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GHLF RESPONDS TO ICER

Omissions from Its Latest Claims

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Introduction

On August 9, 2016, The Institute for Clinical and Economic Review (ICER), released a report addressing "myths" about its organization. The document aimed to clarify "ICER's history, mission, and methods while re-emphasizing the important role patients play in all ICER value assessment reports." In our opinion, This version for printing is very nicely packaged misinformation with exceptional graphic design and well-chosen stock photographs. ICER's need to distribute a report clarifying its mission and methods immediately calls into question the legitimacy of its tagline that it is "a trusted organization".

The ICER-published fact sheet to address multiple "myths" failed to provide key pieces of information that the public is entitled to know. Without being fully transparent, how can the public trust the organization? Because more than half of insurance companies – including Express Scripts and Blue Shield of California – now base their drug coverage decisions on ICER's reports, it's alarming that there isn't any statutory oversight, fact-checking and worst of all, transparency within that process.

GHLF has developed this report, deliberately absent of any stock photography and purposely full of facts and corrections to the record, developed after combing through fact sheets, publicly available documents and public positions taken by ICER leadership. The aim of this report is to respectfully provide a complete picture of the motivation, process and ramifications of ICER so the public – especially the patients and their families who we represent – can understand the basis for ICER's actions and their consequences.

Disclosure: GHLF receives funding from pharmaceutical companies, private foundations such as the William and Flora Hewlett Foundation, and the U.S. Government-funded Patient Centered Outcomes Research Institute. But while we receive some educational funding from pharmaceutical companies, we do not recommend or evaluate drugs as ICER does. GHLF represents more than 100,000 people with all forms of arthritis through its 17-year-old robust online community CreakyJoints, co-founded by an arthritis patient from a dorm room bunk bed in 1999. CreakyJoints' member's lives have been permanently improved because of advances in therapy, and GHLF is intimately and personally aware of the uniqueness and importance of each life (and family) improved by those therapies. We respect our community too much to value their lives with a specific dollar amount or cap. Everyone deserves to be healthy for the full duration of their life.

Omissions from ICER's Claims

CLAIM: ICER claims it was founded in late 2006 as an "academic research project at Harvard." In its first three years, the largest source of funding for ICER came from unrestricted support from the National Pharmaceutical Council." This is a group of pharmaceutical companies.

OMISSION: However, in 2006, the year it claims it was launched, ICER received $430,000 in seed funding from one of the nation's largest insurers, the Blue Shield of California Foundation (BCSF). According to BSCF's website, it funded ICER, "to establish a new collaborative, the Institute for Clinical and Economic Review (ICER), and to develop, test, and firmly establish methods to produce authoritative appraisals integrating the clinical and cost-effectiveness of medical innovations for heal [sic]."

In addition, after ICER announced the scope of its funding on August 9, 2016, the National Pharmaceutical Council (NPC) released this statement:

> *"The National Pharmaceutical Council (NPC) takes exception to the Institute for Clinical and Economic Review's (ICER) continued portrayal of us as an organization that is supportive of ICER's value assessment process. To be clear, NPC's engagement with ICER is not an endorsement of that organization nor its value assessment framework.*
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> *We partner with a number of organizations because we believe that collaboration among stakeholders is important to fostering solutions to improving our health care system and patient outcomes. In fact, NPC has been a member of ICER since 2008, when it was focused on evidence synthesis and methods. Since then, ICER's mission, orientation and funding for new programs, such as value assessment frameworks, have changed significantly. Pointing to NPC's initial funding of ICER to rebut current and ongoing concerns regarding funding sources is not appropriate."*

CLAIM: "Today, ICER receives 70% of its funding from non-philanthropic foundations, the largest source being the Laura and John Arnold Foundation."

OMISSION: ICER received 77% of its disclosed 2013 funding from the insurance sector. This link to ICER's 2013 publicly available IRS-990 allows the public to understand its pro-insurance company motivation. Using words such as "today" and omitting phrases like "as we previously received funding from" diminishes trust of a nonprofit.

Additionally, ICER has established other funding sources such as the Laura and John Arnold Foundation to help offset insurance donations. Yet the insurance ties continue; the head of the LJAF's venture development team, Kelli Rhee, previously managed a venture capital fund for BlueCross BlueShield and said ICER's research would "help develop a fairer, more effective system" for drug pricing.

CLAIM: "We do not represent the interests of the insurance industry."

OMISSION: Eight of the nine directors listed on ICER's 2014 tax filing previously worked in the insurance industry. ICER has now added two board members to represent "the patient perspective," appointed in response to GHLF and other organization's identification that patient voices were and remain absent from the decision-making process.

