Post-Election Coverage and Access to Executives and FDA/CMS Regulators to Examine Shifting Regulatory and Reimbursement Policy

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VIRTUAL EVENT

DECEMBER 7-9, 2020

FDA/CMS Summit

Garner Efficiencies in Regulatory and Reimbursement Processes in a COVID Era

CONFERENCE CO-CHAIRS:

Nielsen Hobbs,
Editor,
Pink Sheet

Charlotte Jones-Burton, M.D., M.S.,
Vice President, Global Clinical Development, Nephrology,
Otsuka Pharmaceuticals

FEATURED FACULTY:

Peter Marks, M.D., Ph.D.,
Director, Center for Biologics Evaluation and Research,
U.S. Food and Drug Administration (FDA)

Patrizia Cavazzoni, M.D,
Acting Director, Center for Drug Evaluation and Research,
U.S. Food and Drug Administration (FDA)

Mary Denigan-Macauley, Ph.D.,
Director, Health Care, Public Health & Private Markets,
U.S. Government Accountability Office (GAO)

John Concato,
Deputy Division Leader, Office of Medical Policy
U.S. Food and Drug Administration (FDA)

Amy P. Abernethy, M.D., Ph.D.,
Principal Deputy Commissioner of Food and Drugs, and acting CIO,
U.S. Food and Drug Administration (FDA)

Isaac Rodriguez-Chavez, Ph.D., MHSc,
CDER Officer, Clinical Research Methodology, Regulatory Compliance and Medical Policy Development, **U.S. Food and Drug Administration (FDA)**

Patroula Smpokou, M.D.,
Deputy Director (acting), Division of Rare Diseases & Medical Genetics, Office of Rare Diseases, Pediatrics, Urologic & Reproductive Medicine, Office of New Drugs, **CDER, U.S. Food and Drug Administration (FDA)**

Richardae Araojo,
Associate Commissioner for Minority Health and Director of the Office of Minority Health and Health Equity,
U.S. Food and Drug Administration (FDA)

Theresa Kehoe, M.D.,
Director (acting), Division of General Endocrinology, Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN), OND,
CDER, U.S. Food and Drug Administration (FDA)

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DIGITAL CAPABILITIES AND FEATURES:

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- Live Q&A chat with conference faculty

REVIEW SHIFTS IN COMPLEX REGULATORY AND REIMBURSEMENT POLICIES BY CONNECTING DIRECTLY WITH FDA AND CMS THOUGHT-LEADERS

The FDA/CMS Summit is the only event that brings both groups together to meet with senior and executive leadership and regulatory leaders within the industry and continues to deliver best available information on FDA and CMS priorities, policy changes, evidence-based practice, federal review processes on various areas of bio/pharma such as CDER, CBER, CDRH and the most cutting-edge advances in healthcare and technology.

JOIN ROBUST DISCUSSIONS WITH REGULATORY DECISION MAKERS AND LEADING THOUGHT LEADERS AS THEY DISCUSS:

- How process shifts and efficiencies enacted during the pandemic may impact the drug development process, reimbursement and patient access moving forward
- Key steps necessary to achieve diversity in clinical trials
- The current and future state of value-based payment models in the wake of the pandemic
- Trends in decentralization and digital enablement of clinical trials
- Implications of the results of 2020 elections on drug pricing reform
- Innovative approaches to clinical trial design for rare disease
- The evolving role of RWE in supporting the uptake of cell and gene therapies

WHO SHOULD ATTEND:

You will benefit from this conference if you are a manager, director or executive at a bio/pharmaceutical or medical device company with responsibility for:

- **Regulatory Affairs**
- **Health Policy**
- **Health Economics**
- **Government Relations**
- **Quality and Regulatory**
- **Public Policy and Strategy**
- **Reimbursement and Access**
- **Patient Advocacy**

FDA and CMS regulators, consultants in the healthcare landscape, investors, law firms and technology providers supporting the regulatory and reimbursement healthcare landscape will also find this event of exceptional value.

