
Baker Tilly Healthcare Consulting

MedTech Bridge Webinar

*Healthcare Economics and Market Access
Keys to Successful U.S. Commercialization*
June 26, 2019



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Speaker Bios



Christina Cool - Christina serves as a Senior Manager for Baker Tilly's Life Sciences and Healthcare Consulting practice. She is an epidemiologist by training with more than a decade of experience in health economics and market access, including life sciences economic studies and analysis (both medical device and pharmaceutical companies), and reimbursement economic studies and analysis. Christina leads projects related to health economics, clinical utility, dossier development and market access. She often serves as lead author or co-author of peer-reviewed health economic studies and is well published in leading medical, payer and healthcare policymaker journals. She is a frequent speaker at various life sciences industry, medical society, healthcare policymaker and healthcare investment conferences. Christina earned a BA in Biology and Sociology from St. Edward's University and a Master in Public Health from Columbia University.

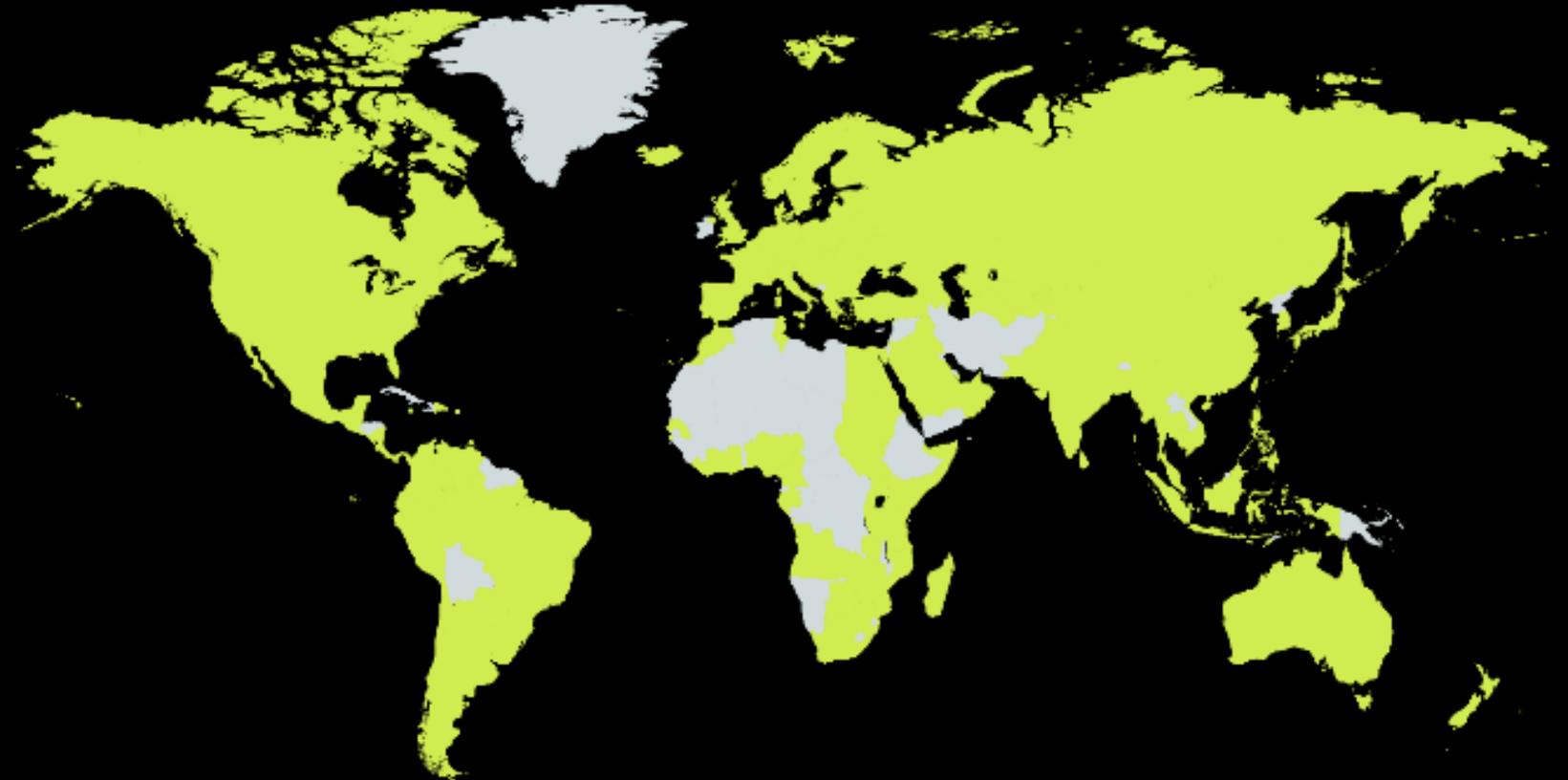


Serafin (Fin) Samson - Fin serves as a Business Development Consultant for Baker Tilly's Life Sciences and Healthcare Consulting practice. He focuses on client development in the Mid-West market and serves as a business consultant for healthcare start-ups. With over 25 years of operational start-up and venture capital investment experience, Fin has led the introduction of novel orthopedic and spine products from initial concept through commercialization and led healthcare VC investments in the areas of medical device, health service and health IT. He has served on multiple healthcare start-up boards and serves on the Hennepin Healthcare Foundation board. Fin earned a BS in Biomedical Engineering from The Catholic University of America, a dual MS in Biomedical and Mechanical Engineering from the University of Michigan and an MBA from the University of Minnesota.

