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Improving Health Care Economic Information (HCEI) Communication

July 18, 2018, 11:00 EDT, 15:00 GMT

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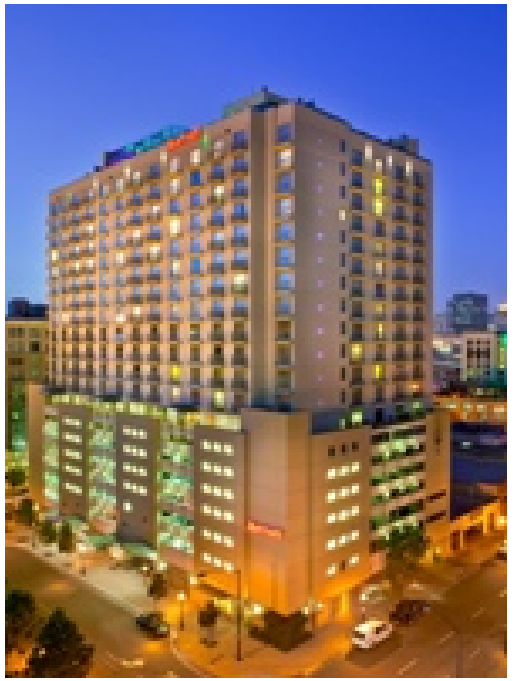

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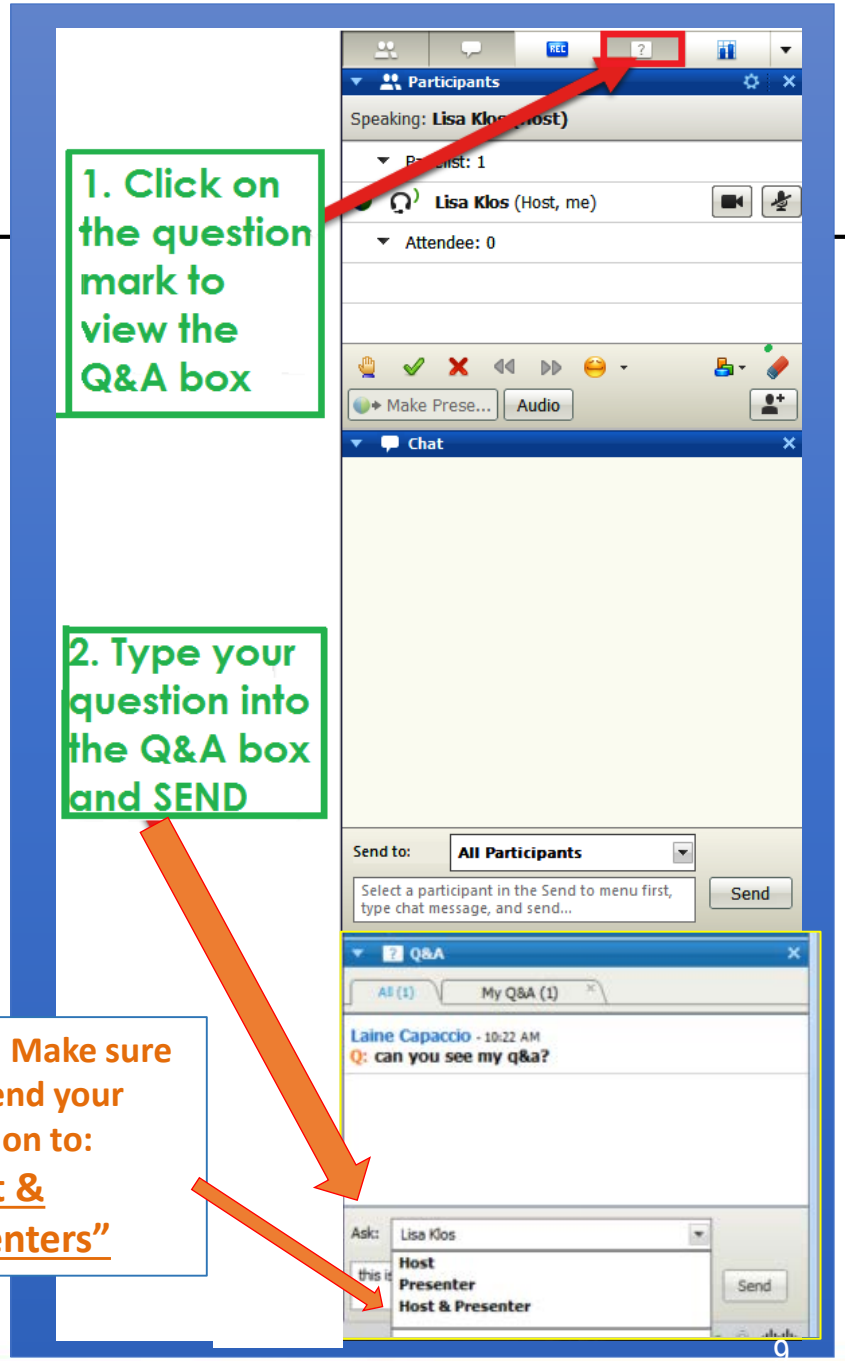

Improving Health Care Economic Information (HCEI) Communication

Publication Planning Professionals Are Key Partners in Building Successful HCEI Exchange

July 18, 2018

Introductions

- **Peter Fendt, PharmD, MBA, RPh**
  Manager, Global Market Insights, Celgene
- **Brian Ung, PharmD, RPh, MS**
  Manager, US Health Economics & Outcomes Research, Celgene
- **Tom Drake, MA, ISMPP CMPP™**
  Director and Founder of Global Outcomes Group

- *Moderator*
- **Michael Platt, MS**
  Executive Director, Virgo Health Education

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Disclaimer

Information presented reflects the personal knowledge and opinion of the presenters and does not necessarily represent the position of their current or past employers or the position of ISMPP.

Objectives

- Describe historic challenges that impeded HCEI communication between Bio/Pharma and stakeholders
- Understand how the 21st Century Cures Act and recent FDA draft guidelines are providing clearer pathways to disseminate HCEI information during pre-approval phases
- Describe key HCEI stakeholders that can be part of a strategic publication plans
- Discuss practical steps to build multidisciplinary teams to incorporate HCEI management into effective publication planning structures