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Alan Sandler,
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Genentech

ESTEEMED **CONFERENCE FACULTY**

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  Principal Deputy Commissioner of Food and Drugs, and Acting CIO,
  U.S. Food and Drug Administration (FDA)
- Peter Marks, M.D., Ph.D.,
  Director, Center for Biologics Evaluation and Research, **U.S. Food and Drug Administration (FDA)**
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  Acting Director, Center for Drug Evaluation and Research,
  U.S. Food and Drug Administration (FDA)
- John Concato,
  Deputy Division Leader, Office of Medical Policy,
  U.S. Food and Drug Administration (FDA)
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  U.S. Food and Drug Administration (FDA)
- Anne Rowzee, Ph.D., Associate Director for Policy, Office of Tissues and Advanced Therapies, Center for Biologics Evaluation and Research, **U.S. Food and Drug Administration (FDA)**
- Elisabeth Piault-Louis, Senior Director, Scientific Lead, Digital Health for Oncology R&D, **AstraZeneca**
- Theresa Kehoe, M.D.,
  Director (acting), Division of General Endocrinology, Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN), OND, CDER, **U.S. Food and Drug Administration (FDA)**
- Kathleen Donohue, M.D.,
  Director, Division of Rare Diseases & Medical Genetics), OND, CDER,
  U.S. Food and Drug Administration (FDA)
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  U.S. Food and Drug Administration (FDA)
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  Associate Commissioner for Minority Health and Director of the Office of Minority Health and Health Equity,
  U.S. Food and Drug Administration (FDA)
- Mary Denigan-Macauley, Ph.D., Director, Health Care, Public Health & Private Markets, **U.S. Government Accountability Office (GAO)**
- Jonathan Kimball, Vice President, Trade and International Affairs,
  Association for Accessible Medicines (AAM)
- Charlotte Jones-Burton, M.D., M.S.,
  Vice President, Global Clinical Development, Nephrology,
  Otsuka Pharmaceuticals
- Annie Kennedy, Chief of Policy and Advocacy, **EveryLife Foundation**
- Howard Sklamberg, Partner, Life Sciences and Healthcare Regulatory,
  Arnold & Porter LLP
- Nielsen Hobbs, Editor, **Pink Sheet**
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  Center for BioMedical Innovation/NEWDIGS
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- Alicyn Campbell, Head of Digital Health for Oncology R&D,
  AstraZeneca
- Yi (Louie) Lu, Senior Manager, Health Economist, Clinical Value and Pharmacy Initiatives, Office of Clinical Affairs,
  Blue Cross Blue Shield Association
- Rujul Desai, JD Counsel, **Covington & Burling LLP**
- Adora Ndu, Pharm.D., JD, Vice President, Regulatory Affairs, Policy, Research, Engagement (PRE), & Reg International,
  BioMarin Pharmaceutical Inc
- Eleanor M. Perfetto, Ph.D., M.S., EVP,
  Strategic Initiatives, **National Health Council**

ESTEEMED **CONFERENCE FACULTY** (CONTINUED)

- Anne-Marié van der Merwe, Global Program Regulatory Director, Innovation, Regulatory Affairs, **Novartis Pharmaceuticals**
- Edmund Pezalla, CEO and Founder, **Enlightenment Bioconsult**
- Judy Sewards, Head, Clinical Trial Experience, **Pfizer**
- Dara Richardson-Heron, M.D., Chief Patient Officer, **Pfizer**
- Robert Dubois, M.D., Ph.D., Interim President and CEO, Chief Science Officer, **National Pharmaceutical Council (NPC)**
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- Anthony Sireci, M.D., M.Sc., Vice President, Diagnostics Development and Medical Affairs, Loxo Oncology, **Loxo Oncology at Lilly**
- Eric Konnick, M.D., M.S., Assistant Professor; Associate Director, Genetics and Solid Tumors Laboratory, **University of Washington**
- Jordan Laser, M.D., Medical Director, Pathology and Laboratory Medicine, Long Island Jewish Medical Center, **Northwell Health;** Associate Professor, Donald and Barbara Zucker School of Medicine, **Northwell/Hofstra**
- Roslyn Daniels, President & Founder, **Black Health Matters**
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- Samuel Caughron, M.D., President & CEO, **MAWD Pathology Group**
- Janet Wittes, Ph.D., President, **Statistics Collaborative, Inc.**
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- John A. Murphy, III, Vice President, Deputy General Counsel, **Biotechnology Innovation Organization**
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- Sarah Karlin-Smith, Senior Writer, **The Pink Sheet and Scrip**
- Katherine High, M.D., Visiting Professor, **Rockefeller University;** Co-Founder, **Spark Therapeutics**
- Daniela Drago, Ph.D., RAC, Senior Director, Regulatory Sciences, **Biogen**
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- Cathy Kelly, Senior Writer, **Pink Sheet and Scrip, Informa Pharma Intelligence**
- Solomon Iyasu, M.D., MPH, Vice President and Global Head of Pharmacoepidemiology, **Merck**
- R. Angelo De Claro, M.D., Associate Director (Acting), Global Clinical Sciences, FDA Oncology Center of Excellence; Division Director (Acting), Division of Hematologic Malignancies, **U.S. Food and Drug Administration**
- Chad Pettit, Executive Director, Marketing, Global Biosimilars Commercial Lead, **Amgen**
- Mark Fleury, Principal, Policy Development, Emerging Science, **American Cancer Society Cancer Action Network, Inc**