BAKER TILLY

At a glance

- Established in 1931
- Industry and service specialization, leading with advisory services
- Ranked as one of the 15 largest accounting and advisory firms in the U.S.
- Largest member of Baker Tilly International – the 8th largest accountancy and business advisory network in the world



147
Territories

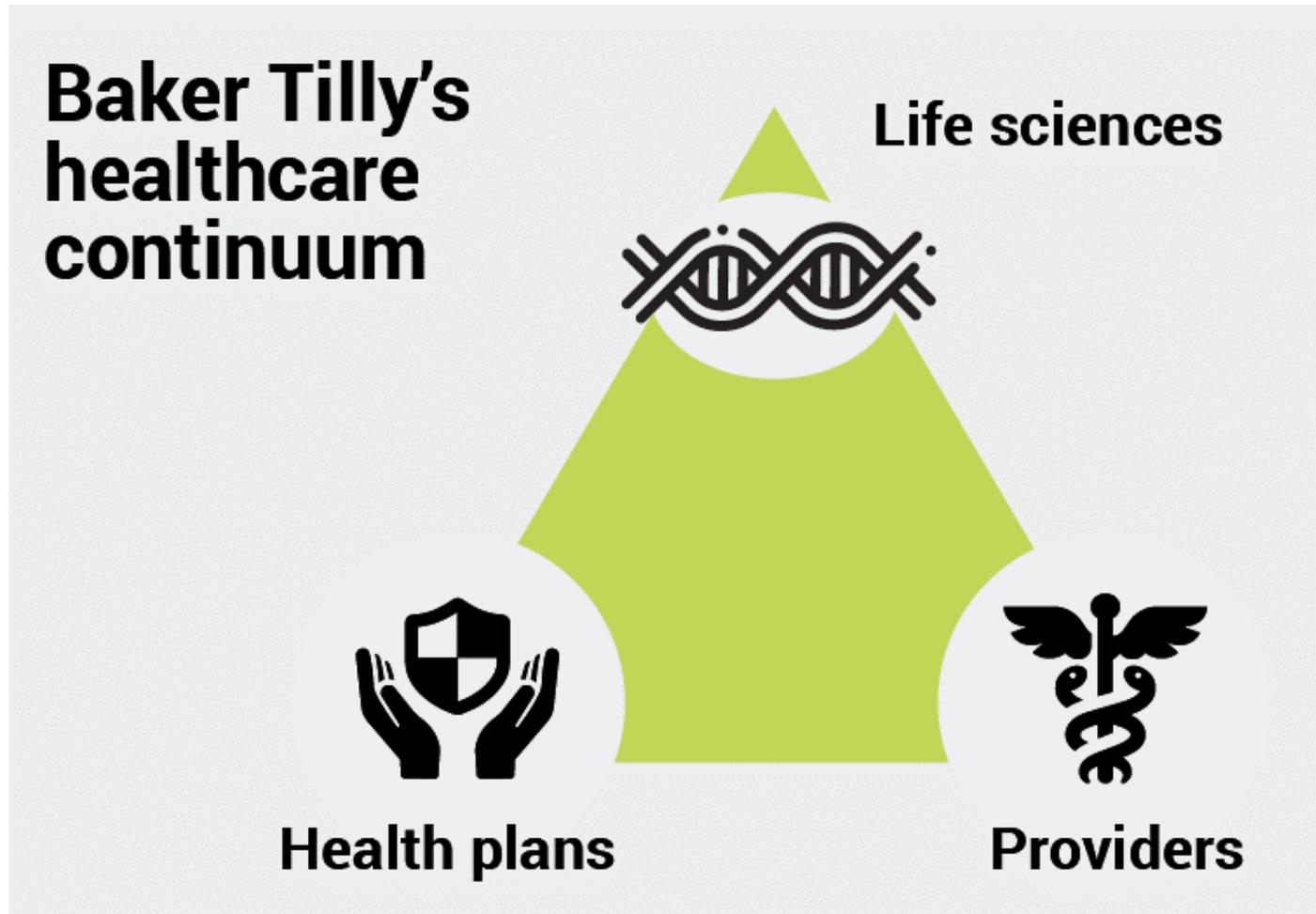


US\$3.4B
Combined
revenue



796
Offices

Healthcare consulting serves stakeholders across full industry spectrum



Representative Clients

Life Sciences



GE Healthcare

stryker

Abbott

OLYMPUS
Your Vision, Our Future

BD **BECTON DICKINSON**

ABIOMED
Recovering hearts. Saving lives.

inspire
UPPER AIRWAY STIMULATION

TEVA
TEVA PHARMACEUTICAL INDUSTRIES LTD.

VERRICA
PHARMACEUTICALS
Reinventing Skin Science

DJO
GLOBAL

CIRCASSIA

Providers



Henry Mayo Newhall Hospital

Geisinger

Hazelden Betty Ford Foundation

The Cooper Health System

Aurora Health Care

WVU Medicine

Main Line Health

RWJ **RWJ Barnabas** **HEALTH** **impact seven**

Lutheran Social Services of Illinois

DukeHealth

GUTHRIE **Adventist HealthCare** **rosecrance**

South Nassau COMMUNITIES HOSPITAL

ARCW
AIDS RESOURCE CENTER OF WISCONSIN
Excellence in HIV Health Care

HENRY FORD VILLAGE
You've earned it.

Stanford
HEALTH CARE

TOWER HEALTH
Advancing Health. Transforming Lives.

