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September 12, 2016

Steven D. Pearson, MD, MSc, FRCP
President
Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
Boston, MA 02109

Re: Institute for Clinical and Economic Review Call for Stakeholder Feedback

Dear Dr. Pearson,

The Advanced Medical Technology Association (AdvaMed) is pleased to provide the following comments in response to the Institute for Clinical and Economic Review's (ICER) request for stakeholder input.

AdvaMed is the national association of manufacturers of medical devices and diagnostics. AdvaMed member companies develop and manufacture the medical devices, diagnostic products, and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings.

As the United States health care system moves more services and care from a volume-based system to risk-based value system, the need for more and better resources to understand value are important. This shift offers the promise to improve the quality of care, become more patient-centered, and slow healthcare cost growth. Medical technology companies are acutely focused on these issues and seek to be partners with patients, physicians, hospitals, other providers and payers to support high quality, patient-centered care in new risk-based value approaches.

We appreciate ICER's goal to help provide value assessments of new services and biopharmaceutical and medical products. We also appreciate ICER's recent efforts to engage with other stakeholders and its request for feedback on its value framework approach. We believe assessing value has to be a flexible process that is continually responding to improvements in science and service delivery and we are encouraged by ICER's openness to address stakeholder concerns in its framework.

In general, we believe ICER's current framework is not well suited for the wide variation and heterogeneity of medical technology products and their associated value propositions. We recommend that ICER make significant changes to its approach and engage the medical technology industry directly to improve and potentially develop more customized frameworks that more appropriately assess different categories of medical technology and diagnostic products.

More specifically, our letter provides comments on the following topic areas: (1) Price versus value; (2) Appropriate evidence for demonstrating the value of medical technologies; (3) Patient access; (4) Timeframes for considering value; (5) Stakeholder engagement; and (6) Transparency. Additionally, we have also attached a letter from Hal Singer, Ph.D., a Principal at Economists Incorporated, an Adjunct Professor at Georgetown University's McDonough School of Business, and a Senior Fellow at George Washington University's Institute for Public Policy. We asked Dr. Singer, to conduct an independent analysis of ICER's framework.

ICER's framework relies too heavily on estimating the cost per Quality Adjusted Life Year (QALY) gained

With its strong emphasis on budget-impact analysis to attribute value to new innovations, in particular medical devices and diagnostics, ICER takes too narrow a view of what determines the value of a medical technology. Medical technologies can offer value for multiple parties within the health care system—improved health for patients, improved productivity for clinicians and staff, and potentially reduced expenditure for payers. Multifaceted value cannot be based predominantly on the incremental cost per QALY achieved, as the ICER framework seems to suggest.

AdvaMed believes medical technology assessment should encompass multiple categories of “value” which should be used in any evaluation of the value of a medical technology. Assessment of value should include clinical impact, non-clinical patient benefits, care delivery economics, and societal benefits. Each of these categories is a relevant value measure at a time when the nation's health care system, reflected in both public and private payer programs, is undergoing rapid transformation, and where patient preference, patient engagement in decision-making about a specific course of treatment, personalized medicine, and broad population health are major goals that stakeholders desire to see in the new system.

While ICER's model references comparative clinical effectiveness, incremental cost per outcomes achieved, other benefits or disadvantages, and contextual considerations, the broader determinants of value we highlight above are not adequately factored into ICER's calculation of cost per QALY achieved. Nor does the ICER framework take into account that value is prioritized differently by stakeholder group and by individual patients within a given patient stakeholder group. The ICER model's use and overemphasis on “value-based price benchmarks” diminishes the variation in prioritization that different stakeholders will consider for determining value drivers. With its emphasis on incremental cost per QALY estimate, individual patient preference and physician clinical expertise about the appropriateness of a particular treatment

option for patient care are inappropriately diminished. In this regard, ICER's assessments can have serious negative consequences for patients' access to all appropriate treatment options that should be available for an individual patient's medical condition because, in part, health plan use of ICER recommendations could lead to significant gaps in access to new technologies.

Evidence demonstrating value of medical technologies must rely on multiple sources and go beyond RCTs

In its individual value assessments, ICER has relied heavily on randomized clinical trials (RCTs) as the most appropriate evidence for demonstrating value. In fact, ICER's calculation and heavy reliance on Quality Adjusted Life Year (QALY) as a measure of value overweighs use of RCTs which is challenging for many medical technologies and diagnostics. While RCTs are a useful tool, practical and ethical barriers due to a lack of clinical equipoise often make it impossible for RCTs to be used for certain medical devices and diagnostics, particularly when concurrent skilled medical interventions such as surgery are a required element of their use. A practical barrier in this instance would involve the RCT demand that neither the patient nor the clinician know whether the patient has been assigned to the study or control group. An ethical barrier would involve, for example, exposing patients to ineffective surgeries from which they cannot benefit and which entail significant risk. The FDA recognizes these concerns, which is why it does not require RCTs in such circumstances.