Introduction

Brian Ung

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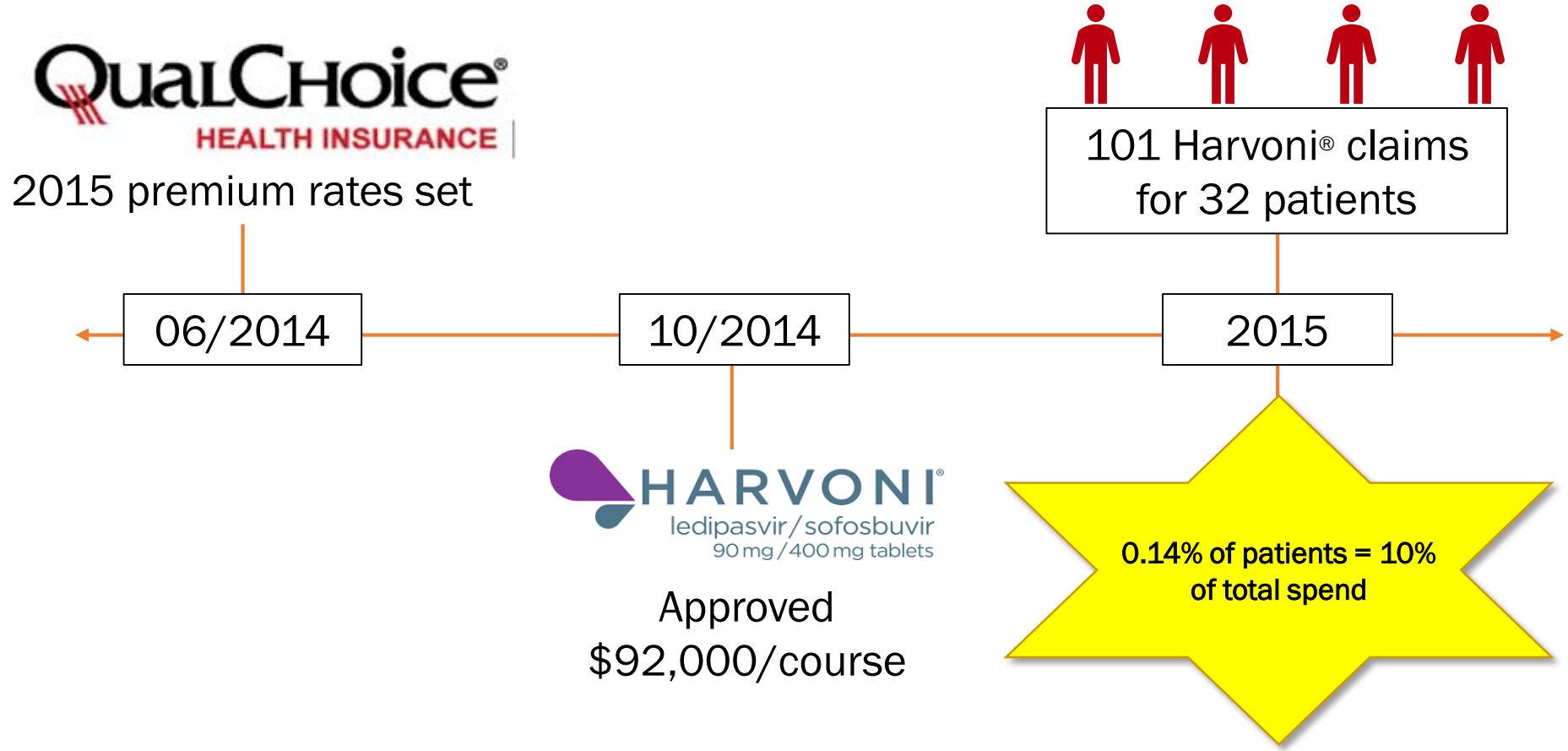
Audience Poll

- Have recent Federal regulations and guidance changed publication planning strategies and tactics at your company?
  - Yes
  - Somewhat
  - Currently under review
  - No

Pre–FDA Approval: Economic Information



Healthcare system cannot plan for the cost of new therapies

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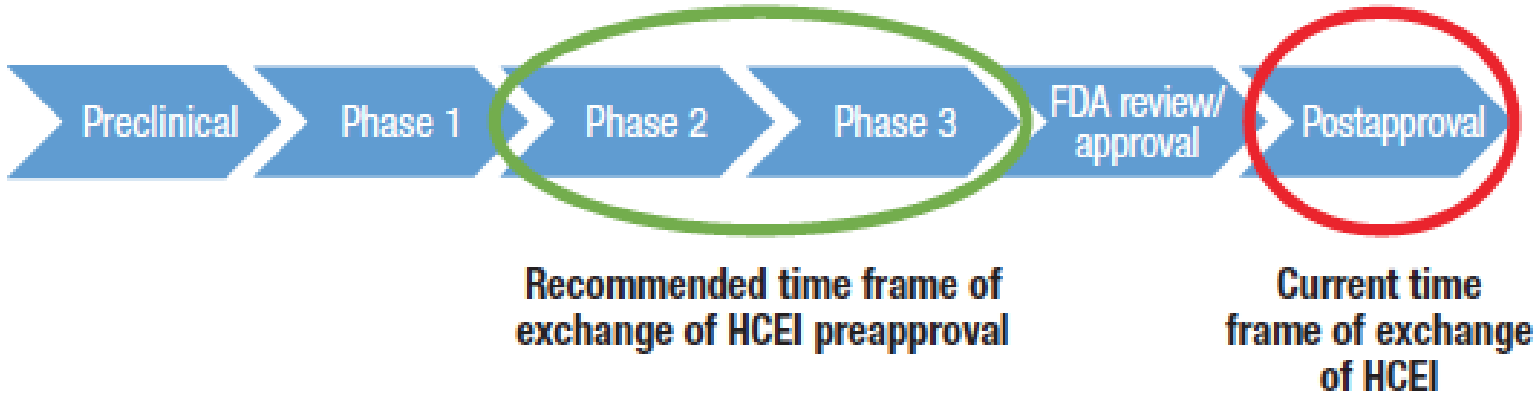
Pre–FDA Approval: Economic Information

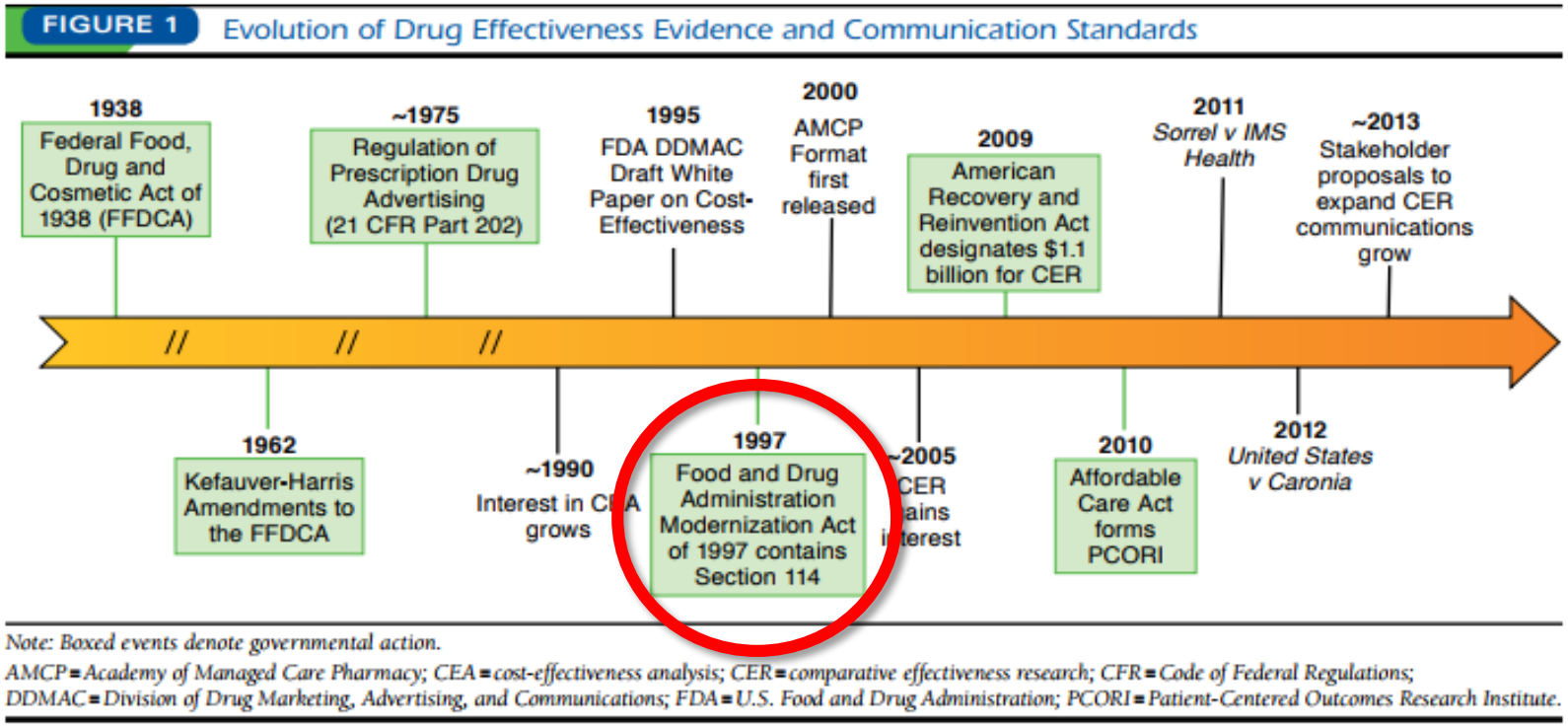
Figure Drug Approval Process and Exchange of Healthcare Economic Information



FDA indicates US Food and Drug Administration; HCEI, healthcare economic information.

