Report
Consumers United for Evidence-based Healthcare (CUE)
Integration of the Consumer Voice: **From Research to Policy**
2015 CUE Annual Membership Meeting
July 24, 2015
8:30 am - 5:00 pm
Viller's Conference Center
Families USA Headquarters
1201 New York Avenue NW, Washington DC 20005

A. Executive Summary

CUE hosted its 12th CUE Annual Membership Meeting entitled, "Integration of the Consumer Voice: From Research to Policy", on July 24th, 2015 in Washington DC (see Appendix A for Membership List). The gathering of CUE advocates was stimulating, according to many personal reports and post-meeting discussions with the Steering Committee (the Planning Committee for the event). CUE members, researchers, policymakers and funders networked, listened to and gave presentations, and participated in lively discussions, all with the aim of building the leadership capacity of consumer advocates in the area of evidence-based healthcare (EBHC). Forty-three people attended the event.

Preparations for the meeting began in January 2015 as CUE Planning Committee members elected to follow a format that took participants through all the stages of EBHC, from research to implementation and policy formation. The event comprised four panel sessions (3-4 speakers each), one Keynote presentation, and a "film screening" of two of CUE's latest educational videos. Each speaker within a panel was allotted 12 to 15 minutes for his or her presentation. Each panel was allotted a 30 minute discussion period, involving questions posed by members of the audience from a microphone on the floor. This format was in response to past evaluation requests asking for more time for audience participation, and allowed maximum interaction of the audience with the speakers while staying within a scheduled time frame and keeping the questions focused.

Panels included both CUE members and outside speakers, allowing for a rich exchange of ideas and perspectives (see Appendix B for Agenda). The Keynote speaker was *Dr. Lori Wilson*, a Surgical Oncologist at Howard University Hospital. She was also featured on the "Emperor of All Maladies", a PBS documentary that aired earlier in 2015. Her talk was entitled, *"Precision Medicine": What Should Patients and Consumer Advocates Expect?* The first panel topic of the day, *Ensuring that Research is Rigorous and Reduces Waste*, included **Dr. Steven Goodman**, Associate Dean of Clinical and Translational Research at Stanford School of Medicine and Co-founder of the Meta-research Innovation Center at Stanford (METRICS); **Dr. Mike Lauer**, Director of the Division of Cardiovascular Sciences at the National Heart, Lung, and Blood Institute (NHLBI) at the National Institutes of Health (NIH); **Ms. Lorraine Johnson**, Co-chair, CUE and CEO of Lymedisease.org; and **Dr. Deborah Zarin,** Director of ClinicalTrials.gov. Panelists for the second panel topic, *What is Needed for Consumers to Truly Engage in Research* **,** included **Dr. Peter Doshi**, Assistant Professor of Pharmaceutical Health Services Research at the University of Maryland School of Pharmacy and Associate Editor of *The BMJ*; **Dr. Lauren Ellis**, at Mathematica; and **Dr. Stephanie Chang**, at the Agency for Healthcare Research and Quality. The third panel topic, *Consumers Partnering to Develop Clinical Practice Guidelines*, included **Dr. Wendy Bennett**, Associate Professor Medicine at Johns Hopkins School of Medicine; **Ms. Marguerite Koster**,

Chair of Guidelines International Network (G-I-N) North America and Practice Leader at the Evidence-based Medicine Services Unit, Kaiser Permanente Southern California; and **Dr. Carol Sakala**, Director of Childbirth Connection Programs of the National Partnership for Women & Families. The final panel topic of the day was entitled *Evidence-based Federal Policy: Is Congress Letting it Happen as it Should?* Panelists included **Dr. Maureen Spill**, a nutritionist at the Center of Policy and Promotion, US Department of Agriculture; **Ms. Jessica Black**, Director of Kids' Safe and Healthful Foods, Pew Charitable Trusts; **Dr. Vince Cogliano**, Director of the Integrated Risk Information System (IRIS) Program, Environmental Protection Agency (EPA); and **Mr. Paul Brown**, Government Relations Manager of the National Center for Health Research. Full speaker biosketches can be found in Appendix C. Audio slidecasts of all presentations and discussion periods are posted on the CUE YouTube page at https://www.youtube.com/channel/UChL0coVlLNb9uH5dOwN5iAQ

It is because of the R13 Large Conference Grant provided by the Agency for Healthcare Research and Quality (AHRQ), that this Annual Meeting was able to take place. We were able to supplement the funds provided by AHRQ to allow breakfast, snacks, beverages, and lunch to be served to participants.