Evidence that is considered appropriate for assessing value of medical technologies will vary for an industry characterized by a heterogeneous mix of therapeutic and diagnostic medical technologies and their primary users. Medical technologies range from implantable orthopedic and cardiovascular devices to minimally invasive surgical instruments to imaging and radiation therapy equipment, and drug delivery devices and point of care diagnostic tests. Devices and diagnostic tests also vary widely in their levels of complexity and degrees of risks and benefits for patients and care providers. Given this diversity, a "one size fits all" set of guideline principles or a specific checklist for evidence generation encompassing such a broad range of technologies is both inappropriate and impossible to develop.

Many medical technologies are also embedded in complex processes of patient care, where patient, provider, and institutional factors can have a significant impact on clinical and economic outcomes and complicate the perceived value of the technology itself. Medical device effectiveness is very often affected by how well they are deployed. Operator expertise and patient care setting have been shown to affect surgical outcomes but appropriate methods for taking them into consideration often are not incorporated into evaluations. As a result, it can be difficult to separate multiple confounding effects from the measurement of the technology intervention and costs. In addition, a learning curve effect in which the measured effectiveness of an intervention improves over time as a result of improving clinical proficiency of the physician and care delivery site experience can confound comparison between one intervention and another. Evaluations of clinical and economic impact must be carefully constructed and timed in order to control for confounding factors, with the recognition that study designs for these types of interventions are more complex than some other traditional interventions.

Furthermore, medical technology innovation often proceeds incrementally and continuously. After devices come to market, product improvements continue to accumulate over time, altering their clinical and cost-effectiveness. Therefore early assessments may underestimate effectiveness, and assessment conclusions may quickly become out-of-date as devices and their uses evolve. Any framework that evaluates clinical and economic value of a medical technology should include provision for regular review to ensure incremental improvements and innovation are adequately considered.

Diagnostic and imaging technologies present their own special analytic challenges. The core challenge is that the value of a diagnostic technology lies in enabling improved clinical decision-making and therapy selection, distinct from the value of the underlying therapy intervention itself. Additional clinical evidence development following product launch may be essential to driving adoption of these technologies and demonstrating their value.

Because of these unique characteristics, value assessment should acknowledge a range of types of evidence and associated methodologies that are appropriate for assessing the value of different types of medical technologies.

One broad alternative approach to RCTs for generating evidence for medical technologies is the use of various types of observational studies that may produce equally or more relevant data for medical technology value assessment. Circumstances when observational studies may be relevant for generating evidence of value for medical technologies include situations when evidence can only be provided through large or long-term studies, when treatment adherence varies among different technologies, when the only alternative to one treatment approach is an alternative such as surgery for which crossover designs are not possible, when providers have different levels of training that may affect patient care outcomes, or when a new technology's value lies in the process efficiency it brings to the health system. Observational studies have an important role to play in generating data that are collected under real-world practice circumstances and can include several different designs: retrospective and prospective studies, cohort studies, case-controlled studies, and cross-sectional studies.

Registries, another broad category of research, generally use observational study methods to collect uniform data, both clinical and other data, to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves a predetermined scientific, clinical, or policy purpose. Registries are used for collecting data on long-term patient follow-up or for patient longitudinal studies. Certain registries, which combine patient data and archived medical samples, have provided for breakthroughs in the understanding of disease diagnosis, progression, and treatment, especially in oncology.

AdvaMed recommends that evidence required for value assessment should use all of the appropriate, sound, and high quality evidence that is available at the time of assessment, including evidence from outside the U.S. Value assessments should also incorporate flexibility to accommodate limited evidence available at approval or launch to allow a novel product with high expected value to be available for patient care.

Finally, many new to market and breakthrough or disruptive technologies can often be proven safe and effective for FDA approval, but still be in the process of developing more data needed for value assessment. These can often be low volume or slowly diffused technologies. In cases that show great promise for treating diseases in new ways or disrupting care patterns, but that may have limited data, ICER should refrain from reviewing these technologies until adequate information is available and outcomes in real-world practice become more widely available. A decision to rate a new technology as low value, simply because it is a new device that is still developing evidence is inappropriate and could have significant impact on patients and the ability to fulfill the promise of care improvement the technology offers.

Cap on annual spending for innovative medical devices/diagnostics will lead to compromised patient access to these products

The ICER model is built on an assumption that spending on new medical devices and diagnostics should increase overall health care spending by not more than the anticipated growth in national Gross Domestic Product (GDP) + 1%. The budget cap puts medical devices and diagnostics at an unfair disadvantage in two ways. First, as long as device spending as a share of total national health care spending is lower than that for prescription drugs, the cap for device and diagnostic spending will always be lower than the cap for prescription drugs. This means that if two technologies, one drug and one device, are launched at the same time for the same indication, with the same effectiveness and the same net price, the device could fall above the cap allowed for devices and not be eligible for coverage and the drug below the cap for drugs and eligible for coverage. By essentially making all new devices and diagnostics coming out in a year compete for revenue under a GDP cap, wrong conclusions about its value will be made. A new device or diagnostic should be compared to the standard of care that is already on the market. If it is cost-effective and has a better budget impact than the standard of care, this new product should be used, regardless of how many other products also have similar cost-effectiveness that year.