REM
WISCONSIN

YALE-NEW HAVEN
HOSPITAL

Volunteers
of America

Health Plans



Blue Cross Blue Shield Blue Care Network of Michigan

Anthem. **BlueCross BlueShield**

HCSC
Health Care Service Corporation

Cigna

HIGHMARK. **Blue Cross Blue Shield**

aetna

EmblemHealth

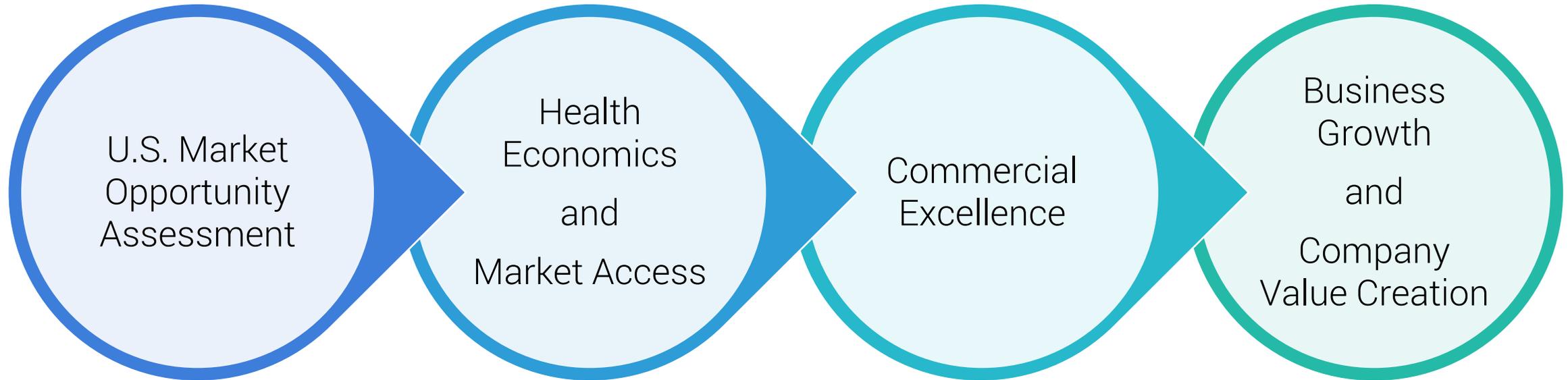
Independence

Horizon. **Blue Cross Blue Shield of New Jersey**

Northwell
Health

BlueCross BlueShield
Minnesota

Key objective: commercial excellence to drive business growth





U.S. Market Opportunity Assessment

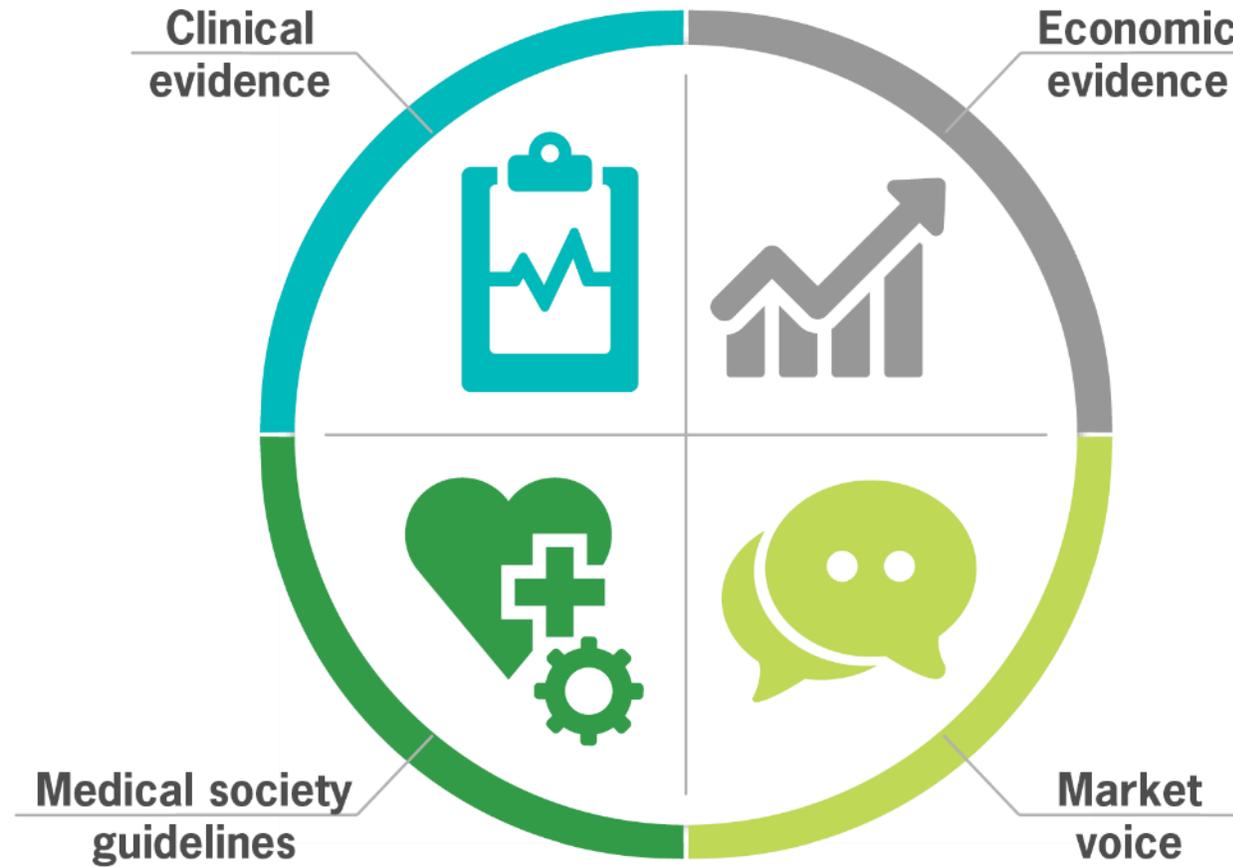
- Primary research
- Secondary research
- Competitive analysis
- Assess how products are reimbursed and paid
- Pricing strategy
- Medicare and commercial payer databases
- Gain perspective of key stakeholders, such as Payers and Providers