The goal of the CUE Annual Membership Meeting continues to be the development of a strong and sustainable network of informed consumer advocates. Post-meeting discussions with the CUE Steering Committee highlighted the excellent roster of speakers.

The meeting evaluations and post-meeting communication with participants provide strong support for our conclusion that the knowledge and experience gained at the meeting contributes to consumer leadership in EBHC advocacy.

B. Detailed Report of Annual Meeting

To begin the meeting, CUE Steering Committee co-chair, Lorraine Johnson, and Director of Cochrane United States, Kay Dickersin, provided a brief welcome and introductions. For the benefit of new members and guests at the Meeting, Reva Datar, CUE Coordinator, started her presentation with a brief overview of CUE's mission and activities. She then presented an update of CUE accomplishments since the 2014 CUE Annual Membership Meeting. This included acknowledgement of the existing support received from AHRQ for CUE conferences and CUE's application to AHRQ for another R13 Large Conference Grant for 2016-2019. Ms. Datar also informed participants of new members that had joined CUE since the last annual meeting and provided an update on CUE's latest partnerships with guideline networks through CUE's Clearinghouse. CUE members were encouraged to answer the call to serve as consumer representatives on guidelines panels, advisory boards, workshops and in other capacities. Invitations that come to CUE and are distributed to the membership are considered CUE clearinghouse activities. In addition, invitations to CUE members to partner with other organizations because they are a member of CUE are also considered clearinghouse activities.

Panel Discussion I: Ensuring that Research is Rigorous and Reduces Waste

Chair: Coco Jervis, Program Director of the National Women's Health Network (NWHN). Ms. Jervis introduced herself and her organization, and provided a primer for the panel topic by discussing one of NWHN's major goals: to ensure that women have all available information about the various drugs and devices that are used and marketed to them. She highlighted the fact that the panel would not only

focus on quality of evidence in terms of research methods, but would also examine issues relating to patient privacy, data sources, and the legal requirements versus the practical applications of data sharing and reporting**.**

What Makes a Research Study "Good"?
Steven Goodman, MD, MHS, PhD

Dr. Goodman emphasized that the first thing that makes a study "good" is that it answers a scientific question relevant to a health decision a consumer might make. A good question has five components; patients, intervention, comparison, outcome measurements, timing of measurements, and the setting (PICOTS). His presentation included several examples in which the question the investigators imply is not actually the question they operationally asked; as a result, consumers need to look closely at the methods to figure that out. Dr. Goodman went on to discuss several dimensions of research quality. First, did the researchers in a study measure all the outcomes patients care about, such as one's ability to perform certain tasks or freedom from serious side effects. Second, does the study design separate the effects of an intervention from other factors (e.g., "confounders") whose effects we are not interested in? Third, was the study run well? Fourth is how big is the effect in absolute terms, how uncertain are we about the effect size, and what do the authors conclude and recommend? Do they report study limitations and meaningfully discuss them? Do they put the study in the context of prior research and explain how this study is strengthened or weakened by prior evidence? Fifth, are there notable conflicts of interest? Finally, is the effect likely to be achievable in the "real world"? Dr. Goodman encouraged participants to think critically about research results and the methods used to reach them. Judging a "good" study is similar to judging a good meal; we often get more agreement on the technical quality of the cooking than the appeal of the food.

Novel data sources for use in intervention studies
Michael Lauer, MD

Dr. Lauer began his talk with a brief anecdote regarding Kodak film and the rise of the digital camera. The Kodak Company was virtually put out of business with the introduction and use of the digital camera, an innovative technology that the film company initially decided not to implement. Dr. Lauer argued that clinical trials similarly need to take advantage of innovative technology, using the electronic health record to rethink and improve how trials are conducted. The randomized clinical trial (RCT) is one of the most powerful tools available for the development and assessment of medical interventions. Unfortunately, randomized trials, and in particular later Phase III RCTs, have become increasingly, some would say prohibitively, expensive. Dr. Lauer asserted that one reason for this is because trials are conducted in a "parallel universe", separate from the sphere of clinical care. All baseline data and follow-up data are collected completely independently of all other activities. Recently, some investigators have developed methods of leveraging existing data and using those data as a platform for conducting RCTs: these platforms include professional registries, electronic health records, and claims files. Dr. Lauer believes that these novel approaches promise to make possible a whole new generation of low-cost, high-impact, large-scale intervention trials that will inform and improve clinical care.