The cap concept also sets up an untenable target for innovative medical devices and diagnostics, for which there are literally thousands of Food and Drug Administration (FDA) approvals in a given year. For devices and diagnostics in 2015, FDA approved 43 original pre-market approvals (PMAs), 829 additional PMA supplemental approvals, and 3,047 510(k) clearances. FDA recently released that there are 175,000 devices used in the US. Spending for medical devices and diagnostics as a percent of total national health care expenditures has been about 6.0 percent for the past 20 years, while prices for medical devices have actually grown far more slowly than the Medical Consumer Price Index or even the overall Consumer Price Index. Over the period 1989 to 2013, medical device prices have increased at an average annual rate of only 0.9 percent, compared to 4.5 percent for the MC-CPI and 2.7 percent for the CPI. While spending increases and decreases for various technologies, the consistency in national health spending, combined with low price growth, shows the high degree of interaction and replacement of products in the market and indicates an industry that is highly competitive. ICER's budget impact criterion is unnecessary for medical technologies and a veiled attempt to artificially drive down prices.

Even if ICER's budget impact concept is intended to be applied only to original PMAs, it assumes that the "value" of a new product in the last analysis is defined fundamentally by its incremental cost per QALY achieved—and that all new medical technologies are accompanied by high costs that need to be controlled. Linking the value of a new product primarily to its cost per QALY does not recognize the impact the innovation can have on improved health outcomes. Nor does it recognize that the innovative product can represent an improvement, both in terms of efficiency and quality, over the current standard of care. As a result, patient access to innovative care may be compromised because payers will translate cost into non-coverage decisions, and company interest in finding innovative approaches to health care conditions may be discouraged. As we have argued above, the value of medical technologies is multi-dimensional and any framework that is applied to individual products should reflect this reality. Additionally, a value framework for diagnostic tests will completely differ from that for a medical device, particularly as it relates to the necessary evidence.

In addition, the assumptions ICER makes regarding market uptake and use for a new technology can dramatically swing estimates for the price benchmarks. ICER has not shown any sensitivity analysis in its reports on the various use rates and has vastly overestimated technology use in previous studies. With the majority of new technologies, physician education and training needs often leads to slow diffusion of the new technology and often only a small portion of the eligible patient pool can actually receive a new technology. This is because physicians may be unaware of the technology, not be trained to use the technology, or be in a facility where the technology is unavailable. It is very difficult to fully understand the uptake rate of a new technology upon approval and applying this budget constraint with limited data and without showing the range of estimates is highly problematic.

In the medical technology industry, the life cycle of a product can be very short and competing products or updated generations of a given product enter the market much more quickly, driving up competition and lowering prices. Additionally, most technologies understand that the Medicare program and many private payers will seek to fit a new technology into existing payment mechanisms such as inpatient Medicare Severity-Diagnosis Related Groups (MS-DRGs) or outpatient ambulatory payment classification (APCs) which naturally creates downward pressure on prices as these technologies enter the market. ICER's artificial mechanism is unnecessary and highly inappropriate.

With the multitude of highly uncertain factors determining both the rate of diffusion and the price dynamics, ICER should eliminate the budget impact criterion from its value framework.

Given the relatively slow medical technology diffusion rates, difficulty measuring use rates, and the problems in setting a spending "limit" on new devices, the notion that ICER's model needs to reflect an "alarm bell" is flawed and should not be a part of the assessment process.

5-year period for limit on value is inappropriate for many medical technologies that provide value over many more years

The ICER model considers cost and value of an innovation only over a short timeframe—5 years. In so doing, it does not recognize that many medical devices and diagnostics have value for much longer period of time, e.g. 20 years for joint replacements, or even for the lifetime of the patient. With diagnostics, for example, long-term outcomes may depend on a variety of treatment decisions throughout a complex care pathway. With the improved negative predictive value of screening tests, such as the HPV screening assay, recommended screening intervals are being lengthened to 5 years and beyond for some screening programs. A model that limits value to 5 years would be inadequate to account for multiple 5-year intervals of screening and thus would be insufficient for public health decision-making. Therefore, applying the full price/cost of a new technology in the short term without accounting for longer term benefits creates a lower value estimate that is inappropriate for many new technologies.

ICER's framework, if applied as drafted, would thus reward a calculus that trades a higher-priced device that needs only be implanted or used once, for a lower-priced device requiring replacement at 5-years' time. Such a choice for short-term low-price over long-term value may ultimately harm health care budgets. ICER should take care that the frameworks it creates does not inadvertently reward short-term innovation dynamics at the expense of health care value and patient care over the longer term. AdvaMed recommends that ICER consider a time-horizon for devices that considers long-term durability of the product and patient longevity.

