 10% of total US health care costs[4]

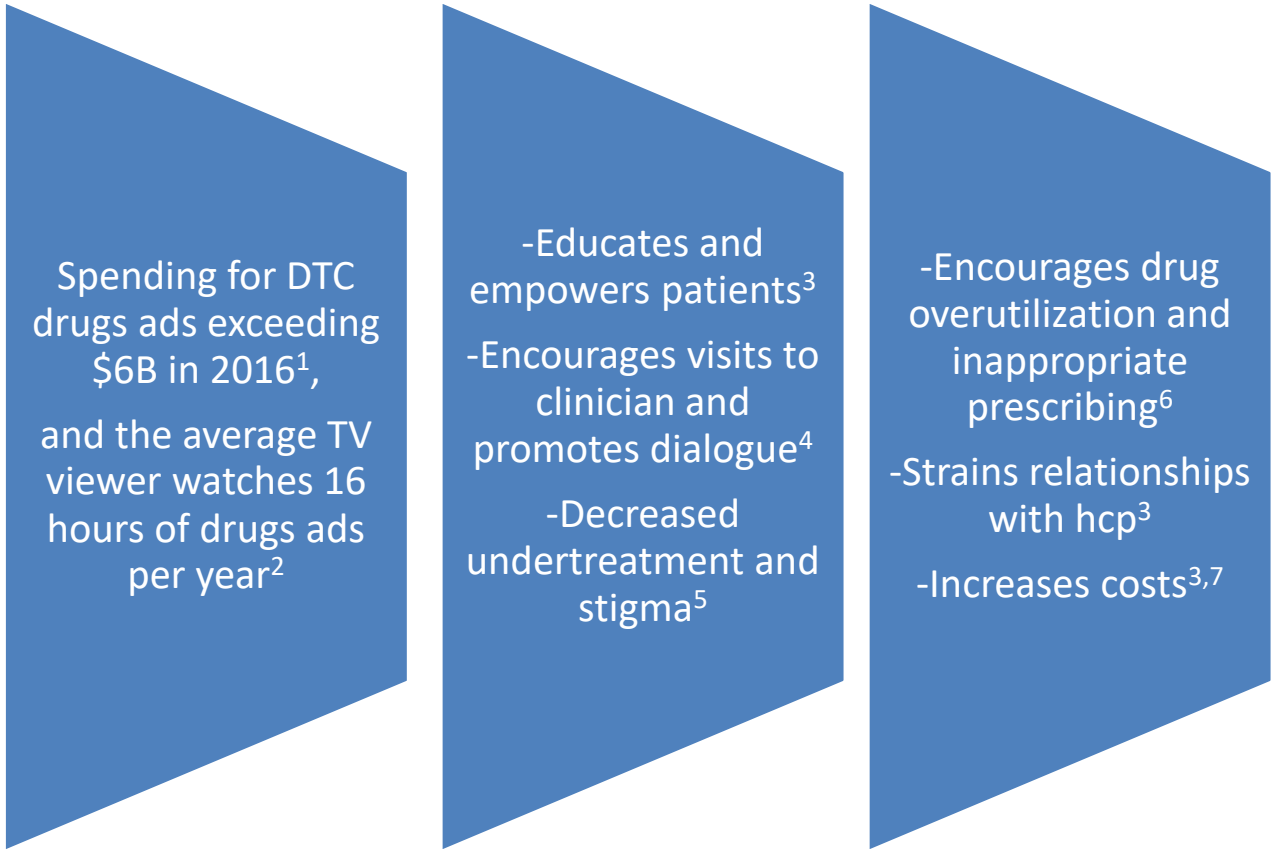
1. Peterson AM, Takiya L, Finley R. Meta-analysis of trials of interventions to improve medication adherence. Am J Health Syst Pharm. 2003 ; 60; 657-65.
2. Haynes RB, Ackloo E, Sahota N, McDonald HP, Yao X. Interventions for enhancing medication adherence. Cochrane Database Syst Rev. 2008 CD000011.
3. IMS Institute for Healthcare Informatics Avoidable costs in US health care. 2013.
4. Benjamin RM. Medication adherence: Helping patients take their medicines as directed. Public Health Rep. 2012;127(1):2–3.

ADVERTISING WORKS!