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All times in EST

DAY ONE
MONDAY, DECEMBER 7

10:45am–11:00am

LIVE

Organizer and Co-Chair's Welcoming Remarks

Nielsen Hobbs, Editor, **Pink Sheet**

11:00am–11:30am

LIVE

FIRESIDE CHAT: A Review of Current Priorities for CBER and How the Pandemic is Impacting FDA Resources, Efficiencies and Shifts in Processes

Peter Marks, M.D., Ph.D.,
Director, Center for Biologics Evaluation and Research,
U.S. Food and Drug Administration (FDA)

Interviewer:
Sarah Karlin-Smith, Senior Writer, **The Pink Sheet and Scrip**

DAY TWO
TUESDAY, DECEMBER 8

10:45am–11:00am

LIVE

Co-Chair's Opening Remarks

Charlotte Jones-Burton, M.D., M.S.,
Vice President Global Clinical Development, Nephrology,
Otsuka Pharmaceuticals

11:00am–11:45am

LIVE

Drug Development and the Supply Chain in the Aftermath of the Pandemic

- Examine how business practices are changing, as well as how these new practices impact resources, costs and drug development timelines
- Discuss what impact the pandemic has had on what manufacturers choose to invest in R&D moving forward
- Explore how the drug supply chain has been impacted and what it would mean to move different components out of China
- Assess the potential capabilities and pros/cons for domestic manufacturing

Jonathan Kimball, Vice President, Trade and International Affairs,
Association for Accessible Medicines

Omar Hafez, Managing Partner, **Avalere Health**

DAY THREE
WEDNESDAY, DECEMBER 9

10:45am–11:00am

LIVE

Co-Chair's Opening Remarks

Nielsen Hobbs, Editor, **Pink Sheet**

11:00am–11:45am

LIVE

Assess the Impact of the 2020 Elections on Drug Pricing Reform

With tightened budgets, a global recession and the soaring costs associated with the pandemic, how will the 2020 election results shape the future of healthcare? This session examines potential courses of action the Administration may take regarding drug pricing reform initiatives and how to manage added pressures to control drug costs and ensure affordability and patient access.

Moderator:
Rujul Desai, Of Counsel, **Covington & Burling, LLP**

Panelists:
Juliette Cubanski, Ph.D., Deputy Director, Program on Medicare Policy, **Kaiser Family Foundation (KFF)**
Robert Dubois, M.D., Ph.D., Interim President and CEO, Chief Science Officer, **National Pharmaceutical Council**
Walid Gellad, M.D., MPH, Director, Center for Pharmaceutical Policy and Prescribing, **University of Pittsburgh**
John A. Murphy, III, Vice President, Deputy General Counsel, **Biotechnology Innovation Organization**

MONDAY, DECEMBER 7

11:30am–12:00pm

LIVE FIRESIDE CHAT: A Review of Current and Future Priorities for CDER

Patrizia Cavazzoni, M.D.,
Acting Director, Center for
Drug Evaluation and Research,
U.S. Food and Drug Administration (FDA)

Interviewer:

Derrick Gingery, Senior Writer, **The Pink Sheet and Scrip**

1:00pm–1:45pm

LIVE Navigating the Regulatory and Reimbursement Landscape Post COVID-19

This session examines how process shifts and efficiencies enacted during the pandemic may impact the drug development process, reimbursement and patient access moving forward.