Process for stakeholder engagement

ICER's processes must allow for all relevant stakeholders to engage in the development of its value assessments and to make meaningful contributions to these reports. Meaningful engagement, as a policy, is imperative, particularly where ICER's assessments focus on diseases or conditions, or on specific medical technologies requiring particular knowledge or expertise. Value, actual or perceived, will very likely differ across a wide range of stakeholders, including patients and patient advocacy groups, providers, payers, and manufacturers of the medical technologies and diagnostic tests.

ICER should incorporate a process for stakeholder engagement that includes not only ample opportunity for stakeholders to provide comments and insights regarding the technology being assessed, but also that explains whether and how those comments were considered in the development of the final report. Clinicians with expertise in the area of assessment should be included in the analysis. A meaningful comment period should be at least 45 – 60 days, in order to allow stakeholders enough time to develop comments that are relevant and useful to ICER. Often, stakeholders are challenged to replicate ICER's analysis, to understand particular assumptions made by ICER, including assumptions about indirect benefits and costs, and perhaps to perform independent analysis and provide feedback within the comment period.

The process could be greatly improved by incorporating the input of relevant stakeholders earlier in the process. AdvaMed has previously commented that the ICER review process could be improved through meetings with interested parties prior to drafting its reports, or at least prior to releasing the initial draft report to the public. Such meetings could promote discussion of specific topics relevant to the review and evaluation, and could uncover issues that ICER may not have considered in advance or during the development of the report. Additionally, the regional affiliated organizations that use ICER reports (CTAF, Midwest CETAP, and New England CETAP) should change their processes to allow real stakeholder input, opportunity for comment, and stakeholder participation.

More transparency needed in ICER value assessment methodologies

Embedded within value frameworks should be a commitment to transparency about the methods used for technology assessment. ICER needs to be more transparent about the models it uses for value assessment, making available to the public the assumptions that are used in the models and results of sensitivity analyses. AdvaMed also recommends that ICER make available the calculations, and coding required making the calculations, it uses for comparative effectiveness analysis.

AdvaMed appreciates the opportunity to provide this feedback to ICER and ICER's willingness to continue to work with stakeholders to improve its processes for assessing value in health care. I believe we share the common goal of improving the quality of care and services available in the US and we are committed to working with you to ensure that patients have access to high quality, life saving and life-enhancing technologies.

We would be pleased to answer any questions regarding these comments and appreciate any opportunities to work with you on these important issues in the future.

Sincerely,

A handwritten signature in black ink that reads "Donald May". The signature is written in a cursive style with a long, sweeping underline.

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September 12, 2016

To Whom It May Concern:

I have been asked by the Advanced Medical Technology Association (AdvaMed) to provide an assessment of a valuation framework proposed by the Institute for Clinical and Economic Review (ICER).¹ I am a Ph.D. economist who specializes in valuation, and I teach advanced pricing to MBAs at Georgetown's McDonough School of Business.² Having carefully reviewed the proposed framework with an economic lens, I conclude that it is inappropriate for application to medical devices.

In particular, I find that there are several problems with the framework that need to be addressed: (1) It relies too heavily on estimating the cost per quality adjusted life year (QALY) gained as a primary basis for establishing a price; (2) Any medical device innovation should be evaluated on a standalone basis, without regard to the growth rate of national gross domestic product or the number of innovations by other medical device makers; (3) Innovations should not be discouraged by virtue of strong uptake percentages; and (4) Annual cost thresholds unfairly penalize medical devices with long lifespans.

In this letter, I briefly describe ICER's proposed framework, and then I explain in detail these four critiques.

1. ICER, *Evaluating the Value of New Drugs and Devices* (2016) [hereinafter *ICER Framework*].

2. For example, I have served as a valuation expert for Apple regarding the value of songs downloaded on the Internet, and for the Baltimore Orioles regarding the value of its television rights. I have also written about valuation and pricing in medical devices. *See, e.g., Is Greater Price Transparency Needed in the Medical Device Industry?*, HEALTH AFFAIRS (2008), co-authored with Robert Hahn and Keith Klovers. My biography and curriculum vitae are available at <http://www.ei.com/hal-j-singer/>.

ICER'S PROPOSED VALUATION FRAMEWORK

ICER's proposed value framework is meant to address a "need for a more explicit and transparent way for [health technology assessment] groups and payers to analyze and judge value."³ ICER sought input from participants in the health care industry, including insurers, pharmacy benefit managers, patient organizations, physician specialty societies, and manufacturers.⁴