Note: One of these new "patient perspective" members is known to "support longer clinical trials to slow down access to new medicines." Patient advocacy groups have asked for an even distribution of patient voices with diverse viewpoints among board members. This is necessary, as is an even distribution of board members from across all industry sectors.

Additionally, Steve Miller, CEO of Express Scripts – the nation's largest PBM – has praised ICER CEO Steven Pearson's work. Miller said Express Scripts would use Pearson's advice to evaluate cancer drug prices. Clearly, ICER's research has been and will continue to be used to help justify restricting access to potentially lifesaving drugs.

CLAIM: "Most of our reports have found that the list price of a new drug is too high for the amount of improvement it offers over other options, but some reports have found that the list price of new drugs can be well aligned with the added value for patients."

OMISSION: The bottom line is the "added value" for patients differs from patient to patient. What works for one patient simply may not work for another. **Less expensive drugs do not mean more effective medicine—they just mean larger profit margins for insurance companies.**

The discussion surrounding ethical and moral obligations is one that ICER largely chooses to ignore. Doctors take an oath to "do no harm," but they are hamstrung as a result of efforts to undo their medically necessary decisions. First and foremost: Is a patient safety-oriented organization supposed to advocate for getting rid of the drug rather than save the life? We fear that ICER's deductions have and will prompt insurers to remove vital medicines from their formularies. As a result, people are at risk of getting sicker, and some may even die.

It is not acceptable to do less when more can be done and the means exist to treat people. Patients have suffered irreversible damage as a result of ICER's determinations, such as Hepatitis C patients afflicted with liver damage before receiving treatment. Though this is mentioned later in ICER's report, it is omitted from this section.

CLAIM: "Patient input has been part of our methodology from the beginning. The ICER value framework was developed to facilitate discussion about value at the broader population level where pricing and coverage decisions are made, not to try to supplant the personalized decision-making that is critical for high quality patient care. But even though ICER value framework is applied at the population level by insurers, provider groups, and drug makers, its structure

reflects our belief that the assessment of value for all decision-makers should be grounded in what matters most to patients."

OMISSION: While ICER's "value framework" is not supposed to supplant the personal decision-making that is critical for high quality care – this is exactly what it does. Patients have been denied access and more patients will be denied access in the future. There has been a tectonic shift in the doctor-patient relationship — today insurers get to override the decisions of doctors, to the detriment of the patient and the frustration of the medical community. ICER can point to one report (their multiple myeloma findings), where patient-advocacy group and drug maker comments were respected.

NOTE: What matters most to patients is that they have access to the medications their doctors—not insurers—deem necessary. This is the story of a young man who was denied access to his much-needed ulcerative colitis medication, resulting in a colostomy at only 21 years old.

CLAIM: "The framework anchors judgements of value in the evidence on comparative effectiveness of treatment options, and explicitly acknowledges that patient guidance on the outcomes that matter most is critical to the assessment of value."

OMISSION: Dozens of patient advocacy groups have submitted comments regarding the potential ramifications of ICER's work. There is no statutory oversight of ICER and approval by patient groups is not necessary (or even solicited) for final reports. If 59% of insurance companies surveyed by Dymaxium say they have used at least one ICER report in coverage decisions, then 100% of those reports should have oversight by the public.

CLAIM: "From the very first day of our assessment process, which is over seven months long, we talk with patients and patient groups and offer multiple chances for informal input as well as formal written and oral comment on draft versions of our reports."

OMISSION: While ICER has allowed seven months for its research, until recently patient groups were given only two weeks. Now outside comment-taking has been extended to three weeks for life and death issues. There is no input permitted on final reports once the judgments are revealed and ramifications are realized. Giving patients a seat at the table, but omitting the fact that it's the kids table (set up in the living room), does not satisfy real and practical concerns.

CLAIM: "The QALY was developed by health economists and doctors in the United States and is now used throughout the world as the gold standard measure of how much better a treatment makes patients through extending life and/or improving the quality of life."

OMISSION: The QALY was ultimately found to be so offensive and contradictory to the beliefs surrounding patient care in the U.S. that its use in computations was disallowed (outlawed) by the Affordable Care Act. The ban on using cost-per-QALY thresholds also seems to reflect long-standing concerns that the approach would discriminate on the basis of age and disability. The worry is that the metric unfairly favors younger and healthier populations that have more potential QALYs to gain.