- Discuss key learnings from how reliance on telehealth, digital enablement of virtual trials and faster protocols impacted patient outcomes
- Explore how COVID-19 impacts the FDA from a resource perspective and the organization's ability to stay consistent with guidance prior to the pandemic
- Consider the pros/cons of extending some of the process efficiencies across therapeutic areas
- Examine how the healthcare landscape might shift – Assess the possibility of centralization of providers due to pressure on the system and how that might impact how care is given and how research is conducted

Moderator: *Rebecca Wood, Partner and Leader of the FDA Practice,* **Sidley Austin LLP;** *Former Chief Counsel,* **U. S. Food and Drug Administration (FDA)**

Panelists:
Alicyn Campbell, Head of Digital Health for Oncology R&D, **AstraZeneca**
John Concato, Deputy Division Leader, Office of Medical Policy, **U.S. Food and Drug Administration (FDA)**
Paul Kluetz, M.D., Deputy Director, Oncology Center of Excellence, **U.S. Food and Drug Administration (FDA)**
Jeffrey Chasnow, Senior Vice President and Associate General Counsel, **Pfizer**

TUESDAY, DECEMBER 8

12:30pm–1:30pm

LIVE Part 1: Achieving Diversity in Clinical Trials — An Internal Approach

- Discuss key steps that the life sciences industry can take to address diversity in clinical trials
- Consider how industry might partner with the FDA to move forward as it relates to advancing equity in clinical trials and access to treatments
- Examine the potential role of CMS in potentially shifting reimbursement requirements to drive behavior change

Moderator: *Charlotte Jones-Burton, M.D., M.S., Vice President, Global Clinical Development, Nephrology,* **Otsuka Pharmaceuticals**

Panelists:
Eliseo J. Pérez-Stable, M.D., Director, National Institute on Minority Health and Health Disparities, **National Institutes of Health**
Dara Richardson-Heron, M.D., Chief Patient Officer, **Pfizer**
Quita Highsmith, MBA, Chief Diversity Officer, **Genentech**
Rear Admiral Richardae Araojo, Associate Commissioner for Minority Health and Director of the Office of Minority Health and Health Equity (OMHHE), **U.S. Food and Drug Administration (FDA)**

1:45pm–2:30pm

LIVE Addressing Challenges and Opportunities in Cell and Gene Therapy Development

The FDA has issued and finalized much guidance and there are over 900 active INDs and several approved gene therapy products.

- Industry leaders and senior FDA officials discuss lessons learned and case examples of recent FDA approvals
- Examine pre-and post-market issues

Moderator: *Michael J. Werner, Co-founder and Senior Policy Counsel,* **Alliance for Regenerative Medicine**

Panelists:
Katherine High, M.D., Visiting Professor, **Rockefeller University;** *Co-Founder,* **Spark Therapeutics**
Daniela Drago, Ph.D., RAC, Senior Director, Regulatory Sciences, **Biogen**
Peter Marks, M.D., Ph.D., Director, CBER, **U.S. Food and Drug Administration (FDA)**
Jennifer Brogdon, Ph.D., Executive Director, Head of Cell Therapy Research, Exploratory Immuno-Oncology, **Novartis Institutes for Biomedical Research (NIBR)**

WEDNESDAY, DECEMBER 9

12:30pm–1:15pm

LIVE Innovating Clinical Trial Design for Rare Disease Drug Development

- Review approaches to clinical trial design
- Discuss possible methods to sign a study with exceptionally small populations
- Consider the implications for leveraging natural history as control group
- Examine innovative approaches to trial design for rare disease

Moderator:
Frank J. Sasinowski, Director, **Hyman, Phelps & McNamara**

Panelists:
Kathleen Donohue, M.D., Clinical Team Leader, Division of Gastroenterology and Inborn Errors Products (DGIEP), OND, CDER, **U.S. Food and Drug Administration (FDA)**
Bradley J. Glasscock, Pharm.D., Group Vice President, Head of Global Regulatory Affairs, **BioMarin Pharmaceutical Inc.**
Janet Wittes, Ph.D., President, **Statistics Collaborative, Inc.**

1:30pm–2:15pm

LIVE Realizing the Full Promise of RWE in Drug Development

- Discuss the current use and integration of patient-level data/ RWE in the accelerated drug approval process
- Examine the ICER/Aetion partnership and pilot program to generate new RWE to garner a greater understanding of the impact of therapies approved under FDA's expedited approval pathways
- Understand RWE role in supporting the uptake of cell and gene therapy development
- Consider the opportunities and implications of the adoption of RWE for various pre-and post-market uses