- The U.S. is one of only 2 countries that allow direct to consumer drug advertising
- In 2016 $6 billion was spent on DTC ads. $24 billion spent in 2012 advertising to doctors
- 10% increase in advertising exposure results in 5% increase in utilization
  - 70% increase in utilization is from new prescriptions
  - 30% increase in utilization if from improved adherence from existing users



DIRECT TO CONSUMER ADVERTISING



1. Statista 2017
2. Brownfield ED, Bernhardt JM, Phan JL, Williams MV, Parker RM. Direct-to-consumer drug advertisements on network television: an exploration of quantity, frequency, and placement. J Health Commun. 2004;9(6):491–497.
3. Delbaere M, Smith MC. Health care knowledge and consumer learning: The case of direct-to-consumer advertising. Health Mark Q. 2006;23(3):9–29..
4. Boden WE, Diamond GA. DTCA for PTCA: Crossing the line in consumer health education? N Engl J Med. 2008;358(21):2197–2200.
5. Auton F. Opinion: The case for advertising pharmaceuticals direct-to-consumers. Future Med Chem. 2009;1(4):587–592.
6. Nelson R. When ads trump evidence: Is direct-to-consumer advertising leading practice? Am J Nurs. 2007;107(10):25–26.
7. Abel GA, Penson RT, Joffe S, et al. Direct-to-consumer advertising in oncology. Oncologist. 2006;11(2):217–226.

COUPONS/ASSISTANCE PROGRAMS

- Offsets member cost-share (>300 drugs, $4B spent by drug companies to support)
- Increase demand for higher-cost drugs and reduce use of generic options when they exist
- Physicians are generally receptive to patient demand for brand-name drugs if the drug is appropriate
- May improve adherence but health benefits of these medications may be only marginally better
- Generally are not income dependent
- Overall drive pharmaceutical costs higher and defeat the intent of most pharmacy benefit designs
- Are often time-dependent and expire for the patient (e.g. after one year). Patients are often reluctant to change to a lower price alternative

David H. Howard, Ph.D.,
N Engl J Med 2014; 371:97-99, July 10, 2014

EXISTING AND PENDING THERAPIES $$$

>100 other drugs that cost more than $400K/year

Glybera: 2012 for a genetic condition that causes increased fat in the blood: $1MM/year

Actimmune: Treats 2 genetic conditions and reduces infections and worsening disease: $572K/year

Soliris: Treats 2 rare diseases, a blood disorder and immune system issue: $543K/year

Ravicti: for treating urea cycle disorders, genetic conditions impacting 2000 in the US: $794,000/year

Carbaglu: Treats a rare genetic condition that causes increased ammonia levels: $585K/year

Spinraza: 2016 for spinal muscular atrophy: $750,000 year one, then $375K/year

Lumizyme: 2010 for Pompe disease, a genetic condition: $625K/year

DOES AN INCREASE IN DRUG SPEND RESULT IN COST OFFSETS ON THE MEDICAL SPEND?

- Cost offsets generally increase with better compliance and in conditions with greater prevalence in society
- Cost offsets are greatest using generic drugs for cholesterol, congestive heart failure, diabetes and hypertension
- Specialty drugs generally increase the overall cost for care but often deliver greater patient benefit than traditional treatments (Hepatitis C treatments)
- Often, the payer of high-cost specialty drugs (and medical procedures) does not reap the benefit due to movement of the patient or employer or insurer within the system
- Value-based assessments are increasingly being utilized in U.S. decision-making processes