Patient-powered Research Registries: Hype or Hope?
Lorraine Johnson, JD

Ms. Johnson began her presentation by describing her recent involvement with PCORNet, the Patient Centered Outcomes Research Institute's (PCORI's) big data project on patient-powered research. Patient-powered research is driven by patients and holds their interests as central to all that is done. Ms. Johnson explained that many technological and sociological factors today combine to allow patient powered research projects to take the helm at seeking solutions to the medical problems that impact patient lives. The technological forces that fuel these changes include computer advancements that allow big data research, which draws upon the 3Vs: volume (vast data pools), velocity (quick research), and variety (types of data). In addition to being able to compile and analyze individual medical data on a large scale, these advances allow research to extend beyond academia and reach patient organizations, which would facilitate both patient engagement and consent. In specifically exploring the benefits of patient-powered registries, Dr. Johnson posited that patient registries permit studies enrolling heterogeneous patient populations, evaluate care as it is actually provided in real world practice; assess complex treatment patterns and treatment combinations; and allow patient outcomes to be evaluated when clinical trials are not practical or are difficult to conduct (e.g., very long-term outcomes are desired). As Ms. Johnson has had personal experience as a Lyme disease patient, the idea of patient-powered research was largely examined in the context of Lyme disease. Patient registries provide critical information about patients with a disease that is not easily attained through RCTs, and open a space for a broader collaborative research community that may enhance the ability to conduct randomized controlled trials and foster a more patient centric research culture. This talk also discussed the launch of My Lyme Data, a project of LymeDisease.org.

What the Law Requires versus What is Actually Being Done at ClincialTrials.gov
Deborah Zarin, MD

Dr. Zarin discussed the current status of efforts to enhance information about clinical trials at ClinicalTrials.gov, which aims to provide a searchable, structured, and curated registry of trial information. Current reviews and meta-analyses that use data from clinical trials are subject to problems associated with selective publication, missing trials and selective outcome measures. In briefly reviewing the successes and benefits of the trial registry, Dr. Zarin explained that ClinicalTrials.gov improves the scientific integrity of trial reporting and will help potential patients get involved in future trials. It also allows research ethics review boards to determine the appropriateness of studies under review. Dr. Zarin cited an article in PLoS Medicine stating that, "Trial results, especially serious adverse events, are more completely reported at ClinicalTrials.gov than in the published article" (Tang, et al.) However, there is ongoing skepticism about trial registration, even among journal editors. In addition, practical execution of registration engenders a variety of challenges. Culture, rules, and regulations in research need to change to bring about universal trial registration and universal summary results reporting. Dr. Zarin asserted that trial sponsors still have room to improve and that they need to make more of an effort to make meta-data available in a manner that is transparent and linked to ClinicalTrials.gov. The presentation concluded with Dr. Zarin proposing that rules for trial registration be better enforced and adhered to by researchers and trialists. It is a scientific and ethical imperative to ensure full and timely

reporting the methods used and results attained from all human experiments.

Panel Discussion II: What is needed for consumers to truly engage in research?

Chair: Jane Chang, Engagement Officer of Health and Environment Program, National Environmental Education Foundation (NEEF). Ms. Chang introduced NEEF as an organization that works with pediatric healthcare providers on guideline-based healthcare and that is trying to create a demand for guideline-based care. She expressed the high value NEEF places on the consumer perspective and recognized the consumer role in research.

How CUE can more systematically engage lay journalists
Peter Doshi, PhD

Dr. Doshi began with an update on "open data". While all stakeholders seem to approve of the idea of open data, we actually have a patchwork of data "owners" with different policies, different levels of data from different trials with different terms on access and use. A group of 85 asset managers and pension funds is teaming up with AllTrials Campaign to put pressure on drug makers to disclose clinical trial data. Evidence-based healthcare teaches us to be skeptical, to question the hype and spin present everywhere from peer-reviewed scientific articles to the lay press. Journalistic professionalism teaches objectivity, speaking truth to power, and to serve the public (not private) interest. These values mean that EBHC and lay journalism are – or at least should be – natural allies. Unfortunately much of healthcare journalism fails us with stories that are uncritical, unbalanced, and incomplete, not providing the information the public needs to make better decisions. CUE members' commitment to Evidence-based Healthcare means that CUE is ideally placed to be a critical and constructive voice in improving lay health journalism. Cultivating relationships with reporters, keeping them accountable, and leveraging techniques from news watchdogs are all valuable ways to put selective pressure on journalists to uphold their professional values—as well as keep one's own constituencies well informed.