Moderator: *Richard Gliklich, M.D., Chief Executive Officer,* **OM1**

Panelists: *Amy P. Abernethy, M.D., Ph.D., Principal Deputy Commissioner of Food and Drugs, and Acting Chief Information Officer,* **U.S. Food and Drug Administration (FDA)**
Jane F. Barlow, M.D., Senior Advisor, **MIT Center for BioMedical Innovation/NEWDIGS**
Solomon Iyasu, M.D., MPH, Vice President and Global Head of Pharmacoepidemiology, **Merck**

MONDAY, DECEMBER 7

2:15pm–3:00pm

LIVE

Assess the Potential for Collaborative Approaches between FDA Regulatory Programs and CMS Reimbursement

This session examines how process shifts and efficiencies enacted during the pandemic may impact the drug development process, reimbursement and patient access moving forward.

- Discuss bridging the evidentiary requirements for regulatory approval and payer acceptability
- Explore how drug effectiveness (and value) data collected for FDA approval could be shared with CMS to expedite reimbursement approvals
- Examine regulatory HTA and EMA interfaces: Joint discussion, joint advice and evidentiary requirements – Consider how to design a drug development program that can meet both needs
- Assess at what point during the FDA approval process/drug development phase should sponsors engage CMS

Moderator:
Sarah Karlin-Smith, Senior Writer, **The Pink Sheet and Scrip**

Panelists:
Peter B. Bach, M.D., MAPP, Director, Center for Health Policy & Outcomes, Department Epidemiology & Biostatistics, **Memorial Sloan Kettering Cancer Center**
Rachel Sachs, Associate Professor of Law, **Washington University in St. Louis**
Jeet Guram, M.D., Senior Advisor, Office of the Commissioner, **U.S. Food and Drug Administration (FDA)**

TUESDAY, DECEMBER 8

3:00pm–3:45pm

LIVE

Defining and Demonstrating Value in Rare Disease

Value is a gating factor for access, since payers want to ensure reimbursement for treatments that address key outcomes. However, defining and demonstrating rare disease therapies' value, which demands more information about the disease, is challenging given limited natural history data and small patient populations.

- Discuss how developers can work with FDA, payers and patients to not only determine upon which value – and ultimately access – should be evaluated
- Assess what factors go into identifying key outcome measures
- Examine what other unique considerations arise in meeting the needs of this patient population (e.g., generate awareness, additional patient support services, call centers, early intervention campaigns)

Patroula Smpokou, M.D., Clinical Team Leader, DGIEP, OND, CDER, **U.S. Food and Drug Administration (FDA)**

Annie Kennedy, Chief of Policy and Advocacy, **EveryLife Foundation**

WEDNESDAY, DECEMBER 9

2:45pm–3:30pm

LIVE

The New Clinical Trial — Trends in Decentralization and Digital Enablement

This session examines the impact of the FDA's guidance updates on clinical trials over the past year, as well as the expanded use of telehealth and digital enablement of virtual trials.

- Examine how the FDA's guidance updates over the past year affected the continuity and efficacy of clinical trials
- Review digital protocols that can help expedite drug research – digitally enabled conduct
- Explore the impact of direct to patient provision of clinical supplies
- Assess the value of digitally enabled remote monitoring and auditing as well as digitally enabled regulatory GCP inspections
- Discuss critical variables to support decentralized trials
- Consider what the future of clinical trials will look like

Moderator: *Isaac Rodriguez-Chavez, Ph.D., MHSc, CDER Officer, Clinical Research Methodology, Regulatory Compliance and Medical Policy Development,* **U.S. Food and Drug Administration (FDA)**

Panelists:
Anne-Marié van der Merwe, Global Program Regulatory Director, Innovation, Regulatory Affairs, **Novartis Pharmaceuticals**
Judy Sewards, Head, Clinical Trial Experience, Global Product Development, **Pfizer**
Kent Thoelke, Chief Scientifc Officer and Executive Vice-President, **PRA Health Sciences** *[invited]*
Dr. Jonathan Cotliar, Chief Medical Officer, **Science 37** *[invited]*

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MONDAY, DECEMBER 7

3:30pm–4:15pm

LIVE

Patient Engagement and Regulatory Decision-Making

This panel examines opportunities for cross-center (CBER/CDER) approaches to incorporate patient engagement in regulatory decision-making.