CLAIM: "The surveys and other tools that have been developed to measure quality of life as part of the QALY often assign a lower quality of life to serious conditions. In many ways this is logical and appropriate because we want to capture the downside for patients of serious side effects, like nerve damage or blindness, which might be caused by some treatments. But this approach has the potential to create an ethical dilemma. For treatments that extend life but do not improve quality of life, the amount of credit (i.e. additional QALYs) attributed to a treatment will depend in part on how sick patients are given their underlying condition. For example, most people would agree that three more months of life in good health is better than three more months of life in a coma, but this means that less benefit, as measured by QALYs, could be attributed to treatments that extend life for patients with serious conditions than to treatments that produce the same extension of life for patients with less serious conditions."

OMISSION: The right to decide who lives and dies, who suffers more and less and the meaning of "quality of life" has not been granted to ICER. Measuring people as less valuable because they are ill should not be the yardstick used to evaluate treatment. Those who are confronting "more serious conditions" are entitled to the same level of care as those who are not. In some cases, providing a higher level of care can reduce pain and possibly extend life as new innovations are introduced.

CLAIM: "Treatments that extend life but do not improve quality of life, the amount of credit (i.e. additional QALYs) attributed to a treatment will depend in part on how sick patients are given their underlying condition. ICER is aware of this possibility and we take several steps to address it. One way we minimize the potential effects is to select quality of life scores whenever possible from individuals who have the condition rather than asking people without the condition to judge "how bad" it would be to have that disease."

OMISSION: ICER is claiming that QALY is a good metric, but its use is flawed. ICER has now taken it upon itself to redefine QALY, which is unacceptable. Even if a patient starts his or her journey in a worse place from someone else, the improvement effect of a drug should not be discounted.

The use of QALY allows ICER to assign a lower quality of life value to patients with serious conditions. ICER's explanation does not take into account that it uses QALY to discriminate against people with debilitative health issues and devalue their lives. Simply put, QALY classifies people who are feeling pain from an illness and who struggle with daily activities as having less value. ICER now feels its job is to re-define QALY to make it tailor-made for its own benefit. Clearly, however, the use of QALY is a non-starter.

CLAIM: "ICER's value framework is anchored in the long-term perspective, with the cost-effectiveness of new drugs being evaluated using what is called the 'lifetime horizon' for patients."

OMISSION: Rather than acknowledge the ethical issues with QALY that ultimately prohibited its use in Obamacare, ICER continues to move forward with its self-appointed right to use it.

CLAIM: "The myth about short-term costs and arbitrary budget caps has arisen because ICER's value framework includes two components: the long-term "care value" based on the lifetime horizon as described above; and a secondary consideration of the potential budget impact over the first five years following a new drug's introduction."

OMISSION: ICER uses the QALY measurement here again as a benchmark while ignoring the fact that our lawmakers deemed QALY unacceptable for use relating to the Affordable Care Act (Obamacare). ICER's justification in this portion includes the following claim: "the incremental cost-effectiveness ratio, also often called the 'cost per QALY' that ICER economic models calculate, all use simulations of future years stretching out to the full lifetime of patients." Though ICER included this statement in its rebuttal, it fails to address the controversy of QALY's use in the first place.

CLAIM: "Some drug makers have claimed that considerations of affordability have no role in judging the value of new drugs, but we continue to believe that short-term affordability concerns are often an important influence on insurance coverage and increases to insurance premiums, and that patients and all other health care participants should have the chance to discuss mechanisms that will ensure we can afford to provide good access to new drugs with excellent long-term value."

OMISSION: ICER simply does not give priority to patient outcomes or survival. The prioritized outcome is *cost* rather than the value of human survival.

ICER has neglected to explain that "the chance to discuss mechanisms that will ensure we can afford to provide good access" refers to the "mechanism" of lower costs to insurers rather than the most effective medications for patients. As stated above, "short-term affordability concerns are often an important influence on insurance coverage."

CLAIM: "This is one of the more remarkable and malicious mischaracterizations of our intentions. If the shared hope is to be able to provide innovative drugs for all patients with serious illness, and to be able to also afford good education for our children and other services, then we believe that transparent discussions about whether prices for drugs and other health care services are reasonably aligned with the value they bring to patients are an important way to help us get there."

OMISSION: This claim stems from statements made by ICER's CEO, Steven Pearson. ICER claims there is wasteful spending on health care in the United States. But ICER is mischaracterizing the issue: life-saving medications are not wasteful spending – they are necessary spending. Even the drug makers who are responsible for the "development of new and effective drugs" are telling ICER that it is hindering progress.