Historical deficiency in HCEI communication between payers and drug manufacturers

FDAMA 114



FDAMA 114 Limitations: ambiguity in language (audience, "competent and reliable scientific evidence"), off-label promotion, pricing not addressed, no further guidance until….

Recent Drug-Related Regulatory Updates

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21st Century Cures Act

Section 3037

- Clarifies FDAMA 114
- Audience Definition
- HCEI Content

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Recent FDA Final Guidances Address HCEI Exchange

1. **Drug and Device Manufacturer Communications With Payers, Formulary Committees, and Similar Entities (2018)**
   - Provides examples of HCEI that do, and do not, relate to an FDA-approved indication
   - Highlights information that should be disclosed to audiences receiving HCEI
   - Elaborates on communication of information on investigational drugs
2. **Medical Product Communications That Are Consistent With the FDA-Required Labeling (2018)**
   - Clarifies communication of material not explicitly included in FDA-required drug labels, but that "may be consistent" with FDA-required drug labels

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Industry Activity

Lilly + Anthem®

Joint commentary: importance of increased communication, current challenges, include new indications and treatment line extensions

Genentech

5 pilot programs testing approaches to payer communication of HCEI

Communication Pre–FDA Approval

Peter Fendt

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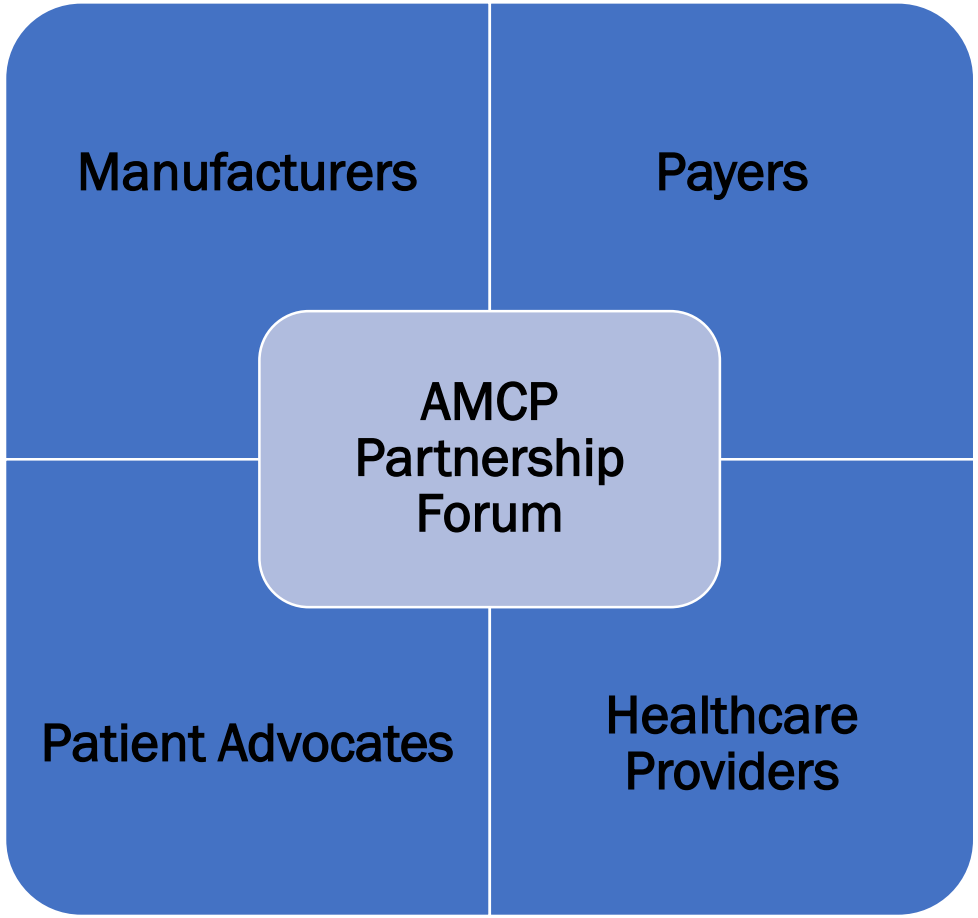
Audience Poll

- As publication professionals, have you been directly involved with any Payer interaction or communication (eg, HE papers, dossiers, other)??
  - Yes
  - Planning to in the future
  - No

Multi-Stakeholder Communication is Increasingly Important



- Formulary planning is difficult without sharing economic data pre-approval for drugs entering the market after health plan submission of its insurance premiums
- Early communication → payer feedback can influence development programs
- Recommendations for final guidance and future regulations should incorporate feedback from all involved parties