Has PCORI's requirement to engage patients in research worked?
Lauren (Lee-Lee) Ellis, MA, PhD

Despite growing interest in patient engagement, there is limited empirical evidence on the nature and effects of engaging patients as active partners in research. To better understand how patients were engaged in research funded by the Patient-Centered Outcomes Research Institute (PCORI) and the effects of such engagement, we conducted qualitative interviews with PCORI-funded investigators and with patients engaged in these investigators' projects. Investigators reported multiple reasons for engaging patients in their projects including to enhance the relevance and feasibility of the research and to improve the dissemination of findings. A variety of approaches were used to engage patients including the use of patient advisory groups, patient focus groups/interviews, and patient co-investigators or patient research team members. Investigators and patients reported that patient engagement impacted the relevance, feasibility, acceptability, and quality of the research. A number of challenges to engagement were also reported including challenges to organizing engagement activities and challenges to selecting, orienting, and interacting with patients. These findings suggest that patient engagement can have valuable impacts on research, especially with regard to the relevance of the research to patients. Modifications to institutional policies, the development of programs and researcher networks, and the provision of

resources and training are key actions needed to address challenges to engagement identified in this study. While more research is needed to evaluate the effects of engagement, these findings offer insights into the kinds of influence that engagement can have on the research process.

How AHRQ will fulfill the Affordable Care Act directive on dissemination and implementation of PCOR findings

Stephanie Chang, MD

This session will review the mandate to AHRQ as described in Section 937 of the ACA, which directs that "AHRQ, in consultation with NIH, shall broadly disseminate the research findings that are published by [the Patient-centered Outcomes Research Institute] PCORI… and other government research relevant to comparative clinical effectiveness research." This session will describe the framework that AHRQ proposes to use to solicit and receive nominations of patient-centered outcomes research (PCOR) findings, the process and criteria by which these nominations will be evaluated, and potential approaches for dissemination and implementation. The goal of this effort will be to disseminate and implement research findings in order to improve patient-centered outcomes. Nominations of PCOR findings for dissemination and implementation will be welcome from all, and AHRQ will specifically solicit nominations from PCORI and other federal research funders, as directed by the ACA, as well as professional societies and healthcare implementation stakeholders. Nominations will be evaluated on the strength of the evidence, the potential impact of the dissemination or implementation of the finding, and the suitability for dissemination and implementation. Dissemination and implementation efforts may be targeted or comprehensive.

Keynote Presentation: "Precision medicine": What should patients and consumer advocates expect?

Lori Wilson, MD

To Dr. Wilson, what precision medicine promises is innovation and a change in the paradigm that we have applied to prevention, screening, diagnostics and treatment. As a surgical oncologist and clinician scientist, precision medicine has been central to her understanding of cancer--clarifying the complexities of the disease so we better understand how it applies to the individual. As a cancer patient, Dr. Wilson quickly became aware that precision medicine can provide understanding without clarity. As her own genetic testing demonstrated a variant of unknown significance, she struggled with how it fit into her individual treatment plan. Results such as variant of unknown significance can be perceived many ways, this is one of the gaps that we need to bridge. The oncology community has made great strides in understanding genetic variations that make us who we are and genetic changes leading to more effective treatment strategies. I dream of a time when precision medicine is embraced by all patients and clinicians and provides affordable personalized care for the individual. Future and ongoing efforts to understand the role of research, partnerships, community engagement and advocacy are necessary to improve outcomes and current disparities.

Panel Discussion III: Consumers partnering to develop clinical practice guidelines

Chair: Caitlin Morris, Steering Committee, CUE; Program Director for Health System Transformation, Families USA. Ms. Morris described Families USA as a national consumer advocacy group that works with a diverse number of state-level organizations. Families USA focuses on advocating for priority populations, primarily those populations in need of Medicaid. As her particular team focuses on payment and delivery reform, she was pleased to be chairing a panel that focused on a portion of healthcare that serves as a link between research and policy formation. Payers are increasingly reliant on clinical practice guidelines (CPGs) to help them decide what to cover, and as we hope to create a more patient-centered health system, patient involvement in guideline development is absolutely essential.