The framework considers four factors in arriving at what it calls "care value": (1) comparative clinical effectiveness; (2) incremental cost per outcomes achieved; (3) other benefits or disadvantages; and (4) contextual considerations.⁵ The first component, comparative clinical effectiveness, estimates the "magnitude of the comparative net health benefit and level of certainty in the evidence on [the] net health benefit."⁶ The second component, incremental cost per outcomes achieved, represents the cost per quality adjusted life year (QALY) gained; if each QALY can be achieved for less than \$100,000, then ICER considers the drug/product to be of "high care value;" drugs/products that cost more than \$150,000 per QALY are perceived to be of "low care value."⁷ The third component, a catch-all bucket entitled "other benefits or disadvantages," is meant to capture impacts "that would not have been considered as part of the evidence on comparative clinical effectiveness."⁸ Included in this list are external benefits ("a public health benefit") or non-market benefits ("reduce disparities across patient groups").⁹ The fourth and final component, "contextual considerations," appears to be another catch-all bucket, which includes "ethical, legal or other issues that influence the relative priority of illnesses or interventions."¹⁰ Yet ICER's estimate of the appropriate price for a technology appears to be predominantly based on the incremental cost per QALY achieved.

To derive a "provisional health system value," the net benefits associated with these four components of value are then weighed against the intervention's short-term budget impact over a five-year time horizon.¹¹ ICER offers the following decision-rule: "If the potential budget impact of a new intervention would contribute to an increase in overall health care costs *at a rate greater than growth in the overall national economy*, health system value would be diminished."¹² Thus, even if the new drug/technology generates benefits in excess of costs (including opportunity costs), the intervention could still be disapproved by ICER's proposed framework so long as it causes health care costs to grow faster than national GDP growth. To estimate an intervention's contribution to

3. *ICER Framework* at 3.

4. *Id.* at 4.

5. *Id.* at 6.

6. *Id.* at 7.

7. *Id.* at 8.

8. *Id.* at 9.

9. *Id.*

10. *Id.* at 10.

11. *Id.* at 13 ("Estimated *net* change in *total* health care costs over an initial 5-year time-frame") (emphasis in original); *id.* at 14 ("*Unmanaged* cumulative 5-year uptake patterns") (emphasis in original).

12. *Id.* at 12 (emphasis added); *id.* at 19 ("5-year potential uptake if not strictly controlled").

health care costs, ICER places the new drug or device into one of four “uptake patterns”¹³—ranging from 10 percent (“low uptake”) to 75 percent (“high uptake”)—to gauge the percentage of eligible patients assumed to use the intervention. Interventions that cause health costs to grow by one percentage point faster than GDP “serves as an ‘alarm bell’ for greater scrutiny.”¹⁴

ICER provides an illustrative example of how devices would be considered under its proposed framework. Given an expected growth in U.S. GDP of 3.75 percent, and given aggregate expenditures on medical devices of approximately \$185 billion in 2014, incremental expenditures across all new medical devices in 2015 would be limited to \$6.9 billion (equal to 3.75 percent of \$185 billion).¹⁵ With an average of 23 new medical devices expected in a given year, the incremental expenditures per new medical device should not exceed \$301 million (equal to \$6.9 billion divided by 23).¹⁶ Any new device that generates more than \$603 million in annual expenditures would set off an “affordability ‘alarm bell.’”¹⁷ Recognizing that its value metric links the fate of all new devices introduced in the same year, ICER suggests that a “low-value” intervention can be remedied by, among other things, “seek[ing] savings in other areas to optimize the entire portfolio of services”¹⁸ or by seeking price reductions.

EVALUATION OF ICER’S PROPOSED FRAMEWORK

ICER’s proposed value framework presents several problems, many of which are particularly acute when applied to medical technologies.

ICER’s Framework Relies Too Heavily on Estimating the Cost Per Quality Adjusted Life Year Gained

Cost per QALY is a widely used tool for evaluating the value of many medical interventions. Special characteristics of medical devices, however, imply that ICER’s heavy reliance on cost per QALY as the fundamental basis for evaluating prices is inappropriate. ICER’s QALY-derived “bright line rule” would generate substantial error costs.

Any QALY-based decision rule rests on strong assumptions, because QALY itself relies on a highly simplified and stylized model of the preferences of healthcare consumers. Weinstein, Torrance and McGuire (2009) identify “identify nine assumptions that underlie the conventional QALY approach as used in societal resource allocation decisions.”¹⁹ Among the more restrictive is that individuals are risk neutral with respect

13. *Id.* at 13.

14. *Id.* at 15.

15. *Id.* at 16.

16. *Id.*

17. *Id.* at 19.

18. *Id.* at 17.

19. Milton Weinstein, George Torrance & Alistair McGuire, *QALYs: The Basics*, 12(1) VALUE IN HEALTH 5-9, 8 (2009).

to longevity, and that individuals have utility that is additive over time. As the authors observe:

These are very strong assumptions about preference that undoubtedly simplify reality, but they are necessary in order for QALYs to represent an individual's utility function for health over time. To say that the empirical evidence is mixed as to whether those assumptions provide a serviceable approximation to reality is probably generous for QALYs. For the most part, the evidence is that most people are probably risk averse with respect to their own longevity (although as societal agents, they may be less so), and there is substantial evidence that additivity over time may or may not hold.²⁰

While QALYs are often viewed as an important conceptual tool,²¹ a QALY-based “bright line rule” such as that proposed by ICER is likely to impose substantial error costs. The cost per QALY thresholds that ICER selects are not specific to medical devices; they are simply “commonly cited cost/QALY thresholds.”²² ICER makes no attempt to determine the extent to which the assumptions underlying QALYs are appropriate for medical devices—many of which are valuable precisely because they reduce certain health risks to risk-averse patients. For example, artificial hips or knees reduce the risk of debilitating falls; intra-uterine devices (IUDs) reduce the risk of unplanned parenthood, giving parents control over the timing of childbirth.