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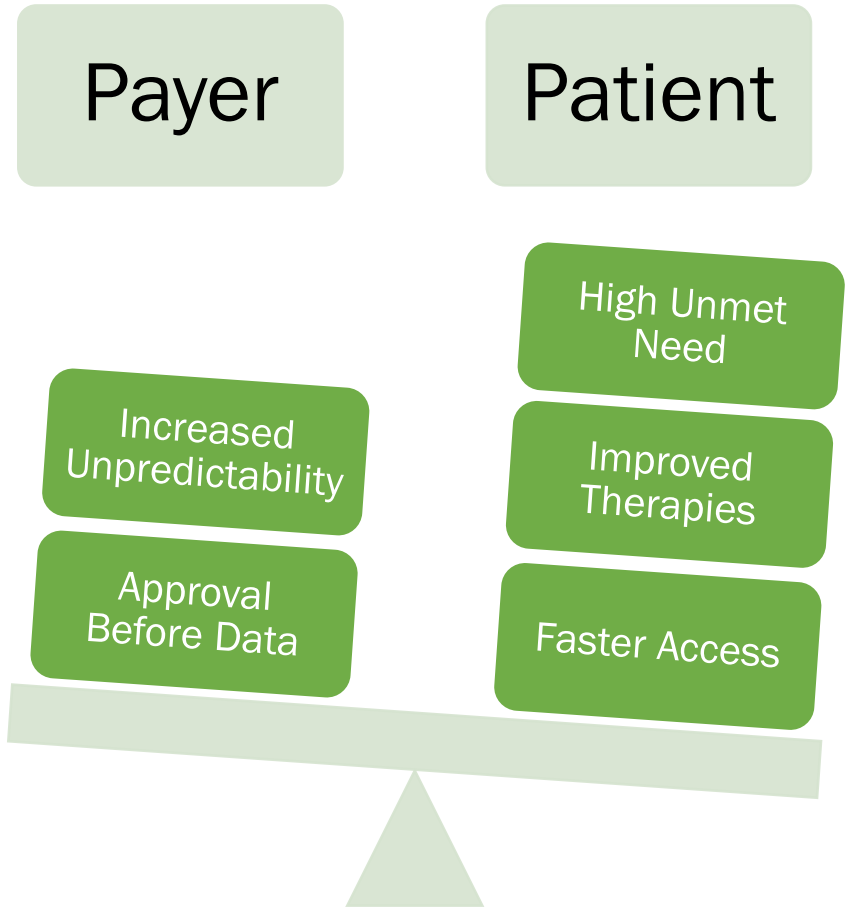
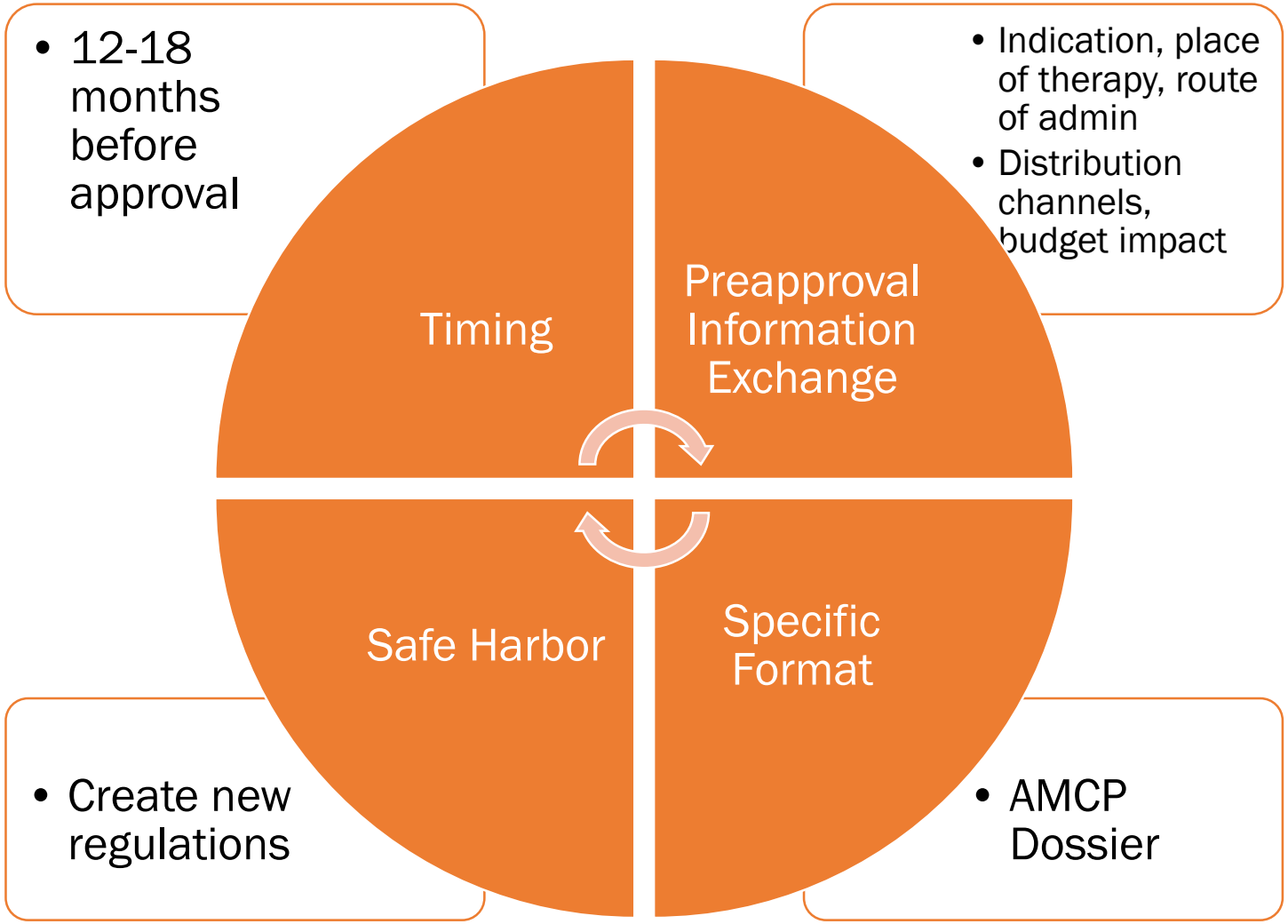
Expedited Regulatory Approval Programs



Expedited approval exacerbates HCEI problem

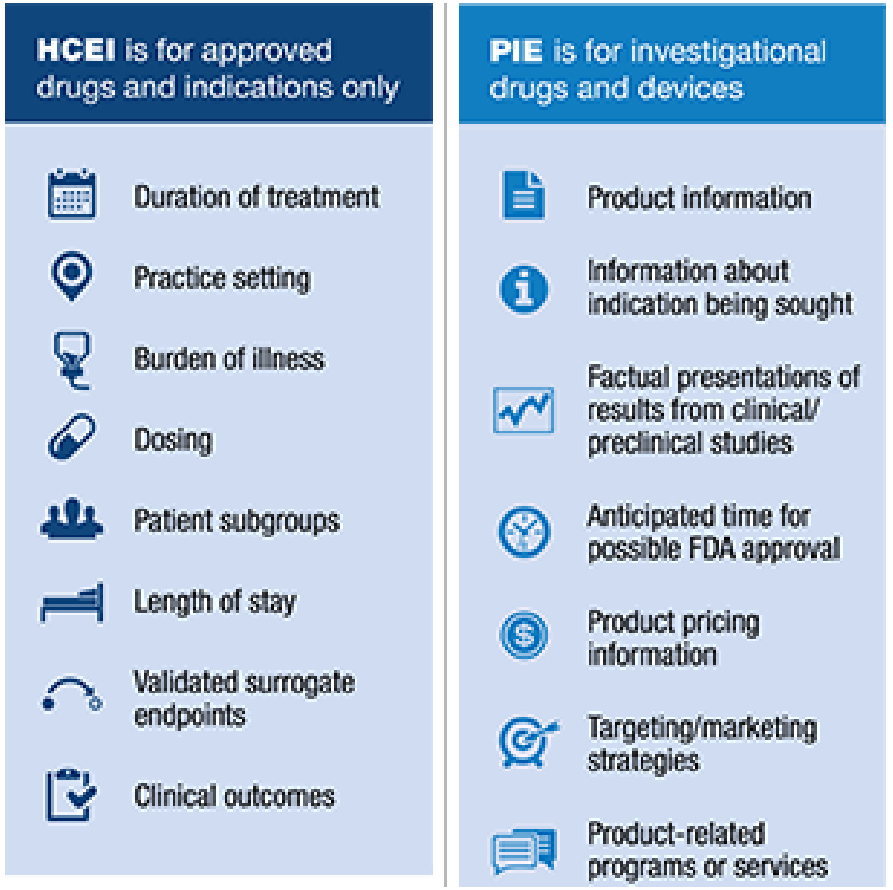
Possible Solutions



FDA Final Guidance:

Drug and Device Manufacturer Communications With Payers, Formulary Committees, and Similar Entities (2018)

- Supports exchange of healthcare information pre-approval
- Emphasizes maintaining communication channels
- Pre-approval information exchange (PIE) must be “unbiased, factual, accurate, and non-misleading”
- Clear statement that the product, its safety, and efficacy is under investigation



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Recent Updates

- Pharmaceutical Information Exchange Act (H.R. 2026) was amended and forwarded January 17, 2018 to full committee in House of Representatives
- Supports proactive information sharing between manufacturers and third-party Payers for emerging therapies/off-label uses
- Allows communication of “competent and reliable scientific evidence” in the form of clinical, pre-clinical, and economic data and results

Future Considerations

Peter Fendt and Brian Ung

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Uncertainty Remains

- FDA guidance is vague in regards to sharing HCEI pre-approval, only directly speaking to drug pricing information
- More clarity is needed from the FDA on what constitutes “unbiased” and “non-misleading” information to be shared with payers for investigational drugs
- Questions still remain around when and how manufacturers could communicate information related to unapproved uses of their products

Industry Cautions Against Inaction

Genentech

Bristol-Myers Squibb

Laurent Carter (BMS, VP and Head of Strategic Care Marketing)

"You've got this nexus of a desire in the…payer and provider marketplace as well as legislation and regulation to open the door. So it's incumbent on us to step through."