US Payers are Inherent Skeptics

- Presume that all technology is cost additive
- Assume that the current standard of care is adequate
- Have demanding data requirements, including the infamous RCT
- Use automated processes to analyze both retro/prospective studies
- They typically never want to be the 'first to cover' a new technology

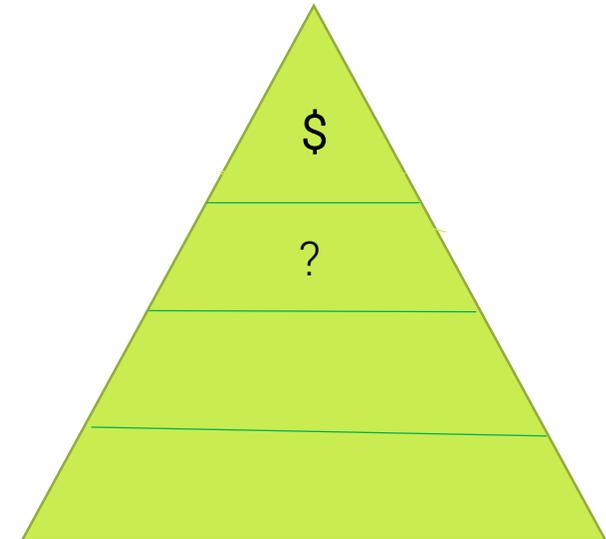
Market access recipe



Coding strategy reimbursement levels

Hierarchy of clinical Evidence

- There is a continuum of Evidence
- The RCT (Typically Level 1 Evidence) comes with a big price tag
- Level II Evidence can build momentum



Developing clinical and economic prospective studies

- Create partnerships with providers for single and multi site prospective studies
- Create, implement, and analyze registries
- Develop and implement studies through chart reviews
- Perform interim analyses of data
- Leverage provider partner networks
- Understand programs such as the Vital Innovation Program at Highmark Health
- Use automated processes to analyze both retro/prospective studies

Clinical Evidence Level II options



Retrospective Claims Study

- Can show on a longitudinal basis how your device has performed
- Is reliant on coding or other methods (i.e., names of physicians using the device) to make a solid case



Retrospective Medical Record Study

- Can track individual device and other measures not available in the claims data
- Can be more expensive and take more time than claims analyses



Meta/Systematic Analysis

- Allows you to compile all kinds of previous studies to increase your total sample and make a stronger study
- Requires enough previous studies with similar characteristics and measures



Registry

- Allows you to track patients prospectively and is less costly than an RCT
- Takes participation of sites and ongoing management

Economic Evidence Models & Analysis



Budget Impact Model

- Should use real world data and speaks to payers with a per member per month impact
- Requires real world data (not lit sources) and transparency, and should be interactive



Longitudinal Analysis

- Shows what is happening beyond the index procedure and can show downstream savings (also can be well understood by payers and providers)
- Payers prefer a PMPM and the technology must have enough volume for the tracking period



Incremental Cost Effectiveness Ratios

- Summarizes the cost effectiveness of a health care intervention as it compares to another intervention
- Not yet widely embraced by U.S. payers



Micro-costing Analysis

- Allows one to evaluate the direct cost associated with a procedure or the time associated with a procedure
- Requires site involvement and time
- Useful when clinical benefits are not highly differentiated

Publications and podium presentations

A Budget Impact Model to Estimate the Cost Dynamics of Treating High-Risk Heart Failure Patients with Advanced Percutaneous Cardiac Assist Devices: The Payer Perspective

David Gregory, MPA, FACHE and Dennis J. Scotti, PhD, MBA, FACHE, FHFMA

Operational Implications of Utilizing 2 Advanced Technologies for Rendering Short-term Hemodynamic Support to Patients Presenting With Cardiogenic Shocks: A View Through the Lens of Hospital Readmissions

Dennis J. Scotti, PhD, MS, MBA; David A. Gregory, MPA; Theodore L. Schreiber, MD; Adhir Shroff, MD, MPA; Daniel R. Buck, MBA, MPH

Outcomes of catheter ablation of ventricular tachycardia with mechanical hemodynamic support: An analysis of the Medicare database

Arash Aryana MS, MD¹  | André d'Avila MD, PhD² | Christina L. Cool MPH³ | Marc A. Miller MD⁴ | Fermin C. Garcia MD⁵ | Gregory E. Supple MD⁵ | Srinivas R. Dukkipati MD⁴ | Dhanunjaya Lakkireddy MD⁶  | T. Jared Bunch MD⁷  | Mark R. Bowers MS, MD¹ | Padraig Gearoid O'Neill MD¹ | Vivek Y. Reddy MD⁴ | Francis E. Marchlinski MD⁵ 

Market Voice

- The provider community can lend its voice to help build your case
- Build out target profiles by doctor by hospital
- Develop and launch a campaign to your targeted profiles
- Make sure to utilize the market to help and build traction and momentum



Medical Society Guidelines

- Published Treatment Guidelines can be as impactful as clinical and economic evidence
- Identify key society leadership to support the case
- Start communication and building these relationships early





Driving market access

- Comprehensive dossiers
- Payer and provider facing dossiers
- Third-party resource for market outreach
- Payer outreach
- Provider outreach

Relationships with Health Plans and ACOs

Health Plan Relationships:

Utilize relationships with many national, regional, and local health plans to facilitate market access for emerging technologies

- Have achieved positive coverage policies from payers including, but not limited to, Aetna, Cigna, Emblem, IBC and Horizon and many BCBS plans

Provider Relationships:

Utilize relationships with providers including, large integrated health systems as well as ACOs to build relationships with life sciences companies, examples include:

- Assisting companies in achieving research collaborations with some of the largest and most progressive systems and ACOs in the nation
- Assisting companies in developing relationships with other entities through Executive Advisory Councils
- Assisted in providing clients with partnerships in risk-arrangement contracts