ICER appears to feel that it is charged with deciding what a life is worth and how much to spend on people with debilitating, rare or fatal conditions. The sickest individuals, according to ICER's logic, must receive the least care because their quality of life is worth less. This is not the charge of any one person or organization. Doing this under the guise of "a conversation" is also a

nonstarter. Once we start putting values on life and health, we start devaluing everyone around us. In addition, though ICER claims it has never said it wanted to take money from patients in order to "fix potholes," below are statements it has made that suggest otherwise.

Text from Steven Pearson Video from 5/26/16: "Why we are here today" – Dr. Pearson underscores the moral vision of Midwest CEPAC (an ICER core program):

> *"This is a chart from an economist at Harvard that looked at state spending in the state of Massachusetts over a decade, and inflation-adjusted spending by the state for health care went up by 59% over that time period and the total was about an increase of $5.1 billion of inflation adjusted. Now you may ask where did that money come from, some of it did come from increased taxes, but where most of it came from was from decreases in state spending on public health, on mental health, on education, infrastructure and house, human services, local aid and public safety. This means fewer teachers, fewer policemen, fewer people again checking public health. This is part of the dialogue that our country needs to have. It's not just within health care but it's the fact that healthcare is a part of the societal choice that we make around how we try to provide benefits for all of our citizens and it is not easy. I think this is part of the reason that we are here today."*

Text from ICER's Frequently Asked Questions (FAQs) document on ICER website:

> *"Not paying for drugs based on the value they bring to the system often leads to waste that saddles our children and their children with future budget deficits based on our inability to objectively look at the evidence and value of new drugs. We're siphoning off resources for other things we need like better schools and more resources for local police, roads and bridges. Our reports will guide policymakers and health care stakeholders in their efforts to get excellent drugs to market quickly at a price that is affordable to patients and the health system, without hindering the development of new and effective drugs."*

CLAIM: "Insurers have always made—and will continue to make—coverage decisions that restrict access to innovative new drugs for some patients. These decisions tend to happen behind closed doors without full transparency in the review of evidence or the justification of the coverage policies. ICER reports seek to provide a common, openly available and trustworthy resource for patients and all participants in health care discussions about coverage policy."

OMISSION: ICER reports led to the denial of access to much needed medications. Major insurance companies and pharmacy benefit managers, including Blue Shield of California, CMS and Express Scripts, are using ICER's research to inform coverage decisions. The reports may not be the only factor used to deny coverage, but ICER information has become part of the decision-making process.

CLAIM: "As part of the policy roundtable discussion at the ICER meeting immediately following the introduction of the first new drug for hepatitis C, clinical experts suggested that the most feasible way to manage the large number of infected patients needing treatment was to prioritize treatment for those with more advanced disease. Many insurers, whether they referenced the ICER report or not, adopted early policies covering new medications only in patients who had some evidence of liver damage."

OMISSION: Evidence of liver damage means that it is too late for many with Hepatitis C. ICER's recommendations have empowered insurers to allow people to knowingly get sicker before they are helped. Lawmakers found this so morally offensive that there have been court cases to overturn ICER's judgements and the actions by insurers.

This year, New York Attorney General Eric Schneiderman sued Capital District Physician's Health Plan (CDPHP) for unlawfully restricting medical access for patients with chronic hepatitis, even though the drugs were shown to effectively treat the disease. The AG said CDPHP denied coverage unless patients demonstrated an "advanced" state of the disease, including moderate to severe liver scarring. Shortly afterwards, several additional insurers altered policies to cover treatment for chronic hepatitis C.

In Seattle, Washington, patients sued the Washington State Health Care Authority. The Plaintiffs were Washington Medicaid enrollees who contracted Hepatitis C ("HCV"), a chronic, contagious liver disease, but who had not received the life-altering medication they had been prescribed. As it progresses, HCV causes severe liver damage, among many other effects including heart attacks, diabetes, fatigue, joint and muscle pain, depression, nerve damage and jaundice. The virus's progressive damage, known as "fibrosis," is scored on an ascending fibrosis score of F0 (no liver damage) through F4 (cirrhosis of the liver). Though the disease is both widespread and deadly, WHCA was determining coverage based on the "fibrosis score." The judge in this case concluded that the WHCA was required to return to providing coverage for prescription medications to treat Hepatitis C virus ("HCV") without regard to fibrosis score, consistent with existing state and federal Medicaid requirements. A judge ultimately ordered the state to provide the lifesaving hepatitis C drugs for all Medicaid enrollees.