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Conclusion

- Recent legislation, regulatory guidance from the FDA, and key stakeholder involvement have improved pre-approval and post-marketing HCEI communication
- These steps provide a framework for sharing information beyond traditional clinical trial data, but communication and utilization of HCEI has not been fully embraced in the US
- Barring additional updates to these FDA guidances, drug manufacturers and payers could develop internal processes and best practices supporting the adoption and use of HCEI
- These efforts could result in market-driven regulatory change, ultimately improving formulary decisions and budget forecasting

Acknowledgements

- Peter Fendt and Brian Ung wish to thank:
  - Michael Toscani, Rutgers Pharmaceutical Industry Fellowship program, Rutgers University, for his review of and assistance with this manuscript and Randy Vogenberg, their co-author on their article

How the Changing Environment for HCEI Impacts the Publication Planning Team

Tom Drake

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Audience Poll

- Do you routinely work with your HEOR/RWE colleagues in developing and/or executing publication plans?
  - Always
  - Sometimes
  - Rarely
  - Never

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HCEI & Pre-Approval Publication Planning

HCEI Stakeholder Focus

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"David Nash, MD, is truly one of the great visionaries in healthcare," said Scott Becker, publisher of *Becker's Healthcare*.

David B. Nash, MD, MBA
Dean, Jefferson School of Population Health
Thomas Jefferson School of Medicine
Philadelphia, Pennsylvania

Audiences for HCEI Data

Regulators and/or HTA Agencies	Providers	Pharma	PharmDs, NPs, allied HCPs
Formulary Decision-makers	MCOs	ACOs/IDNs	Quality Commissions
Medicare/M'caid	Medical Associations	Employers	Patients/caregivers

Source: Peeples/Drake AMWA HEOR Writer Workshop 2017

AMCP Backs FDA's Guidance on Product Communications

ALEXANDRIA, Va., June 13, 2018 /PRNewswire-USNewswire/The Academy of Managed Care Pharmacy (AMCP)

AMCP Applauds FDA for Final Guidance on Payer and Manufacturer Communications to Improve Patient Access to Emerging Therapies

AMCP has been leading efforts to clarify and modernize payer and manufacturer communications, both in the pre-FDA approval and post-FDA approval space

AMCP | Academy of Managed Care Pharmacy®

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AMCP Partnership Forum - Guidance

- Key stakeholders: managed care organizations, pharmaceutical companies, academia, healthcare professionals, and patients—discussed how they might facilitate communication of HCEI about a drug's assets before the FDA approval of the drug.

- Allowing for proactive and continuous "preapproval information exchange" of clinical and economic information about investigational drugs between manufacturers and decision makers who manage a population's health at least 12 to 18 months before a drug's approval

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Pre-Approval Payer Engagement Insights

What Evidence/Information Are Payers Requesting in Pre-Approval Phase from Manufacturers?

1. Specific Product Information
2. Dossier requests (AMCP Dossier)
3. Other requests include: face-to-face meetings, discussions at conferences, and company webinars

Source: Webinar - Payer Pre-Approval Product Evaluations – Understanding what they want and when, M. Drummond, U. of York and L. Fazio, Dymaxium, www.healtheconomics.com

Payer Evidence Needs During Pre-Approval

Research finds that Payers are most interested in the following areas in descending order of importance:

1. Clinical Trial Information
2. Product Pricing
3. Economic Information (cost-effectiveness results)
4. Budget Impact Information
5. Current Therapy Backgrounders
6. Disease State Information

Source: Webinar - Payer Pre-Approval Product Evaluations – Understanding what they want and when, M. Drummond, U. of York and L. Fazio, Dymaxium, www.healtheconomics.com

Pre-Approval Information - Ideally Payers Want?

1st Health Economic (Requested by nearly 2 to 1)

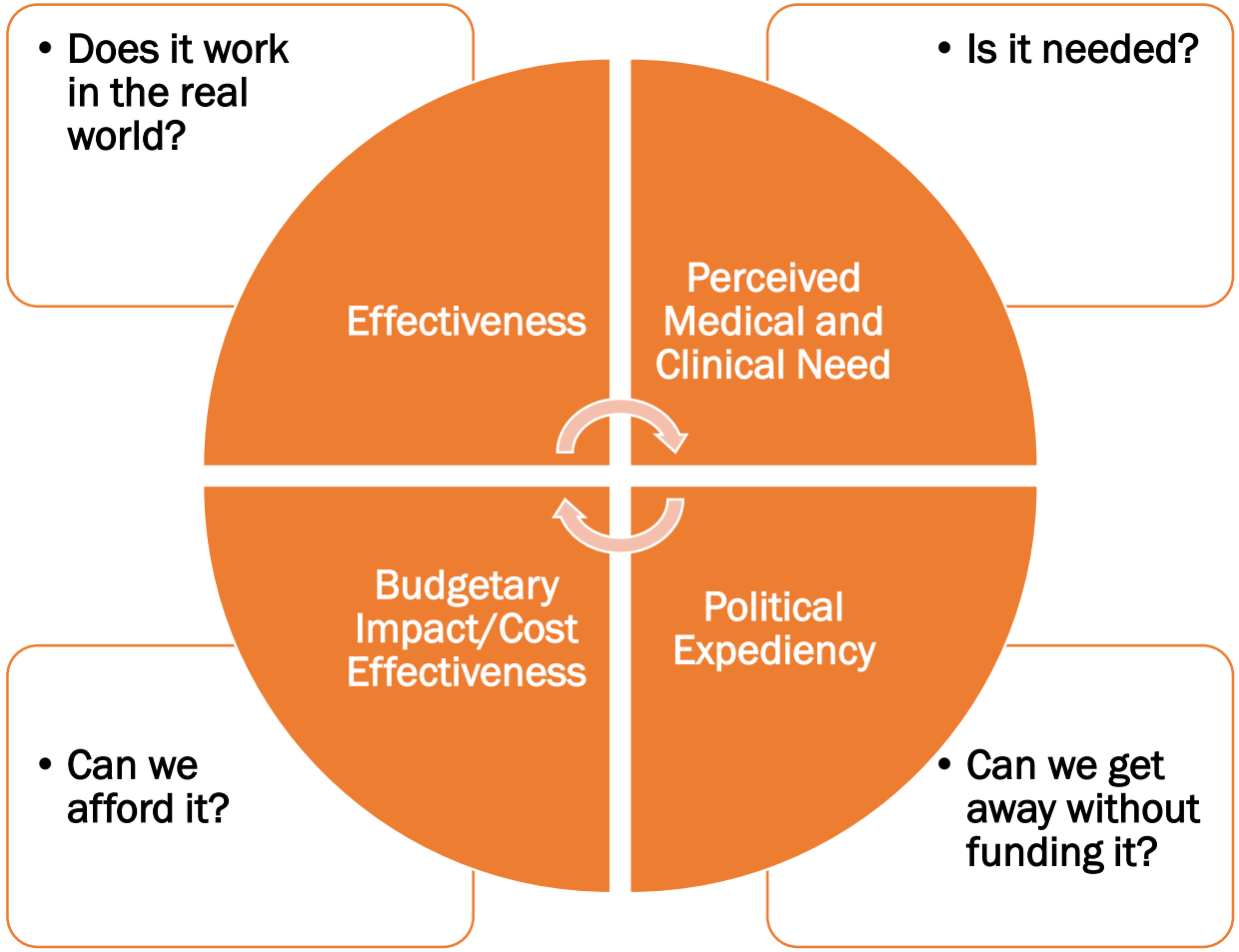
2nd Clinical Trial

3rd Efficacy

4th Safety

Source: Webinar - Payer Pre-Approval Product Evaluations – Understanding what they want and when, M. Drummond, U. of York and L. Fazio, Dymaxium, www.healtheconomics.com