Executive Advisory Council – Key Provider and Payer Opinion Leaders

- Understand viewpoints of Provider and Payer executive leadership and Key Stakeholders
 - CEOs, CFOs, CMOs, CNOs, Vice Presidents, and Presidents of delivery systems
 - Executive Directors and Medical Directors from major payers
 - Senior level executives at healthcare venture capital firms
- Key topics that impact market adoption of new innovations and corporate initiatives
 - Review of new product value propositions
 - Value based programs and risk arrangements
 - Impact of quality metrics
 - Hospital assessment of technology innovations
 - Addressing key provider needs

Commercial excellence “sweet spots”



Product start-up and Commercialization

Establish validation and launch strategy

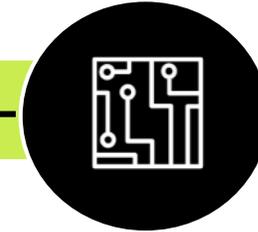
- P.O.E.M. and capability-based strategy
 - Commercial diligence
 - Financial diligence
 - Competitive diligence
 - Market access landscape assessment
 - Reimbursement/access risk
- Commercialization strategy
 - Product development and launch
 - Commercial execution
 - Field force structure
 - Sales process engineering
 - Performance management



Post launch growth optimization strategy

Expanding market share strategy

- Expanding network of payers/coverage
- Expanding network of provider adoption
- Expand individual providers
- Reinvigorate stagnating brand
- Expand customer channel utilization
- Customer centric segmentation - profiling - life value assessment



Alternate customer Channel strategy

Expanding customer community

- Self-insured employer strategy and outreach
- Integrated payer/provider systems (HIS)
- Federal healthcare systems
- Health networks sales process advisory and key accounts management

Introduction to The Critical Importance Of Employers: The Big Picture of Self-funded Plans

**78 Million Active Employees and 160 Million Lives (63%)
Covered by Employers**

Small Employers

- 5.7 Million Employers
- 28 Million Employees
- 57 Million Lives
- Employers cover 53% of workers in small companies

Medium Employers

- 37,700 Employers
- 12 Million Employees
- 24 Million Lives
- Employers cover 65% of workers in medium companies

Large Employers

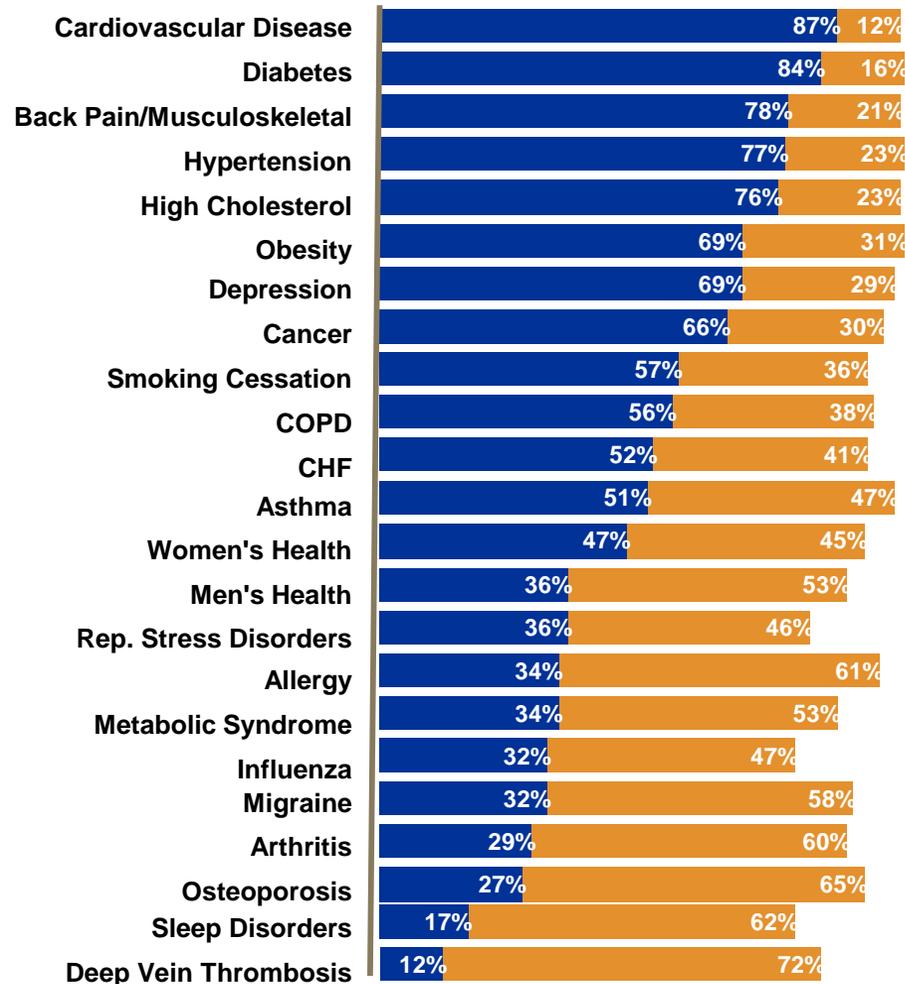
- 6,800 Employers
- 11 Million Employees
- 22 Million Lives
- Employers cover 68% of workers in large companies

Jumbo Employers

- 1,750 Employers
- 27 Million Employees
- 55 Million Lives
- Employers cover 60% of workers in jumbo companies