Summary of Therapy Value Frameworks.*

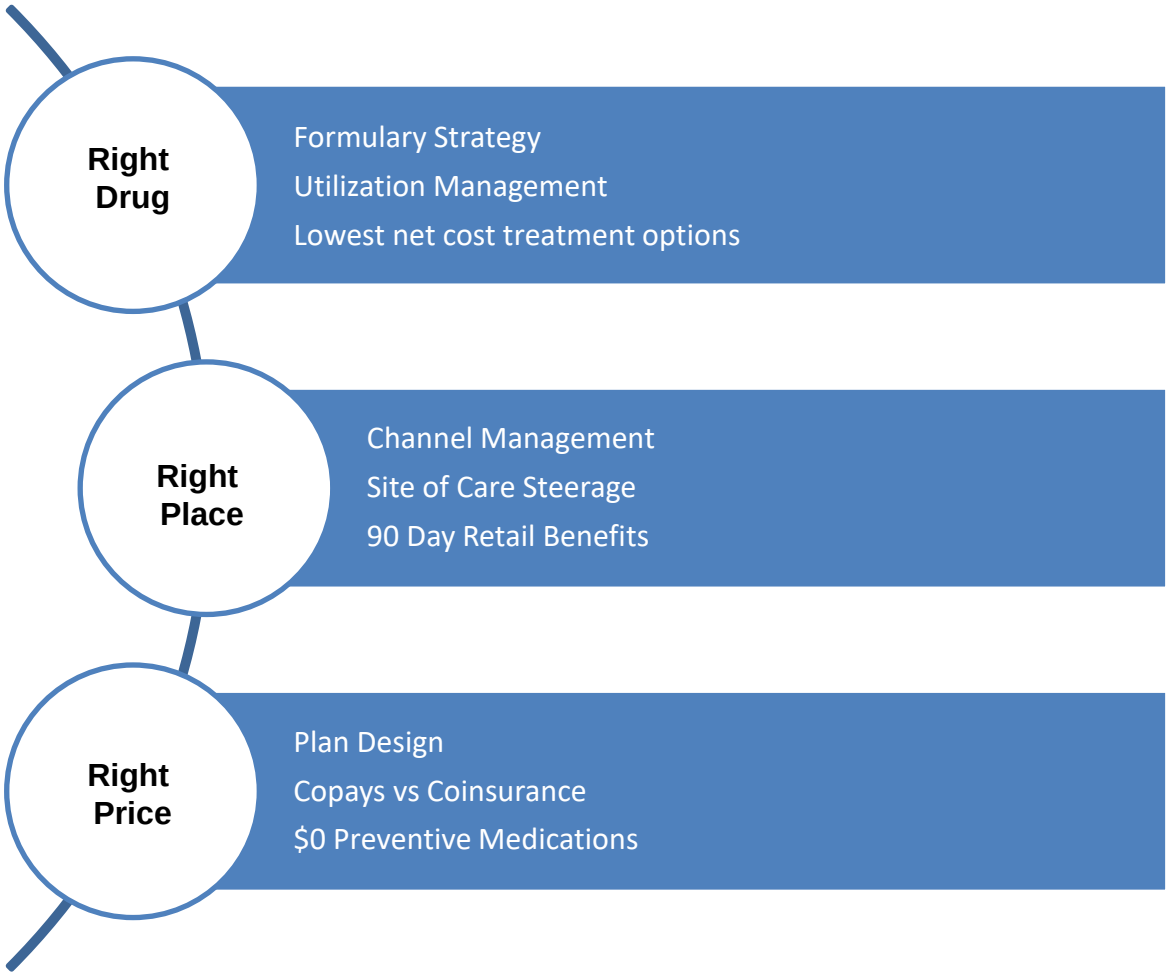
Organization	Factors Considered	Description
American College of Cardiology–American Heart Association (ACC–AHA)	Clinical benefit vs. risks Magnitude of net benefit Precision of estimate based on quality of evidence Value (cost-effectiveness)	Magnitude of treatment effect ranges from class I ("benefit [greatly exceeds] risk," "procedure or treatment is useful or effective") to class III ("no benefit, or harm," "procedure or treatment is not useful or effective and may be harmful"). Precision of treatment effect ranges from level A ("data derived from multiple randomized trials or meta-analyses") to level C ("only consensus opinion of experts, case studies, or standard of care"). Value corresponds to cost-effectiveness thresholds (high: less than $50,000 per QALY; intermediate: $50,000 to $100,000 per QALY; low: more than $150,000 per QALY). The framework lists the clinical benefit and value designations without combining them.
American Society of Clinical Oncology (ASCO)	Clinical benefit Overall survival Progression-free survival Response rate Toxicity Bonus factors Palliation Time off all treatment Cost per month	A therapy can be awarded up to 130 points. Clinical benefit (≤80 points) reflects end point and magnitude of benefit, with preference given to evidence on overall survival if available. Toxicity (±20 points) reflects the rate of grade 3 to 5 toxic effects with treatment relative to standard of care. Bonus point score reflects palliation (10 points if therapy improves symptoms) and increased time off all treatment (≤20 points). The framework doesn't combine each drug's point score and cost.
Institute for Clinical and Economic Review (ICER)	Incremental cost-effectiveness plus care value components Comparative clinical effectiveness Other benefits and disadvantages Contextual considerations Budget impact	Cost-effectiveness ratio must not exceed a threshold ranging from $100,000 to $150,000 per QALY. Selection of final threshold is based on: (a) comparative clinical effectiveness, reflecting "judgments of the health benefit magnitude" and "strength of a body of evidence"; (b) other benefits and disadvantages, including such outcomes as factors influencing adherence or return to work; and (c) contextual considerations, including "ethical, legal, or other issues" (e.g., high burden of illness, availability of alternative treatments). Budget impact is acceptable if a drug's introduction is compatible with an annual health care budget increase of GDP growth plus 1%. ICER reverse-engineers a "value-based price benchmark" that independently satisfies both the cost-effectiveness and budget-impact criteria (see text).
Memorial Sloan Kettering Cancer Center	Efficacy (survival) Toxicity Novelty Research and development cost Rarity Population health burden	Framework assigns values to each domain. Efficacy is assessed as improvement in overall survival, if available. Efficacy score also reflects evidence quality. Toxicity is a drug's impact on probability of severe side effects and treatment discontinuation. Novelty is scored as 1 (novel mechanism of action), 0.5 ("known target but different mechanism of targeting"), or 0 ("next-in-class"). Research and development cost corresponds to the "number of human subjects enrolled in the approval trials for the first indication." Rarity is the 2015 projected disease incidence. Population health burden is the annual years of life lost to the targeted disease in the United States. "Fair price" is the product of the scores, each of which is scaled by a user-adjusted weight.
National Comprehensive Cancer Network (NCCN)	Efficacy Safety Evidence quality Evidence consistency Affordability	Each area is scored on a scale of 1 to 5, with 1 indicating least favorable and 5 most favorable. The framework presents the scores separately. There is no explicit synthesis. Stakeholders judge acceptability on the basis of their overall impression of the listed factors.