Key Payer Questions – Drives Access



Source: Incorporating Value into Planning for Early Development Compounds: The Impact of Market Access Trends,
Shana Traina, PhD Global Market Access CVM, Janssen, Kimberly Dittmar, PhD, ISMPP CMPP™ Scientific Director, Cello Health Communications,
Parallel Session, 14th Annual Meeting of ISMPP

Building Publication Plans Using HCEI

Utilize ISMPP's Resources & Educational Archives

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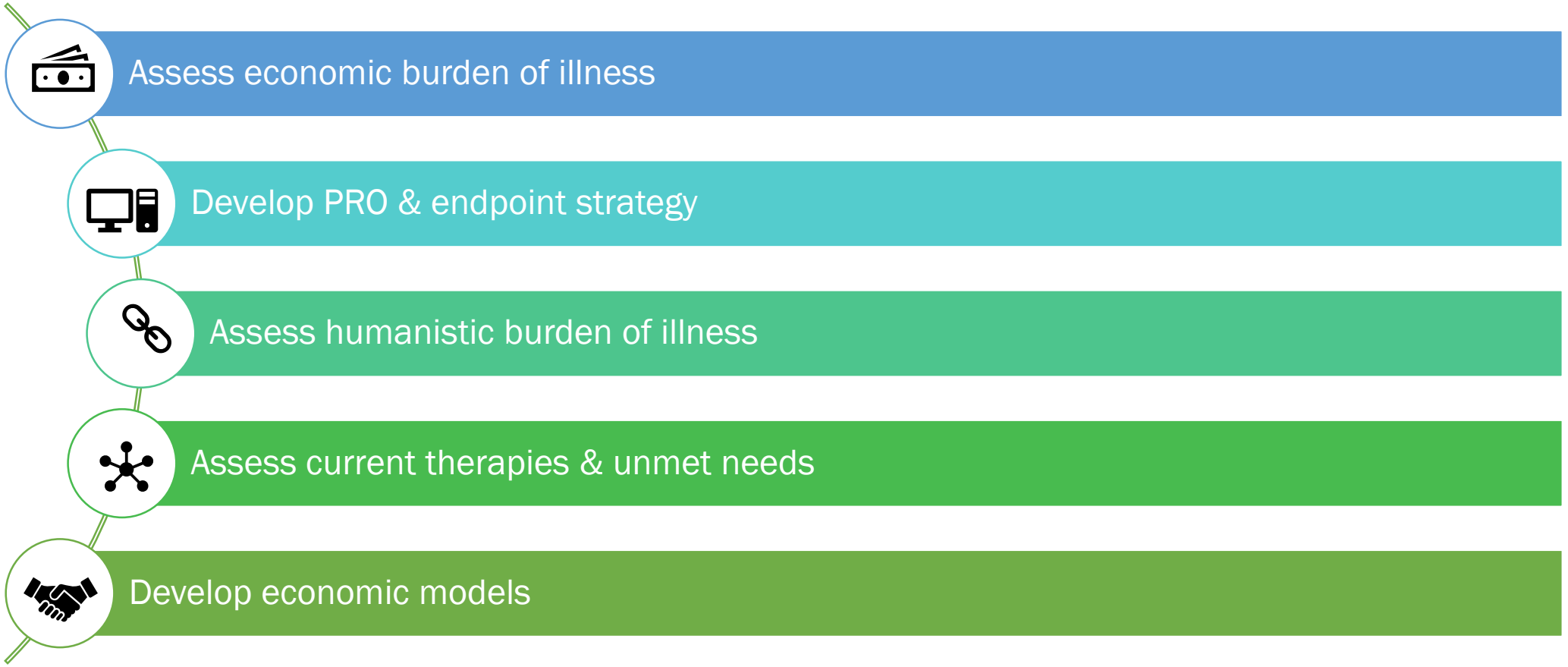
Gap Analysis Helps Identify HCEI/HEOR Research Opportunities

HEOR strategies increasingly integrated in earlier product development: Phase 1 through Phase 3



Source: "Mind the Gap" Life Cycle Management and HEOR Integration, Kristen Quinn, PhD Senior Medical Director, Peloton Advantage, LLC, Ilia Ferrusi, PhD Associate Director, HEOR, Novartis Pharmaceuticals Corporation, Parallel Session, 14th Annual Meeting of ISMPP 2018

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HEOR Evidence Sources for Gap Analysis

Do not forget the grey literature

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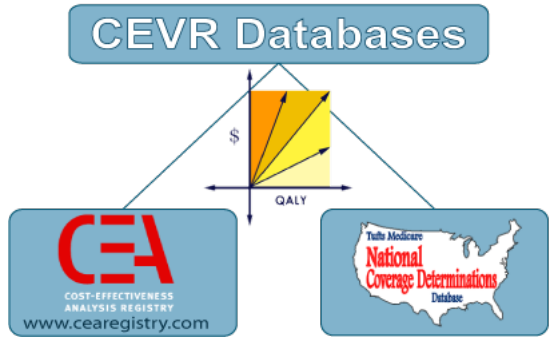

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Source: **"Mind the Gap" Life Cycle Management and HEOR Integration**, Kristen Quinn, PhD Senior Medical Director, Peloton Advantage, LLC, Ilia Ferrusi, PhD Associate Director, HEOR, Novartis Pharmaceuticals Corporation, Parallel Session, 14th Annual Meeting of ISMPP 2018

HEOR & RWE Opportunities in Gap Analysis

	Early Clinical	Phase 3 & Launch	Approval/Marketed
Gap Analysis Topics	• Disease state positioning • Establish unmet need	• Evolution of disease state • Aspects of patient burden • Establish value proposition	• Comparative effectiveness • Value demonstration
		Repeat Analysis Routinely	
Typical HEOR Data	• Disease burden surveys • Cost-analysis / economic burden studies	• Economic evaluations • Meta-analyses/comparative effectiveness • Quality-of-life studies	• Patient registries

Source: **"Mind the Gap" Life Cycle Management and HEOR Integration**, Kristen Quinn, PhD Senior Medical Director, Peloton Advantage, LLC, Ilia Ferrusi, PhD Associate Director, HEOR, Novartis Pharmaceuticals Corporation, Parallel Session, 14th Annual Meeting of ISMPP 2018

Publication Plan Implications

- Engage HEOR stakeholders early in publication strategy and planning
- Fill Data Gaps: HEOR disease state analysis & publications to establish disease burden
- Payers look for data to support value, much of which cannot readily come from randomized controlled trials
- Incorporate value measures early in clinical program
  - Think about them in Phase 1, test in Phase 2 and construct right measures in Phase 3

Source: Incorporating Value into Planning for Early Development Compounds: The Impact of Market Access Trends,
Shana Traina, PhD Global Market Access CVM, Janssen, Kimberly Dittmar, PhD, ISMPP CMPPTM Scientific Director, Cello Health Communications, Parallel Session, 14th Annual Meeting of ISMPP

Utilizing RWD/RWE Is Essential in Developing a More Complete Value Story

Real World Data

Generalize/confirm Findings from RCT

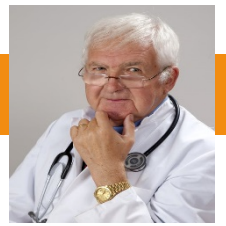
Additional insights into patient treatment journey