55% of Rx spend

Disease States Of Importance To Employers



Disease State Importance Level

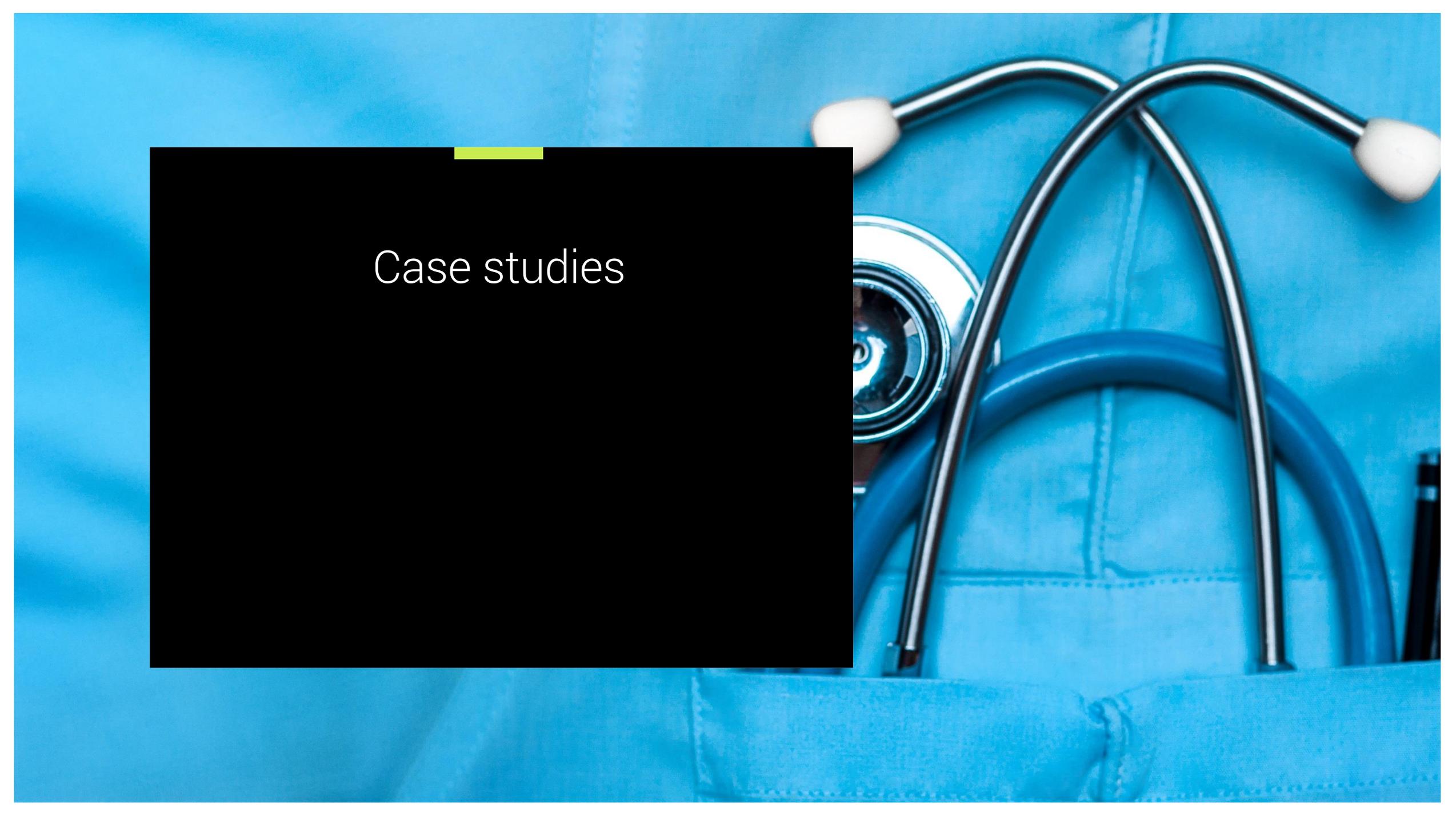
- > CV -> Hypt -> Cholesterol -> Hrt Failure
- > Diabetes
- > Cancer
- > COPD Respiratory Diseases
- > 69% of Employers state that depression is a disease state of high importance
- > Nearly one-third or more of employers rate newly added conditions of metabolic syndrome, osteoporosis, women's and men's health as highly important

■ High Importance
 ■ Medium Importance
 n=116



U.S. Distribution

- Understand path to market access
- Formulate and establish distribution strategy approximately 6 months ahead of commercial launch
- Potential options for distribution
 - Third-party logistics from warehouse to shipping to financial collection
 - Strategic partnership
 - Independent sales consultants
 - Direct sales infrastructure

A blue medical bag with a stethoscope and a pen. The stethoscope is silver with white earpieces. The bag has visible stitching and a pocket at the bottom. A black pen is partially visible on the right side.

Case studies

Case study: Abiomed pVAD

- Clinical trial was halted due to futility
- Assisted in reformulation of clinical design
- Budget Impact Modeling
- Lead author in American Health & Drug Benefits Publication
- Demonstrated reduced MAEs (i.e., death, heart attacks, strokes)
- Reduced hospital re-admissions and resource consumption
- Increased cost savings
- Facilitated Payer outreach
- Facilitated coverage by Aetna, Cigna, UnitedHealthcare, HealthNet, Humana and other major plans



Success in Achieving Payer Coverage – Abiomed pVAD

- After publishing several economic and clinical publications Baker Tilly was tasked with assisting in payer outreach efforts with national and regional health plans
- Baker Tilly helped the client profile the appropriate targets to conduct initial outreach
- With relationships at major health plans, Baker Tilly was able to facilitated meetings between Medical Policy teams and KOLs
 - KOLs presented their own clinical evidence to payers in addition to their experience in observing patient outcomes using this technology as compared to the standard of care (the balloon pump)
 - Following our meetings with health plans, Baker Tilly successfully assisted our client in achieving payer coverage at 10+ plans, including Aetna, CIGNA, UHC and HCSC
- These efforts directly expanded coverage to at least 50+ million additional covered lives and many other covered lives through the adoption of positive coverage policies from other health plans