Noting that “no threshold that is appropriate in all decision contexts,”²³ a 2014 article in the *New England Journal of Medicine* recommends adopting thresholds “based on the available resources for the relevant decision maker and possible alternative uses of those resources.”²⁴ The authors propose thresholds as high as \$200,000.²⁵ Because the ICER proposal does not take the available resources or opportunity costs of its audience into account, its “one size fits all” solution is likely to be a poor fit.

Given significant economies of learning in the device industry, an early snapshot of a device's QALY-derived value can be quite misleading. Medical devices undergo a rapid series of incremental improvements once they are introduced; an improved model typically replaces a device within 18 to 24 months. Thus, the performance of many devices generally improves over time. In a classic study of the sensitivity of cost-effectiveness to changes over time as measured by QALYs, David Cutler and Robert Huckman found that the cost-effectiveness of angioplasty in New York State changed

20. *Id.* at S9.

21. *Id.*

22. *ICER Framework* at 8.

23. Peter Neumann, Joshua Cohen & Milton C. Weinstein, *Updating Cost-Effectiveness—The Curious Resilience of the \$50,000-per-QALY Threshold*, 371 *NEW ENGLAND JOURNAL OF MEDICINE* 796-797 (2014).

24. *Id.*

25. *Id.*

from a *net cost* in each of the first three years 1982-1983 to a *net benefit* of \$18,000 per patient per year by 2000.²⁶

Moreover, many medical devices interact with other procedures or health care providers, further complicating the estimation of incremental benefits of a medical technology in terms of QALY. Unlike the case of a new drug, device makers must educate and train physicians on how to use the new medical technology. Spinal screws and rods are used for spinal fusion surgeries to address back problems; they necessarily involve the delivery by a skilled physician. Whenever two treatments are administered in combination—here, the spinal screws and the surgery—attributing the incremental benefit of one (the screws) is a daunting empirical task. Another example of complex interaction effects involves screening and diagnostic medical devices; for example, a scanner might detect cancer earlier than otherwise, but the treatment that follows the early detection will impact the QALY in ways that are arguably more profound than the medical device. A metal screw used to treat a bone fracture is clearly vital to the patient’s quality of life, but ascertaining the incremental benefit in QALY would turn on post-operation treatments, including the patient’s level of exercise and diet.

Finally, many medical devices provide benefits that are important to practitioners and patients, but are not well measured by a QALY approach. For example, a technology that allows discharge of a patient from a hospital two weeks early and reduces the pain associated with the procedure would be unlikely to generate a high QALY score, since it would not be associated with an extension of life and the benefits are of relatively short duration; yet the value to patients and hospitals would be considerable.

Any Medical Device Innovation Should Be Evaluated on a Standalone Basis Without Regard to the Growth Rate Of National Gross Domestic Product or the Number of Other Device Innovations

Setting aside the problem of characterizing a medical device in terms of cost per QALY, the second stage of ICER’s proposed framework could deny funding for a new device for arbitrary reasons. Pegging medical device budgets to GDP growth and the number of new devices results in inefficient outcomes. Using the example provided by ICER above, spending on all new medical devices cannot exceed \$6.9 billion under normal GDP growth conditions (3.75 percent), assuming generously that spending on existing medical devices stays constant from one year to the next; any inflation in existing medical devices would crowd out opportunities for entry under the ICER framework. If GDP growth slows to say one percent per year, then the aggregate budget for new devices under the ICER framework falls from \$6.9 billion to \$1.5 billion.

ICER’s valuation framework also penalizes medical devices during times of peak innovation. If entry among device makers is robust in a given year, then the per-device budget falls. For example, while 23 new device makers would have a budget of \$301

26. David M. Cutler & Robert S. Huckman, “Technological Development and Medical Productivity: Diffusion of Angioplasty in New York State,” Working Paper 9311, National Bureau of Economic Research (October 2002).

million each (under normal GDP growth), 46 new device makers would have to make do with \$151 million apiece. With GDP growth of one percent and 46 new entrants, expenditures on any new device in excess of a mere \$80 million would set off ICER's "alarm bells." It bears noting that new medical devices must be approved or, in the case of a new iteration of a device already approved, be "cleared." When a cleared device replaces an older version, it is not obvious whether, under ICER's framework, it would be entitled to the budget of the former device or the incremental cap space for the new version.