Engaging patients to prioritize Kaiser Permanente's clinical practice guidelines
Wendy Bennett, MD

The goal of Dr. Bennett's research is to improve the methods for assuring study questions, outcomes, and interventions are meaningful to patients, caregivers and other stakeholders with multiple chronic conditions (MCCs). Having recently begun this study at Johns Hopkins University, Dr. Bennett shared with participants some of the preliminary data that her team has collected. Dr. Cynthia Boyd, the Principal Investigator of the study, and her research team have translated the knowledge from systematic reviews into guidelines that are more relevant for patient-centered care for people with MCCs. Much of the existing health care (and research and evidence that guides health care) is disease, or organ system-based. Yet, most people with one chronic condition actually have multiple, and care that focuses on one condition, or one problem, at a time, is by definition not patient-centered. Patient-centered care seeks to combine the best available scientific evidence on the magnitude of the effects of treatment with individual characteristics (which influence individual risks of outcomes) and preferences for specific outcomes. However, addressing the needs of people with MCCs is challenging given our current evidence-based medicine processes and methods. Dr. Bennett and her stakeholder co-investigators have been engaging people with MCCs from Kaiser Permanente-Colorado and the Kaiser Permanente's National Guideline Program to identify important clinical questions and outcomes. In the 2nd phase of the project, the team will refine methods of evidence synthesis for people with MCCs using innovative, stakeholder-informed approaches for evidence synthesis and multi-dimensional benefit harm assessment. Ultimately, Dr. Bennett hopes that the research will inform the process for creating trustworthy and rigorous guidelines that address patient-centered care for people with MCCs.

How can we ensure that guideline panels truly engage consumers?
Marguerite A. Koster, MA, MFT

Since the publication of the Institute of Medicine's 2011 report on "Developing Trustworthy Clinical Practice Guidelines," involvement of patients and/or consumer representatives has been seen as a critical step in ensuring the "trustworthiness" of Clinical Practice Guidelines (CPGs). While a number of prominent guideline organizations have included patients/consumers on CPG panels, some for many years, other organizations have yet to do so. Ms. Koster provided a brief overview of the key barriers to patient/consumer involvement in guideline development, particularly among United States' medical

specialty societies and healthcare organizations. Specific barriers cited by Ms. Koster include the fact that patient/consumer involvement is not a current requirement in the NGC Inclusion Criteria, the lack of resources to incorporate consumers into guideline development (e.g., structure, training, and cost), and a minimal awareness of CUE among guideline developers. She went on to address current and future efforts of groups such as the Guidelines International Network (G-I-N) and its regional community, G-I-N/North America, to educate guideline developers on the successful processes and roles of patient/consumer involvement and facilitate engagement with organizations such as Consumers United for Evidence-based Healthcare (CUE). Ms. Koster proposed that CUE and other patient/consumer groups lobby for their inclusion in NGC criteria, laying out specific strategies to best involve patients/consumers in guideline development. Other efforts to be made include proactively reaching out to guideline developers to offer consultation on including consumers on guideline panels, and fostering active partnerships in G-I-N/NA, AHRQ, PCORI and other initiatives/events. Finally, Ms. Koster discussed opportunities for CUE and its member organizations to engage guideline developers, encouraging CUE members to undertake the strategies she proposed earlier in the presentation (See section D).

Consumer Involvement in Clinical Practice Guidelines: The View from G-I-N PUBLIC
Carol Sakala, PhD, MSPH

In line with Ms. Koster's presentation, Dr. Sakala first described *Clinical Practice Guidelines We Can Trust,* the 2011 report from the Institute of Medicine (now National Academy of Medicine), explaining its recommendation for patient and public involvement through participation on guideline development groups and implementation strategies targeting all groups affected by guidelines. G-I-N PUBLIC, the Patient and Public Involvement Working Group of Guidelines International Network, has created a toolkit to help developers and disseminators of clinical practice guidelines involve consumers in all phases of the guideline development and use cycle. Dr. Sakala shared G-I-N PUBLIC's perspectives on consumer involvement in guidelines, highlighting that guideline developers need guidance for patient and public involvement, have specific needs, and still face many barriers. Within G-I-N PUBLIC's framework of consultation, participation, and communication, Dr. Sakala emphasized the importance given to consumer participation on guideline development groups. CUE members and conference participants were encouraged to advocate that all US-based guideline developers understand the standard for consumer involvement in guidelines, use the G-I-N PUBLIC Toolkit as a resource for implementing this standard, and recognize that CUE helps identify consumers who can contribute to guideline development and implementation.