Case study: Emerging OSA medtech company

- Client situation
 - Medtech company commercializing a device to treat obstructive sleep apnea (OSA)
 - Clinical evidence demonstrated positive long term outcomes and quality of life
 - Endorsed by key professional medical societies
 - Despite clinical evidence and professional society endorsements, failed to gain coverage
- Assessed client clinical and economic evidence and compared relative to standard of care and alternative treatments
- Engaged with former and current health plan Medical Directors to evaluate evidence
- Synthesized evidence in concise and comprehensive dossier
- Facilitated Payer and Provider outreach
- Landmark positive coverage decision by large commercial payer

Achieving Payer Coverage – Emerging OSA medtech company

- Baker Tilly was asked with leading payer outreach efforts with eleven national, regional, and/or local health plans
- We provided enhanced dossier package to Medical Policy teams at targeted health plans
- Using our personal relationships at major health plans, we were able to facilitated meetings between Medical Policy teams and KOLs that were high utilizers of the technology
 - KOLs presented their own clinical evidence to payers in addition to their experience in observing patient outcomes using this technology as compared to the standard of care to treat OSA
- Following our meetings with health plans, we successfully assisted our client in achieving payer coverage at over 70% of the plans we were assigned (8 of 11 and counting), including Highmark, Aetna, IBC, and Excellus
- These efforts directly expanded coverage to at least 30+ million additional covered lives and many other covered lives through the adoption of positive coverage policies from other health plans

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Appendix

Unique, integrated practice model

Industry specialist – Engagement leader



Commercial excellence practice
(Product development and launch,
growth optimization)



Clinical excellence practice
(Clinical trial management,
drug/device safety)



**Market access
optimization practice**
(Real-world evidence generation,
market access risk assessment,
payer submission strategy)



**Business intelligence and
decision analytics**
(Pricing analysis, competitive intelligence,
payer/rebate reporting)

Baker Tilly Capabilities for Self-insured Employer Strategy

- Design of health economic study protocol
- Execution of health economic study
- Profile and identify Self-insured Employers to serve as pilot study sites
- Leverage existing Self-insured Employer relationships to recruit pilot study site
- Leverage existing pharmaceutical relationships for health economic study collaborations
- Manage pilot study sites
- Conduct health economic model analytics (e.g., longitudinal cost study)
- Third-party publications and podium presentations
- Support training of organization to sell in the Self-insured Employer market

Life sciences leadership team

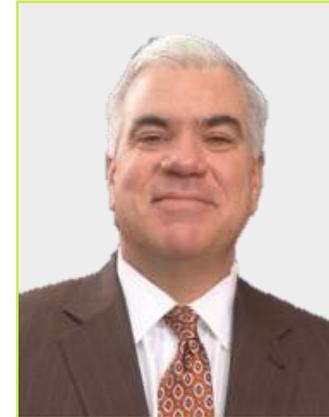


David Gregory

Principal and Team Lead

Life Sciences/Healthcare Consulting

- As practice leader, oversees all life sciences engagements and client relationships and often initiates and leads partnership initiatives with providers and payers
- Published multiple clinical utility and economic studies featuring medical technologies and is a frequent keynote presenter and panel moderator at national life sciences events



John Finan

Practice Director, Commercial Excellence

Life Sciences/Healthcare Consulting

- Specialty in assisting pharmaceutical and medical device clients address growth optimization challenges in both the product development/launch phase and in-line brand growth reinvigoration phase
- Experience ranges across retail, institutional and specialty product channels



Christina Cool

Senior Manager

Life Sciences/Healthcare Consulting

- Epidemiologist by training with more than a decade of experience in market access, including developing economic value analyses, and life sciences economic and reimbursement studies and analyses
- Leads projects related to health economics, clinical utility and market access



James Pierce

Practice Director

Life Sciences/Healthcare Consulting

- Epidemiologist by training with twenty years of experience across clinical/medical affairs, market access, business development/due diligence, patient outcomes, value based contracts, global HTA submissions and big data/analytics
- Comprehensive knowledge of IT needs in clinical trials, drug safety, compliance, regulatory and manufacturing

International life sciences leadership team



Mike McKee

Partner, Firm Leader – Life Sciences and International Attest Manufacturing/Distribution

- Routinely works closely with management on corporate matters such as financings, M&A, initial public offerings and other expansion-related activities
- Assists both domestic and international companies in a variety of industries including manufacturing, distribution, life sciences, software and clean tech



Jeff Jorge

Principal, International Growth Services Practice Leader International Growth Services

- Responsible for delivering growth strategy formulation, implementation and turnkey international market entry support to companies in multiple industry sectors and foreign markets – with particular emphasis in the Americas and large, fast-growing and emerging economies such as Mexico and Brazil
- Responsible for helping companies reach double digit annual growth rates and operational expansion into more than 40 international markets

Life sciences core team consultants



Keith Needham

Manager

Healthcare Consulting

- More than seven years experience in healthcare, including payer, provider, data management and analysis and health economics



Thomas Puch

Senior Manager

Enterprise Transformation Services

- Extensive experience with business intelligence and statistics
- More than 20 years business analytic solutions in healthcare, consumer products, manufacturing, advertising, transportation, government and telecommunications



Katie Schaldenbrand, MPH

Manager

Healthcare Consulting

- Over 5 years of healthcare experience currently working in the payer space, extensive experience working with provider data and expertise using SAS to manage and analyze healthcare data



Kelly Seeger, MSPH

Senior Consultant

Healthcare Consulting

- More than five years in international health, economic development and publications and market access