The mechanical nature of the formula also means that the cap for any given device will actually be lower than should be allowed under the total cap concept. The cap is based on an assumed average cost for all devices. But if devices are all capped at the projected average, the result will be a true average that is lower than the average used to establish the cap. This is so because no device's price can exceed the assumed average, but some devices will have prices lower than the assumed average.

Moreover, relative to new drugs, new medical devices are penalized under ICER's framework purely based on devices' smaller share of health care expenditures. To make this concrete, assume that device spending and drug spending each contributed 13.3 percent to total health care spending (rather than 13.3 percent for drugs versus 6.0 percent for devices). Now aggregate spending on new devices could be \$15.4 billion under ICER's framework, and the budget per new device assuming 23 new devices would be \$668 million (as opposed to \$301 million).

For devices, imposition of an arbitrary price cap may also actually increase prices over the long run. Prices for medical technology have been falling in real terms for the last two decades.²⁷ For the most common implantable devices, prices have been falling sharply in both real and nominal terms.²⁸ This is the case because a new device's ability to capture the monopoly rents associated with innovation only lasts for a few years, until competing products enter the market. By artificially suppressing initial prices, application of the ICER model would substantially reduce the incentive for new entrants and thus potentially result in higher prices in the long term.

The funding (and hence fate) of an upstart device maker should not be tethered to GDP growth or the number of new entrants in that year. There is no economic reason that links expenditures for a given device to these extraneous factors. Instead, the demand for a given device should be based purely on the benefits—and not just those benefits that can be expressed in terms of QALY—the device generates. So long as benefits exceed the seller's asking price for the device, the buyer enjoys what economists call "consumer surplus." No new device should set off an "alarm bell" simply by virtue of its price

27. Gerald Donahoe & Guy King, "Estimates of Medical Device Spending in the United States" (October 2015), *available at* <http://advameddx.org/resource-center/estimates-medical-device-spending-united-states-3>.

28. Genia Long, et al., "Recent Average Price Trends for Medical Devices, 2007-2011" (February 2013), *available at* <http://advamed.org/resource-center/recent-average-price-trends-implantable-medical-devices-2007-2011>.

exceeding some arbitrary cutoff based on GDP growth and the number of new devices introduced that year.

Innovations Should Not Be Discouraged By Virtue of Strong Uptake Percentages

As explained above, a health care consumer (for example, a hospital or patient-insurer combination) will purchase a device so long as the private benefits exceed the price. Demand and thus uptake will be especially strong for innovative devices that generate significant consumer surplus. Yet ICER's valuation framework perversely discourages funding of such innovative devices by imposing a lower price as the percentage of eligible patients treated rises. The framework fails to appreciate that the private benefits attached to a device do not depend in any way on the (social) uptake percentage. Harry's hip replacement generates value to Harry regardless of how many other patients receive the same hip that year. The device maker might enjoy economies of scale with greater uptake, potentially leading to lower prices for hip replacements, but Harry's willingness to pay for the new hip is unfazed.

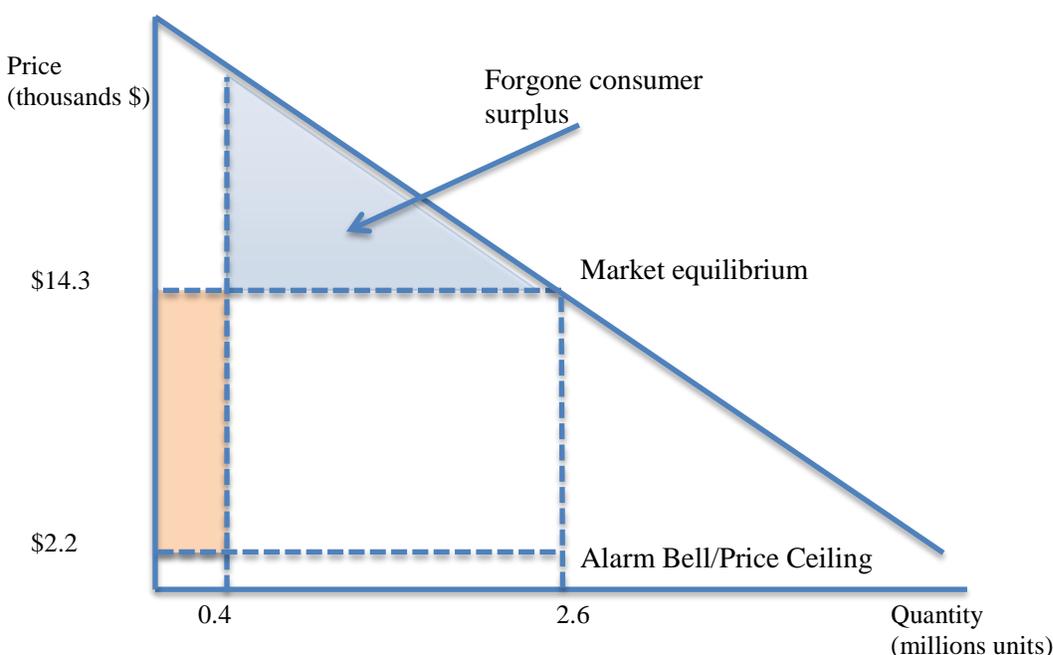
ICER reveals how its framework could be used to put downward pressure on PCSK9 drugs. The drug is originally priced at \$14,350.²⁹ To achieve ICER's threshold \$150,000 cost per QALY, the price would have to fall to \$7,735.³⁰ But even at that price the drug would set off ICER's "alarm bells" because it would exhaust its (arbitrary) \$904 million allotment under the GDP-growth threshold. According to ICER, at a price of \$14,340, the demand for the drug was 2.6 million units.³¹ Figure 1 illustrates the impact of ICER's valuation framework on consumer welfare.