CLAIM: "On the other hand, ICER's meeting on new treatments for patients with multiple myeloma included a policy roundtable discussion in which major insurers noted that they did NOT feel that the nature of the condition and the available evidence supported the idea of patients being required to try less expensive drugs and "failing first" before being granted coverage for more expensive options. This policy perspective was included as one of the primary messages of the final ICER report."

OMISSION: ICER does not address its own description above regarding the policy of "failing first." Patient advocacy groups have been working to engage ICER on the belief that patients should not be required to risk their lives and wellbeing to "fail first" on a medication before being provided the medications that their doctor originally prescribed in order to thrive or recover. Patients, doctors and others who fight for patients look toward a "succeed first" policy. Additionally, ICER failed to reveal the tone and tenor of the responses from drug makers. This

wasn't merely overwhelmingly negative—drug makers pointed out flaws in ICER cost-benefit analysis and expressed grave concern.

- *Bristol-Myers Squibb:* "While assessments of cost-effectiveness may prove useful in comparing treatments, they have significant limitations, and the lack of available mature data sources preclude the drawing of valid conclusions. Therefore, these assessments should not be used for decision-making that determines access to innovative medicines. As a company focused on improving the lives of patients worldwide, Bristol-Myers Squibb actively encourages the healthcare community to join us in advocating for keeping treatment decisions where they ultimately and rightfully belong—between a patient and his or her healthcare team."

- *Takeda:* "We think this effort in its current form fails the test of "first, do no harm". ICER adopted the narrow payer perspective for its analysis. This methodology forgot the patients and excluded both the costs and benefits to patients, caregivers and society that are invisible to payers. Hence, time spent in the hospital or doctor's office to get care, convenience of administration, impact of rare but significant adverse events, cost of missing work or benefits of spending more time with family, to name a few, have all been ignored in this analysis. While the benefits of this analysis are uncertain, outside of a narrow payer perspective, the potential for harm is very concerning. We urge ICER to first do no harm. Harm patients by restricting their access, harm research by demotivating it and harm society by stating that new advances are not worth the cost. ICER should spend more time talking to patients, their caregivers, nurses and doctors and collect more real-life data before concluding on the value of anti-multiple myeloma medicines.

- *Amgen:* "Given the stakes for patients, Amgen believes that all economic reviews on the value of medicines should aim to achieve the highest level of transparency, strive for very broad stakeholder engagement, and place scientific rigor and patient interests at the center of the analysis. Some of these technology assessments, however, express results in terms of dollars per quality-adjusted life-years (QALYs) gained relative to specific threshold values (cost-effectiveness), or in terms of payer budget impact. Amgen believes that thorough and balanced assessments should rely on direct data from rigorous comparative trials when available rather than using opaque methods to combine multiple, disparate trials to arrive at different estimates of efficacy, or make assumptions to create unrealistic "worst-case" scenarios. Results produced by independent organizations should be informed by experts, made fully transparent and available, and undergo complete and independent peer-review."

- *Novartis:* "ICER's pricing recommendations in the draft report are not based on ENTRESTO's long-term value and the cost-effectiveness analysis. The draft price benchmark is based on short-term budget impact and costs without accounting for full patient outcomes."

CLAIM: "ICER's purpose is to stimulate a public discussion of these questions and we do not believe that the right answer is to restrict access to innovative medicines for patients who are

likely to benefit. Patients already suffer restrictions to access when drug prices are too high for them to afford, and our goal is to provide a way to get to a "win-win-win" outcome where price is aligned with value, access is broad, clinical use targeted and appropriate, and new investments in future innovation assured."

OMISSION: The "win-win" for patients is to have access to their medication no matter the cost and no matter the state of their illness. ICER "aligns price with value" without concern for the individuals. The true value is in halting the progress of a debilitating disease and/or saving a life. Insurers are now usurping the role of your doctor and the FDA. We should be celebrating and employing innovative treatments, not fearing them. ICER "member" CVS/CVS Caremark, the second largest pharmacy benefit manager (PBM) in the United States, announced on August 2, 2016, the removal of 35 drugs from its formulary, including breakthrough treatments for cancer and diabetes.

CLAIM: ICER stands for "Institute for Clinical and Economic Review".

OMISSION: ICER is *also* a term used by health economists that stands for "Incremental Cost-Effectiveness Ratio". Basing healthcare interventions on a cost effectiveness ratio is a form of rationing, and its use can theoretically accelerate limitations, or caps, put on amounts or types of treatments available to patients. ICER claims that it is a trusted non-profit, but ironically, its name represents its true motive.