Life sciences core team consultants (cont.)*



Chinar Verma, MPH

*Senior Consultant
Healthcare Consulting*

- More than 5 years in healthcare with experience in patient experience, healthcare research and analysis



Lana Mills

*Senior Consultant
Healthcare Consulting*

- More than 5 years as a SAS developer in the healthcare payer industry and subject matter expert on Medicaid payer data



Dylan Silverman

*Staff Consultant
Healthcare Consulting*

- Experience with claims data analysis, market landscape assessment, literature and policy analysis



Sabrina Rahman, MPH

*Staff Consultant
Healthcare Consulting*

- More than 5 years in healthcare with experience in patient experience, healthcare research and analysis

* *The Baker Tilly Healthcare Consulting practice has an additional 40+ resources that may be available for additional requests*

Additional life sciences leadership



Mike Duke

Principal and Provider Team Leader

- Specializes in leading large revenue optimization process redesign and transformation projects that improve overall net revenue and reduce operating costs



Mike Patti

Principal and Payer Team Leader

- Focuses on implementing solutions to help payer organizations navigate the operational transformations required to address issues such as new reimbursement models that connect quality outcomes, cost and utilization efficiency to payment levels, new customer markets, and increased customer demands



John Runte

Principal, Enterprise Transformation Services

- Extensive work encompassing complex project management, process redesign, new product development, information system strategic planning, information system design, and implementation with a focus on program management of large complex transformation projects, application integration solutions and modern analytics



Todd Wilkerson

Director, Enterprise Transformation Services

- Brings 20 years of consulting experience in customer relationship management, with on premise and SaaS-based package and custom solutions
- Leads solution delivery for the growth strategies practice, focused on CRM and customer experience solutions for clients

Advisors/subject matter specialists



Dr. Jim Cross

- Previously served as Vice President and head of National Medical Policy Operations at Aetna, where he managed clinical and reimbursement policy
- Oversaw operations for national pre-certification, clinical claims review, clinical appeals, and external review



Dr. Gary Owens

- Previously served as Vice President for Medical Management and Policy at Independence Blue Cross
- Managed medical review services, including pre-certification of medical services, hospital care level reviews, high-technology, radiology services pre-certification, discharge planning activities and has case management experience



Serafin (Fin) Samson

- Led product innovation with orthopedic and spine medical device start-ups
- Previously served as a Venture Partner for Affinity Capital, which made early-stage healthcare venture capital investments.
- Serves as a business consultant with medical device and health IT start-ups



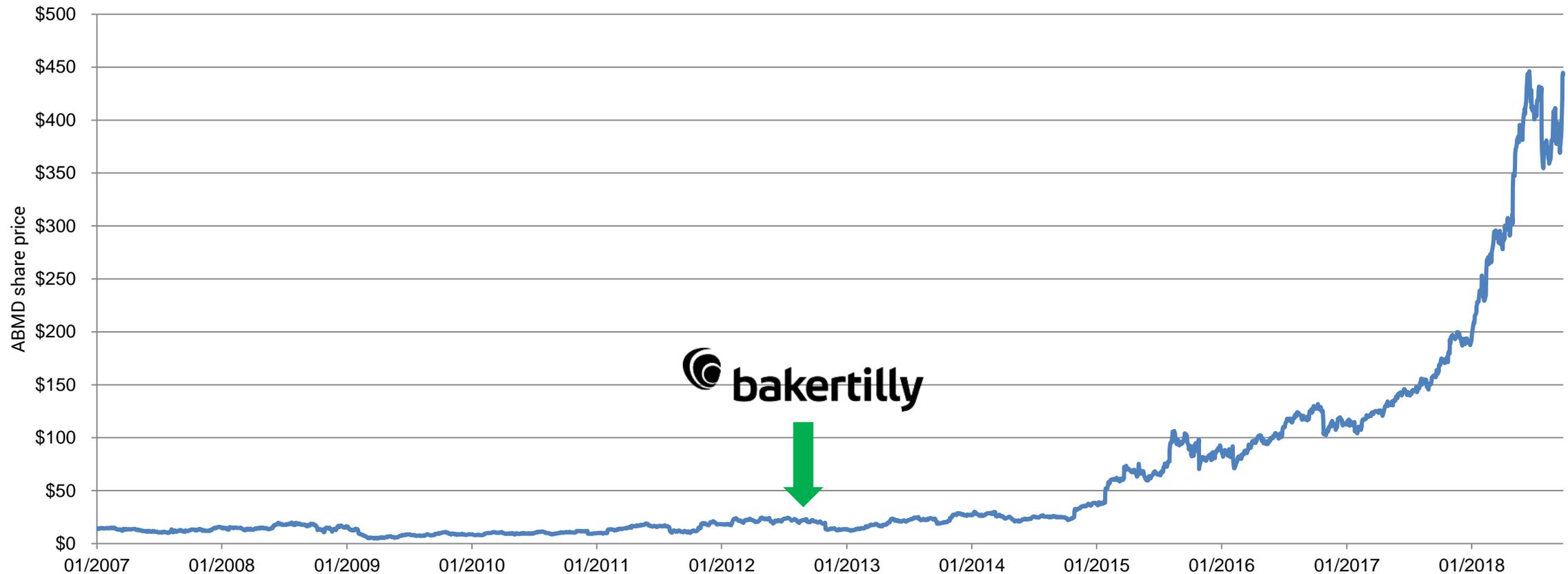
Dennis Scotti

- Diverse and distinguished background in university education, academic research, and professional consulting focusing on the healthcare industry
- Manages projects in practice areas, such as economic value analysis of life science products, strategic planning and marketing, and educational seminars

Abiomed (ABMD) stock performance

Baker Tilly key contributor to value creation

Abiomed stock performance



Emerging OSA medtech company stock performance

Baker Tilly key contributor as third-party resource for payer outreach