29. *Id.* at 20.

30. *Id.*

31. *Id.*

FIGURE 1: ICER'S VALUATION FRAMEWORK SERVES AS A PRICE CEILING



To fit under its arbitrary maximum budget for a new drug of \$904 million, the price of PCSK9 drugs would have to fall to \$2,177, yielding just over 400,000 units. The (original) consumer surplus associated with the market-determined equilibrium is the area under the demand curve bounded from below by the price of \$14,350 per unit. The forgone consumer surplus resulting from ICER's framework is depicted as a light blue triangle, depicting the reduction in consumer welfare associated with a market contraction from 2.6 to 0.4 million prescriptions. At the lower price, some additional surplus is obtained on the smaller base of prescriptions (shown in orange), but consumer welfare will be lowered on net to the extent that the blue triangle exceeds the orange rectangle. To keep the figure simple, I omit the forgone producer surplus (also recognized as a deadweight loss) associated with the compulsory reduction in output. The example makes clear that any new drug (or device) that enjoys high uptake will be forced to incur a sizable haircut; the bigger the uptake, the greater the consumer surplus, the bigger the haircut.

ICER's Yearly Analysis Creates Timing Issues and Disproportionately Penalizes Medical Devices with Long Lifespans

The effective life of many medical technologies—for example, scanning devices and surgical units—is often much longer than that of a particular drug.³² Furthermore, as

32. Medical device effective life declarations suggest that the majority of devices have effective lives of seven years or more. *See, e.g.*, Commonwealth of Australia's Effective Life Declaration, Health and Community Services, Table A, available at <http://law.atolaw.gov.au/atolaw/view.htm?docid=ITD/DEP20032/00001> (accessed Sept. 8, 2016).

noted above, the efficient and efficacious use of such technologies depends upon training medical staff and doctors in their proper use, as well as “learning-by-doing” know-how acquired only through extended use and experience.³³

Consequently, the cost of a medical device is often front-heavy, where significant fixed costs must be incurred in installing, training, and creating the necessary infrastructure to properly apply such devices. While variable costs may decrease over the long term (such that marginal costs may fall beneath the QALY threshold as determined by GDP growth and uptake levels), any implementation of new medical technologies may set off the “alarm bells” due to short-run outlays, while not accurately reflecting the overall cost structure and value of such devices.

An especially serious problem with use of the five-year window is that both the value and the cost-reductions due to medical technologies may accrue over a very long time period. For example, artificial hips and knees have a useful life that can exceed twenty years. The vast majority of the costs associated with the device occur in the first year from implantation and rehabilitation. The cost reductions due to reduced dependency and nursing home use, as well as reduced comorbidities from such illnesses as diabetes and heart disease because the patient can maintain a greater degree of activity, by contrast, will accrue over the lifespan of the device.

In sum, any attempt to value medical technologies with a rigid five-year window will confront serious timing issues. To quote Buxton’s Law, “It is always too early until, unfortunately, it’s suddenly too late.” ICER’s framework would likely overestimate the costs, by not amortizing them over the relevant lifespan of medical device. Put differently, the five-year window currently proposed does not match the value of the device to the costs incurred over the relevant timeframe.

CONCLUSION

For the forgoing reasons, ICER’s proposed framework should not be used to guide purchase decisions relating to medical technologies. ICER purports to consider other amorphous factors that are not captured by QALY, but at the end of day, cost per QALY is paramount. It is not clear whether ICER’s framework would account for device-related savings from outside the health system, such as increased productivity, labor force participation, and reduced dependency. An acceptable price under the ICER framework must not exceed \$150,000 per QALY, and further price reductions can be justified based on factors—such as GDP growth and the number of new devices introduced in a given year—unrelated the net benefits of the device in question. The ICER framework appears to be nothing more than a crude mechanism to put downward pressure on the price of medical devices.

33. Indeed, NSF International offers certification courses for medical device usage offering learning-by-doing opportunities beside experienced experts. *See* NSF-DBA, Medical Device Diploma, *available at* https://www.nsf.org/newsroom_pdf/110719_Medical-Devices-Diploma-Program.pdf (accessed Sept. 8, 2016).