- Review case examples of how patient engagement was used to inform regulatory decisions
- Garner CBER and CDER perspectives on benefits of internal information sharing and patient engagement support in regulatory decision-making
- Next steps and lessons learned

Moderator: *Adora Ndu, Pharm.D., J.D., Vice President, Regulatory Affairs, Global Head of Policy, Research, Engagement (PRE) & Reg International,* **BioMarin Pharmaceutical Inc.**

Panelists:

Anne Rowzee, Ph.D., Associate Director, Policy, Office of Tissues and Advanced Therapies(OTAT), Center for Biologics Evaluation and Research (CBER), **U.S. Food and Drug Administration (FDA)**

Eleanor M. Perfetto, Ph.D., M.S., Executive Vice President, Strategic Initiatives, **National Health Council**

Elisabeth Piault-Louis, Senior Director, Scientific Lead, Digital Health for Oncology R&D, **AstraZeneca**

Theresa Kehoe, M.D., Director (acting), Division of General Endocrinology, Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN), OND, CDER, **U.S. Food and Drug Administration (FDA)**

TUESDAY, DECEMBER 8

4:00pm–4:45pm

LIVE

Evolving Diagnostic Testing to Support Treatment Decision-Making

Value is a gating factor for access, since payers want to ensure reimbursement for treatments that address key outcomes. However, defining and demonstrating rare disease therapies' value, which demands more information about the disease, is challenging given limited natural history data and small patient populations.

- Discuss the value of diagnostics in directing treatment decision-making
- Examine potential hurdles that stand in the way of patients receiving clinically appropriate testing
- Explore ways to advance the field and increase access to this important testing and what stakeholders need to be present and who needs to come to the table
- Examine standards for quality and consistent sensitivity and who ultimately is responsible for ensuring quality standards
- Consider how payer viewpoints on diagnostics and what matters most to them and how will they determine if they will cover diagnostics

Anthony Sireci, M.D., M.Sc., Vice President, Diagnostics Development and Medical Affairs, Loxo Oncology, **Loxo Oncology at Lilly**

Samuel Caughron, M.D., President & CEO, **MAWD Pathology Group**

Mark Fleury, Principal, Policy Development, Emerging Science, **American Cancer Society Cancer Action Network, Inc**

WEDNESDAY, DECEMBER 9

3:30pm

LIVE

Closing Remarks

Nielsen Hobbs, Editor, **Pink Sheet**

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FDA Regulatory Modernization Code COVID-19 — Global Collaboration Workshare Inclusive of Mutual Recognition

ON-DEMAND

- Review the Pros and Cons of global workshare (e.g. Project Orbis)
  * What are roadblocks and barriers?
  * What can a sponsor company do to enable more success?
- Identify and explore opportunities to better leverage global collaboration for GMP inspections, e.g. broader use of mutual agreements for inspections – consideration of mutual recognition for gene therapy products
- Discuss FDA perspectives on how to do virtual inspections moving forward
- Leverage mutual recognition and global collaboration to address COVID 19 issues and support development and regulate products

Moderator:

Howard Sklamberg, Partner, Life Sciences and Healthcare Regulatory, **Arnold & Porter LLP**

Panelists:

Mary Denigan-Macauley, Ph.D., Director, Health Care, Public Health & Private Markets, **U.S. Government Accountability Office (GAO)**

Linda Bowen, M.Sc., RAC, FRAPS, Head, Regulatory Policy & Intelligence, **Seattle Genetics**

R. Angelo De Claro, M.D., Associate Director (Acting), Global Clinical Sciences, FDA Oncology Center of Excellence; Division Director (Acting), Division of Hematologic Malignancies,, **U.S. Food and Drug Administration**

Examine Value-Based Payment Models in the Wake of the Pandemic

ON-DEMAND

- Understand the current state of value-based reimbursement models and value-based outcomes
- Assess where we are on the value-based healthcare curve and the impact of the pandemic

Moderator:

Mark Trusheim, Strategic Director, **NEWDIGS;** *Visiting Scientist, Sloan School of Management,* **Massachusetts Institute of Technology**

Panelists:

Edmund Pezalla, CEO and Founder, **Enlightenment Bioconsult**

Jim Curotto, Vice President, Integrated Account Management, **Merck**

Jeet Guram, M.D., Senior Advisor, Office of the Commissioner, **U.S. Food and Drug Administration, (FDA)**