Panel Discussion IV: Evidence-based federal policy: Is Congress letting it happen as it should?
US Department of Agriculture (USDA): An evidence-based approach to dietary guidelines
Maureen Spill

Dr. Spill first explained that the USDA Center for Nutrition Policy and Promotion (CNPP) works to improve the health and well-being of Americans by developing and promoting dietary guidance that links scientific research to the nutrition needs of consumers. Systematic reviews serve as a primary source of evidence used to inform dietary guidance. The Nutrition Evidence Library (NEL) has developed

systematic review methods appropriate to nutrition and policy research and has strengthened these methods over the years as systematic review methodology has advanced. At present, NEL methodology uses the following steps: (1) Topic identification & question development; (2) Search, screen, and select studies to review; (3) Extract data and assess the risk of bias of the research; (4) Describe and synthesize the evidence; (5) Develop conclusion statements and grade the evidence; and (6) Identify research recommendations. This process allows for nutrition and public health research to be reviewed and synthesized through a rigorous, transparent approach that minimizes bias. Dr. Spill highlighted that there are also opportunities to include consumers in stakeholder groups and allow for more public comment periods.

US Department of Agriculture (USDA): Politics and evidence
Jessica Black, RD, MPH

Ms. Black began her presentation by stating that the USDA is at the core of most US food policy. From co-leading the development of the Dietary Guidelines for Americans with the Department of Health and Human Services to setting nutrition standards for food programs such as The National School Lunch program and the Child and Adult Care Food Program, USDA has significant opportunity to impact American diets. Ms. Black discussed the public controversy regarding some of the USDA Dietary Guideline policies, and how can science help to resolve the conflicts and lead to the most effective outcomes. Recent updates to the dietary guidelines, based on scientific evidence, include an increased emphasis on and inclusion of quantity and variety of fruits and vegetables, a reduction in consumed sodium, saturated fat and trans fats, a requirement for additional whole grains, and promotion for nutrients of concern like calcium and potassium. Due to the vast impacts of dietary guidelines on schools, manufacturers, and society in general, science and its policy implications are extremely vulnerable. Ms. Black explained that there have been proposals in both the House and Senate that would limit the authority of the USDA to update the guidelines, unless evidence was produced with Grade 1 level science (while most pieces of evidence are moderate-level guidance).

Environmental Protection Agency/Integrated Risk Information System: An evidence-based approach for environmental health hazards
Vince Cogliano, PhD

The EPA's IRIS program supports the Agency's mission to protect human health and the environment by developing authoritative information on how chemicals in the environment can affect human health. IRIS assessments identify the adverse health outcomes of chemicals and characterize relationships between exposure and response. The EPA and other health agencies use IRIS assessments to support public-health actions to prevent or reduce exposure to harmful chemicals. The IRIS program stays focused on the science, separate from political, economic, and technical considerations that also have a role in public-health decisions. The IRIS program has embraced and is implementing systematic review. IRIS assessments, however, cover topics outside the realm of systematic review, including analyzing mechanistic information and modeling exposure-response relationships. The IRIS program brings structure and reproducibility to these areas by applying principles of systematic review. A notable feature of the IRIS program is its transparent and inclusive involvement of the public and the scientific community--including experts identified by the National Academy of Sciences. Then IRIS assessments receive a rigorous, independent peer review in a public forum. These elements--systematic processes,

involvement of the broad scientific community, and rigorous public peer review--keep IRIS assessments focused on the science. This abstract does not necessarily represent the views or policies of the U.S. Environmental Protection Agency.

The Food and Drug Administration (FDA): 21st Century Cures. What CUE needs to know and actions to take
Paul Brown