Greater understanding of economic value

Real-world clinical effectiveness

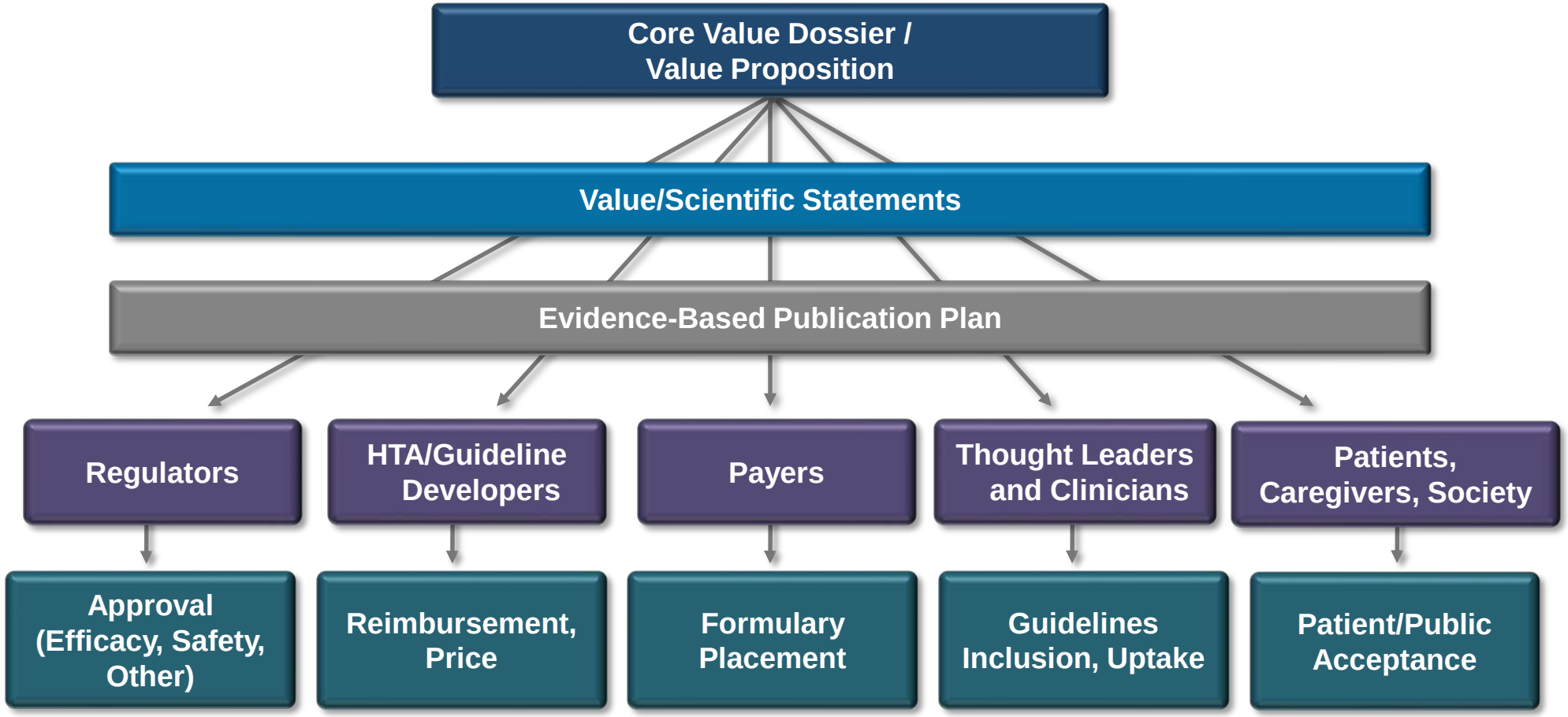
Strategy to communicate the value proposition

Regulators	Patients	Payers	Physicians
Approval (efficacy, safety)	Education and awareness	Formulary uptake and reimbursement	Guideline inclusions



Source: The Role of RWE in a Value-Based World: Who's Listening? Melissa Hagan, PhD, MPH Director, HEOR – Value Evidence Generation, Peloton Advantage, LLC, Judy Lenhart, PhD Senior Director, Global Scientific Communications Celgene, Parallel Session, 14th Annual Meeting of ISMPP

Value Communication/Publication Plan*



HTA=health technology assessment * Source ISMPP HEOR Workshop 2013

Has Publication Policy Adapted to the Growing Importance of Real-World Data?

- Over the last decade the number of real-world publications has greatly increased, supporting a growing emphasis on publishing real-world data in the publication policies of clinical journals
- High impact factor journals have significantly increased publication of real-world articles in the last few years in comparison to clinical trials
- Real-world data are increasingly influential in medical research as they enable the assessment of new interventions in the context clinical practice, and are becoming recognised as contributors to regulatory decisions

Poster #34: **Has Publication Policy Adapted to the Growing Importance of Real-World Data?** Jason McDonough, PhD, CMPP[1]; Anisha Mehra, PhD[2]*; Alex Fower, MSc[2]; Charlotte Bell, BSc[2] and James Wallis, MRes[2] [1]Cello Health Communications, Yardley, PA, USA; [2]Cello Health Communications, Farnham, Surrey, UK, 14th Annual Meeting of ISMPP 2018

Thank you & Questions!

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Upcoming ISMPP U

DATE	TOPIC	FACULTY
September TBD	*Critical Manuscript Review*	Under discussion
October TBD	*Data Sharing and Privacy Regulations*	Under discussion

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Thank you!

Have a great day!

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REFERENCES

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References

1. Centers for Medicare & Medicaid Services. NADAC as of 2016-12-21. https://data.medicaid.gov/Drug-Pricing-and-Payment/NADAC-as-of-2016-12-21/ 6ebu-k7ew. Accessed April 20, 2017.
2. Examining Medical Product Manufacturer Communications: Hearing before the Subcommittee on Health of the Energy and Commerce Committee, 115 Cong (2017) (written statement for the record of Katherine ["Kat"] Wolf Khachatourian, PharmD, MBA, Vice President, Pharmacy Services, Strategy, and Delegation Oversight, Qualchoice Health Plan Services). http://docs.house.gov/meetings/IF/IF14/20170712/106225/HHRG-115-IF14-Wstate-KhachatourianK-20170712. pdf. Accessed July 24, 2017.
3. LaMattina J. Gilead's CEO admits to 'failures' in setting price of $1,000-a-pill breakthrough. Forbes. December 8, 2016. www.forbes.com/sites/johnlamattina/ 2016/12/08/gileads-ceo-apologetic-about-sovaldis-1000-per-pill-price-tag/ #6d75876e1a97. Accessed July 25, 2017.
4. Perfetto EM, Burke L, Oehrlein EM, Gaballah M. FDAMA Section 114: why the renewed interest? J Manag Care Spec Pharm. 2015;21:368-374.
5. US Food and Drug Administration Modernization Act of 1997, Pub L No. 105-115, 111 Stat 2296, §114.
6. Neumann PJ, Claxton K, Weinstein MC. The FDA's regulation of health economic information. Health Aff (Millwood). 2000;19:129-137.
7. 21st Century Cures Act, Pub L No. 114-255, 130 Stat 1033. December 2016.
8. Center for Drug Evaluation and Research. Drug and device manufacturer communications with Payers, formulary committees, and similar entities— questions and answers: guidance for industry and review staff. Final Guidance. June 2018. https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537347.pdf. Accessed June 13, 2018.