* GDP denotes gross domestic product, and QALY quality-adjusted life-year.

N Engl J Med 2015; 373:2595-2597, December 31, 2015

SOLUTIONS: MAINTAINING AFFORDABILITY

PHARMACY PLAN DESIGN



BENEFITS OF INTEGRATION

- Greater identification of patients for condition outreach and management
- Lower inpatient admission and readmission rates
- Develop pharmacy management programs that span medical and pharmacy (e.g. step through pharmacy options prior to medical Rx)
- Single point of contact for members improves satisfaction and adherence
- ROI between 1.6 to 10.2 based on condition
- Total medical cost savings opportunity
- Reduced organizational workload to integrate and understand separate data reporting

Published in November 2008 in Managed Care Magazine at http://www.managedcaremag.com/archives/0811/0811.carveouts.html.

CHALLENGES OF NON-INTEGRATED BENEFITS

- Many conditions require medications supplied from both the medical and pharmacy benefit areas
- In one national health plan, 86% of calls to pharmacy were related to medical benefit needs, not pharmacy[1]
- Lack of coordination between medical and pharmacy vendors
- Multiple patient outreach efforts may be confusing and lead to decreased adherence
- Pharmacy resources may not have access to social, behavioral health and other resources that can improve adherence, improve coordination of care, and reduce cost
- May result in delays in intervention depending on how early indicators of clinical need are communicated to the appropriate team members
- Increased medical costs[2]

1. 86% of the engagement value of large national account customers calling Cigna Home Delivery Pharmacy in Q2 2014 associated with the customer's medical plan costs.
2. 2015 Cigna Study of Value of Integration – analysis of integrated clients vs. those with Cigna medical and outside PBM, full year 2014 book of business – average medical savings. Individual client/customer results will vary and are not guaranteed.

1

WELLNESS AND INCENTIVE PROGRAMS

- Goal is to decrease overall TMC through better health
- Programs should initially drive health status awareness but evolve to encourage positive change and health metrics that demonstrate effectiveness
- Incentives should be balanced regarding participatory versus results oriented objectives
- Success is highly dependent on management engagement and support
- Programs should always be customized by client taking into account the culture, resources and practical issues around support and impact on organizational processes
- Segmented approaches by population and disease drivers are preferred over “generic” programs that may not be a good fit.

PHYSICIAN APPROACHES

- Gaps in care notices
- Generic opportunity data
- Evidence-based medicine education
- Specialty-primary care collaboration (Project ECHO)
- Value-based physician programs
- Increasing cost awareness

REAL-WORLD SUCCESS CONSIDERATIONS FOR ORGANIZATIONS

- Understand what benefits can and cannot control
- Are plan designs geared toward total medical cost optimization?
- Does the plan improve the user-friendliness of the health system or increase complexity?
- Are all components of the health plan coordinated such as behavioral health, EAP, wellness and disease management?
- If there are multiple vendors, how can integration be improved?