Mr. Brown stated purpose of the 21st Century Cures Act; "To accelerate the discovery, development, and delivery of 21st century cures." However, he noted, numerous nonprofit organizations from the Patient, Consumer, and Public Health Coalition question how lowering standards for medical products will result in improved cures and healthcare treatments. As more and more respected consumer advocates, scientists and public health researchers closely examine the 350+ page Act, they are expressing dire warnings that this bill endangers patients' health. Nationally respected cardiologists Rita F. Redberg and Sanket S Dhruva said the bill would "subject millions of Americans to unsafe and untested medical devices." Former FDA Commissioner, HIV/AIDS activists, and many others agree. Mr. Brown explained that the House bill was sold by offering an extra $8.75 billion for NIH and that promotion for the bill is heavy on emotional appeals and light on evidence. It features stories and anecdotes about how the Act will save the lives of children with terminal illnesses. What's not mentioned is that the Act lowers the FDA's standards of evidence for all treatments, whether urgently needed or not. And the NIH funding helped encourage university researchers across the country to support the bill, especially those who are not focused on FDA approval standards. The Senate is currently working on its version of the bill. Mr. Brown urged CUE members to take this opportunity to persuade their Senators that their bill strongly safeguards evidence-based FDA approval policies and that efforts to undermine those safeguards in the House bill should be rejected.

C. Summary of Recommendations made in presentations

Table 1: Recommendations and Resources provided by CUE Annual Meeting Speakers

Title of Talk	Speaker	Recommendations for CUE	Resources for Consumer Advocates
What makes a research study "good"?	Steven Goodman	• When evaluating research 'evidence', consumers should check that researchers used proper methods and measured all patient-important outcomes	http://www.healthnewsreview.org/ http://metrics.stanford.edu/ METRICS Conference 2015
Novel data sources for use in intervention studies	Mike Lauer		*The Innovator's Dilemma* by Clayton Christenson *The Creative Destruction of Medicine* by Eric Topol *The Patient Will See You Now* by Eric Topol http://sites.duke.edu/rethinkingclinicaltrials/
Patient-powered research registries: Hype or hope?	Lorraine Johnson	• Consumer advocates can consider getting involved in	My Lyme Data

		patient registries as potential tools for future clinical trials	https://www.lymedisease.org/
What the law requires versus what is actually being done at ClincialTrials.gov	Deborah Zarin	• CUE should continue to advocate for open data sharing by researchers and trialists on ClinicalTrials.gov	https://clinicaltrials.gov/
How CUE can more systematically engage lay journalists	Peter Doshi	• CUE should become the critical voice in improving lay health journalism • CUE and CUE members should develop relationships with reporters and hold them accountable • CUE should establish itself as a group that brings key, evidence-based information to the attention of journalists	http://www.healthnewsreview.org/ 21st Century Cures: Is US medicines bill a colossal mistake? http://www.opensecrets.org/
Has PCORI's requirement to engage patients in research worked?	Lee-Lee Ellis	• Let researchers and guideline developers know about the challenges to patient engagement • CUE can provide solutions to many of these challenges by acting as a resource for researchers/scientists and consumers	Patient and Stakeholder Engagement in the PCORI Pilot Projects: Description and Lessons Learned
How AHRQ will fulfill the Affordable Care Act directive on dissemination and implementation of PCOR findings	Stephanie Chang		Department of Health and Human Services FOA to PCORI
"Precision medicine": What should patients and consumer advocates expect?	Lori Wilson	• CUE should focus on the current disparities among consumer groups and empower them with more opportunities to advocate and engage in health research	Cancer: The Emperor of All Maladies PBS Special
Engaging patients to prioritize Kaiser Permanente's clinical practice guidelines	Wendy Bennett		Treating an Illness Is One Thing. What About a Patient With Many? Transparency Matters: Kaiser Permantente's National Guideline Program Methodological Processes
How can we ensure that guideline panels truly engage consumers?	Marguerite Koster	• Consumer advocates should find new ways to make guideline developers more aware of CUE, emphasizing the need for trained consumer representatives on panels.	Institute of Medicine- Clinical Practice Guidelines We Can Trust

		• CUE & G-I-N/NA partnership (e.g., CUE working on a white paper w G-I-N) • CUE should engage with other groups that also bring consumers and guideline developers together • CUE should lobby for inclusion of patient/consumer involvement in NGC criteria	National Guidelines Clearinghouse Criteria Guidelines International Network North America
Consumer Involvement in Clinical Practice Guidelines: The View from G-I-N PUBLIC	Carol Sakala	• CUE should impress upon the Guideline entities in this country to improve their methods of involving consumers and patients	G-I-N PUBLIC Toolkit
US Department of Agriculture (USDA): An evidence-based approach to dietary guidelines	Maureen Spill	• CUE and NEL should work together to include more consumers in reviews and public comment periods	Dietary Guidelines for Americans Nutrition Evidence Library
US Department of Agriculture (USDA): Politics and evidence	Jessica Black		www.healthyschoolfoodsnow.org
Environmental Protection Agency/Integrated Risk Information System: An evidence-based approach for environmental health hazards	Vince Cogliano		http://www.epa.gov/iris/ IRIS Assessment Status
The Food and Drug Administration (FDA): 21st Century Cures. What CUE needs to know and actions to take	Paul Brown	• CUE members can contact their Senators to demand evidence-based FDA approval policies • CUE members can join the Center for Research Action Alert List to stay updated on the on goings of the bill	http://energycommerce.house.gov/cures