References (cont'd)

9. Center for Drug Evaluation and Research. Medical product communications that are consistent with the FDA-required labeling—questions and answers: guidance for industry. Final Guidance. June 2018. https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537130.pdf. Accessed June 13, 2018.
10. Brennan Z. Medical product communications: industry seeks to reform FDA draft guidances. Regulatory Focus. April 21, 2017. www.raps.org/Regulatory-Focus/ News/2017/04/21/27387/Medical-Product-Communications-Industry-Seeks-to-Reform-FDA-Draft-Guidances/. Accessed August 1, 2017.
11. Kelly C. Pharmacoeconomic communications to payers getting multiple pilots by Genentech. Pink Sheet. June 6, 2017. https://pink.pharmamedtechbi. com/PS120805/Pharmacoeconomic-Communications-To-Payers-Getting- Multiple-Pilots-By-Genentech. Accessed July 25, 2017.
12. Academy of Managed Care Pharmacy. AMCP Partnership Forum: enabling the exchange of clinical and economic information pre-FDA approval. J Manag Care Spec Pharm. 2017;23:105-112.
13. US Food and Drug Administration Safety and Innovation Act, Pub L No. 112-144, 126 Stat 993, §902.
14. Academy of Managed Care Pharmacy. Pre-FDA approval Partnership Forum. www.amcp.org/Pre-FDAApprovalPartnershipForum/. Accessed April 17, 2017.
15. Dow AK. FDA says yes to pre-approval communications with Payers but reaffirms its approach to restrictions on off-label communications. Health Law Advisor. January 20, 2017. www.healthlawadvisor.com/2017/01/20/fda-says-yes-to-pre-approval-communications-with-Payers-but-reaffirms-its-approach-to-restrictions-on-off-label-communications/. Accessed July 28, 2017.
16. Guthrie, B. (2018, January 17). All Actions - H.R.2026 - 115th Congress (2017-2018): Pharmaceutical Information Exchange Act. Retrieved February 13, 2018, from https://www.congress.gov/bill/115th-congress/house-bill/2026/all-actions?overview=closed#tabs
17. United States House of Representatives- Seal of the House picture. (n.d.). Retrieved February 14, 2018, from https://goo.gl/images/rwamRA

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ISMPP Resources – 2018 US Conference

Parallel Sessions

- **"Mind the Gap" Life Cycle Management and HEOR Integration**, Kristen Quinn, PhD Senior Medical Director, Peloton Advantage, LLC, Ilia Ferrusi, PhD Associate Director, HEOR, Novartis Pharmaceuticals Corporation
- **Incorporating Value into Planning for Early Development Compounds: The Impact of Market Access Trends**, Shana Traina, PhD Global Market Access CVM, Janssen, Kimberly Dittmar, PhD, ISMPP CMPPTM Scientific Director, Cello Health Communications
- **The Role of RWE in a Value-Based World: Who's Listening?** Melissa Hagan, PhD, MPH Director, HEOR – Value Evidence Generation Peloton Advantage, LLC, Judy Lenhart, PhD Senior Director, Global Scientific Communications Celgene

Posters

- Poster #8: **Evaluation of Data Reporting in Real-world Publications in Clinical Versus Health Economic Journals,** Alaina Mitsch, PhD, CMPP™1,*; Jason McDonough, PhD, CMPP™1; Kimberly Brooks, PhD, CMPP™1; Erin Brant, CMPP™1; Anisha Mehra, PhD2 1Cello Health Communications, Yardley, PA, USA; 2Cello Health Communications, Farnham, UK.
- Poster #34: **Has Publication Policy Adapted to the Growing Importance of Real-World Data?** Jason McDonough, PhD, CMPP1; Anisha Mehra, PhD2*; Alex Fower, MSc2; Charlotte Bell, BSc2 and James Wallis, MRes2 1Cello Health Communications, Yardley, PA, USA; 2Cello Health Communications, Farnham, Surrey, UK.
- Poster #35: **Real-world evidence (RWE) publications are an integral part of company evidence submissions for payer discussions**, Hester van Lier, Miriam de Boeck, Victoria Edwards, Eline Hanekamp, Tessa E. Hartog, Grace Richmond and Remon W.M. van den Broek Excerpta Medica, Amsterdam, Netherlands

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Moderator: Michael Platt, MS

Michael Platt, MS (Virgo Health) has 22 years of experience in the pharmaceutical, biopharmaceutical, medical device, and healthcare delivery fields. His expertise includes pre-launch/launch/post-launch medical communications activities designed to educate and inform healthcare professionals, patients, caregivers, and other stakeholders. He has broad experience in publication planning and adult-based education, including 10+ years in continuing education and pharmacy education credentialing/certification. Michael has managed teams of professional writers, scientific managers, editors, meeting planners, and designers who develop professional, compliant medical and clinical communications, with a focus on clinical data publications and associated meeting activities. He is a past CMPP Board Member, CMPP Vice-Chair, and also an active member of the ISMPP U Committee. As a past-Chair of ISMPP U, Michael assisted in establishing Needs-based sessions for ISMPP U that meet educational gaps for publication professionals.

Tom Drake, MA, ISMPP CMPP™

Tom Drake, MA, CMPP (Global Outcomes Group) has been involved in medical communications for over twenty-five years. In 1990 Tom founded and launched the healthcare trade publication, Product Management Today (PMT). He was publisher and editorial director for its first six years. As PMT's editorial director, he worked with several the founders of International Society for Pharmacoeconomics and Outcomes Research (ISPOR). Tom has been involved in most areas of medical communications including: global publication planning, continuing medical education (CME), Health Economics and Outcomes Research (HEOR), Real-World Evidence (RWE), thought-leader development and digital and web-based communications. Tom has supported communication projects in all major therapy areas and supported orphan drug programs. In 2014 Tom launched the Global Outcomes Group, an independent healthcare communications agency supporting HEOR/RWE and Medical Communications for the bio/pharma and medical device industries. Tom has been an active member of ISMPP since 2008, was chair of the ISMPP-U committee in 2015 and remains a committee member. Tom is also an active member of AMWA, ISPOR and the recently formed, MAPS (Medical Affairs Professional Society).

Peter Fendt, PharmD, MBA

- **Peter Fendt, PharmD, MBA (Celgene)** is a pharmacist by training who graduated from the University at Buffalo School of Pharmacy, as well as the University at Buffalo School of Management. Throughout pharmacy and business school Peter was involved in various consulting opportunities, including for a local pharmacy school, independent pharmacy and healthcare system. In addition, his School of Management experiences included a focus on the US healthcare system and its ongoing evolution. Peter completed a Global Market Insights post-doctoral fellowship with Celgene Corporation/Rutgers University, during which he was able to gather insights from market research projects as well as business intelligence efforts which engaged practicing physicians, caregivers and patients. During his fellowship he also acted as Adjunct Faculty for Ernest Mario School of Pharmacy, and was a founding member of a pharmacists' professional network at Celgene. Peter is currently employed as a member of the Global Market Insights team at Celgene Corporation, supporting primarily hematology products and more broadly the hematology/oncology franchise on key focused projects. In his free time Peter enjoys making music, cooking, and writing.

Brian Ung, PharmD, RPh, MS

- **Brian Ung, PharmD, RPh, MS (Celgene)** is a licensed pharmacist and graduate from the University of Maryland School of Pharmacy. Throughout pharmacy school, Brian gained experience in a variety of managed care pharmacy, market access, health economics & outcomes research settings. Brian completed a Health Economics & Outcomes Research post-doctoral fellowship with Celgene Corporation/Rutgers University, served as Adjunct Faculty for Ernest Mario School of Pharmacy and obtained a Masters of Science in Health Outcomes, Policy & Economics from Rutgers School of Public Health. Brian has authored numerous poster presentations and peer-reviewed manuscripts. He is currently employed as a member of the US HEOR team at Celgene Corporation, supporting both oncology and inflammation/immunology products. Brian enjoys watching basketball, listening to podcasts and writing in his personal time.