AN EXAMPLE OF INTEGRATION ACHIEVEMENT

$77 PMPY medical savings

Chronic condition and health coaching

$24 PMPY saved

Customers with specialty conditions

$31 PMPY saved

Other (e.g., medical management)

$22 PMPY saved

THE CONNECT EFFECT®

Savings of **$320** PMPY for carve-in vs. carve out customers with a chronic condition who interact with a coach

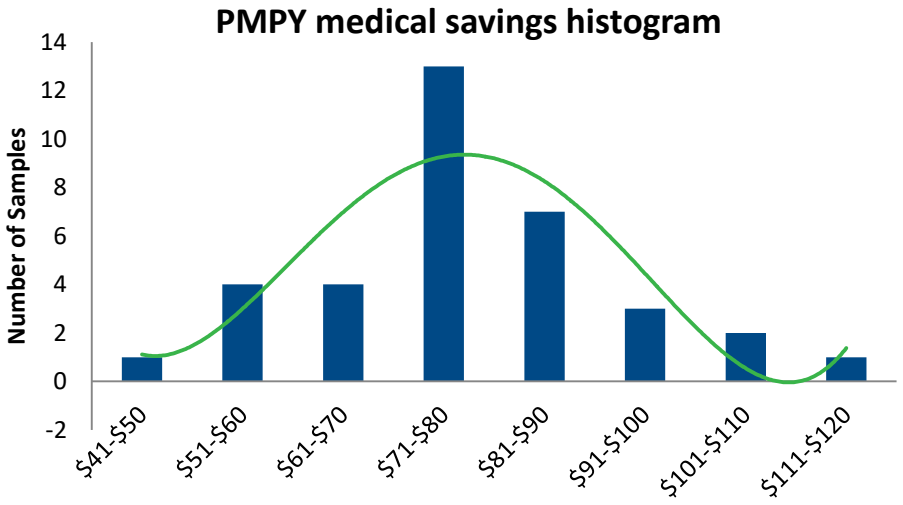
Savings of **$740** PMPY for diabetic carve-in customers who interact with a coach:

- Inpatient 11.7% lower
- ER visits 4.7% lower[1]

MATCHED CASE-CONTROLLED RESULTS—MEDICAL SAVINGS

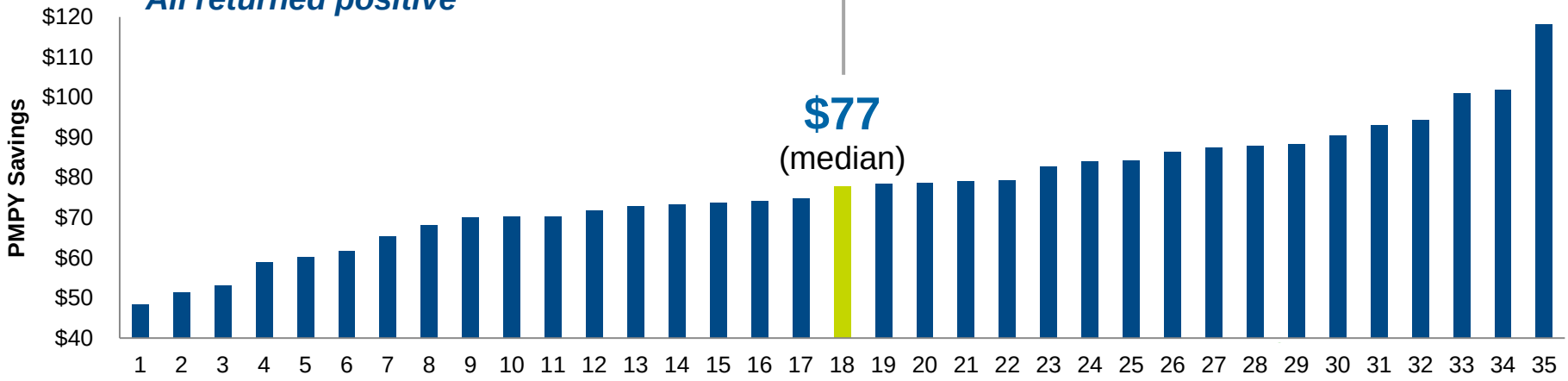
$77 PMPY

Medical savings for
Cigna Pharmacy
Carve-in vs. PBM carve-out



$48–$118 PMPY savings

PMPY medical savings by 35 distinct matched samples All returned positive



$77
(median)

Questions?