Part II. Achieving Diversity in Clinical Trials — An External Approach

ON-DEMAND

- Discuss how the life sciences industry could engage in public/private partnerships with academia, vendors and community organizations with expertise in inclusivity/diversity initiatives to drive change
- Engage patient advocacy groups to garner patient insights from a diverse perspective throughout the development lifecycle
- Discuss patient and community leader involvement/engagement in research and development

Moderator:

Charlotte Jones-Burton, M.D., M.S., Vice President, Global Clinical Development, Nephrology, **Otsuka Pharmaceuticals**

Panelists:

Michael Curry, Esq., Deputy CEO, General Counsel, **Massachusetts League of Community Health Centers**

Roslyn Daniels, President & Founder, **Black Health Matters**

Elizabeth Ofili, M.D., MPH, Founder and CSO, **AccuHealth Technologies Inc.;** *Professor of Medicine (Cardiology),* **Morehouse School of Medicine;** *Chief Medical Officer,* **Morehouse Choice Accountable Care Organization**

ON-DEMAND CONTENT (CONTINUED)

The Path from Clinical to Commercialization

ON-DEMAND

- Review how the landscape changed over the long and short-term? Examine how COVID-19 has affected this path and discuss what companies on the cusp of commercialization should be addressing
- Consider strategies for how companies responding to COVID-19 focus can focus both on COVID-19 related products and their existing pipeline

Edmund Pezalla, CEO and Founder, **Enlightenment Bioconsult**

Addressing Reimbursement Barriers for Cell and Gene Therapies

ON-DEMAND

- Discuss new models and frameworks for assessing cell and gene therapy value
- Explore how payors and health technology assessment bodies could adapt their processes to capture the benefit of transformative therapies

Yi (Louie) Lu, Ph.D., Sr Manager, Health Economist, Clinical Value and Rx Initiatives, Office of Clinical Affairs, **Blue Cross Blue Shield Association**

Mark Trusheim, Strategic Director, **NEWDIGS;** *Visiting Scientist, Sloan School of Management,* **Massachusetts Institute of Technology**

Sarah Pitluck, Head, Global Pricing & Reimbursement, **Spark Therapeutics**

Update on Achieving Biosimilars Uptake and Cost Savings Impact in the U.S.

ON-DEMAND

- Assess the impact of an influx of multiple biosimilars for a single indication on pressure on pricing
- Examine the status of financial incentives for physicians to start new patients on biosimilars
- Discuss payers' perception of safety and efficacy
- Explore the impact of increased education on Biosimilars for providers and patients through speaker programs, educational materials, patient support programs and hub services
- Review current status of patent defense limitations
- Compare the impact of fundamental differences in regulatory processes and market dynamics of EU versus U.S. uptake rates for Biosimilars

Interviewer:

Cathy Kelly, Senior Writer, **Pink Sheet and Scrip, Informa Pharma Intelligence**

Panelists:

Karina Abdallah, Pharm.D., Strategy and Outcomes, Medicare Advantage Pharmacy Services, **Blue Cross Blue Shield of Michigan**

Bhavesh Shah, Senior Director, Specialty Pharmacy Strategy and Market Access and Hematology Oncology Pharmacy, **Boston Medical Center Health System**

Chad Pettit, Executive Director, Marketing, Global Biosimilars Commercial Lead, **Amgen**

Regulatory Oversight of Diagnostics Beyond the Pandemic

ON-DEMAND

- Examine the current state of affairs regarding regulation of lab developed testing
- Discuss how the COVID-19 pandemic has illustrated some of the current dilemmas facing industry and what next steps could be taken as well as lessons learned
- Explore critical items most important for policymakers to keep in mind as the conversation continues to evolve regarding oversight of these tests

Eric Konnick, M.D., M.S., Assistant Professor; Associate Director, Genetics and Solid Tumors Laboratory, **University of Washington**

Jordan Laser, M.D., Medical Director, Pathology and Laboratory Medicine, Long Island Jewish Medical Center, **Northwell Health;** *Associate Professor, Donald and Barbara Zucker School of Medicine,* **Northwell/Hofstra**

Anthony Sireci, M.D., M.Sc., Vice President, Diagnostics Development and Medical Affairs, Loxo Oncology, **Loxo Oncology at Lilly**

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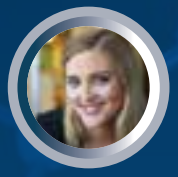

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