D. Summary of Conference Participant Evaluations

The 2015 CUE Annual Meeting brought together a diverse group of informed consumer advocates, comprising scientists, consumers, patients, and policy partners, for a day of high level discussion and shared learning. Post-meeting participant evaluations provided feedback on the knowledge gained as well as the participants' overall experience.

Cochrane United States staff members encouraged the 43 individuals who attended the Meeting to complete a written evaluation of their experience. Each individual was given a survey instrument (see Appendix D) consisting mainly of questions measured on a five-point Likert scale.

Twenty six participants returned the evaluation, although not all respondents answered all questions. All speakers at the meeting were rated positively. Evaluation scores and comments revealed that respondents were overwhelmingly positive about most sessions; mean respondent scores greater than '4' on a scale of 1 to 5, where '5' was the highest score, were considered to be 'positive'. Mean scores did not fall below '4' for any of the presentations. The two highest scoring presentations were, "What makes a research study 'good'" and "How can we ensure that guideline panels truly engage consumers?"

Open-ended comments were given by five respondents, all of which indicated overall satisfaction. Participants expressed an appreciation for room set-up, session topics addressed, and panel discussions. The only suggestion given to improve future conferences included pushing for greater speaker diversity. All feedback will be considered when planning future meetings.

Table 2: 2015 CUE Annual Meeting Evaluations – Short Answer

Respondent	Comment
2	"This was an excellent meeting- the context was captivating and thought-provoking and informative, covering both research and policy"
3	"Made me think about how consumers are important and how I need to bring more of my work into this type of education and advocacy"
4	"I really enjoyed the day to listen to so many perspectives. It was really useful. Thank you for letting me attend".
6	"I really liked this CUE meeting. Lots of discussion. Great room set-up. Very informal and informative".
8	"Great panels, session after lunch ran a little long, needed one more break. Thank you! Interesting varying array of topics to keep audience engaged".
9	"Very informative panels and open discussion. Speakers were dynamic and encouraged dialog".
10	Really appreciate timely topics, e.g., 21st Century Cures
12	"Wish there were more diversity of race/ethnicity in panel speakers. I look to opportunities like this to expand my pool of experts that are relatable/diverse for the constituents I work with".
15	"Excellent topics-sessions"

E. Summary of 'Film Screening' Evaluations

Conference participants were shown two of CUE's latest "short-shorts" and given comment cards to evaluate each video's content and production quality (e.g., music, setting, cinematography). Content was evaluated on a Yes/No basis and quality was evaluated on a rating scale between 1 and 5 with '1' signifying very poor quality and '5' signifying extremely good quality. The evaluation also provided two comment sections for each video. The first of these comment sections specifically asked the participant to state which piece(s) of advice was/were the most memorable while the second asked the participant for any additional comments. Appendix E contains a copy of these comment cards.

Twenty participants returned their evaluation forms for these videos, although not all participants answered every question. Production quality for the videos were given a positive rating overall, with all quality sections in both videos receiving a mean score of '4'. Based on short-answer responses and evaluation scores, participants found the second video, "How to Successfully Contribute to a Guideline Panel", to be more appealing than the first video, "When you are asked to serve on an advisory panel".

Most participants felt that they did not learn anything new from either video, but that they did feel more motivated to get involved with advisory panels. On average, participants felt that the second video better prepared them to serve on a guideline panel than the first.

Seventeen participants provided short-answer responses. According to these responses, the most memorable pieces of advice were to be strategic and confident when contributing to a panel and to prepare for a guideline panel by reading all the provided materials. Comments suggested that while most participants found the production of the videos to be well done, the content (particularly of the first video), was not very informative. Other comments suggested that future videos include speakers with greater diversity of age, do a better job of "setting the stage" for each topic, and last slightly longer than just 3-4 minutes. Participants also commented that the videos looked professionally done, and that the summaries at the end of each were very helpful. When planning future meetings, all feedback will be considered.