



# Value: “Real World” Points

November 8, 2015

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The Opinion Pages OP-ED CONTRIBUTOR

## Why Drugs Cost So Much

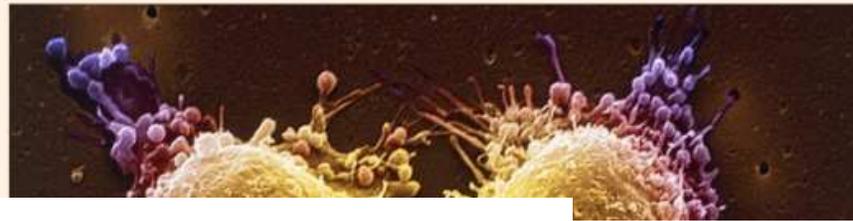
By PETER B. BACH JAN. 14, 2013



January 15, 2015 7:08 pm

## Healthcare: Counting the cost of cancer

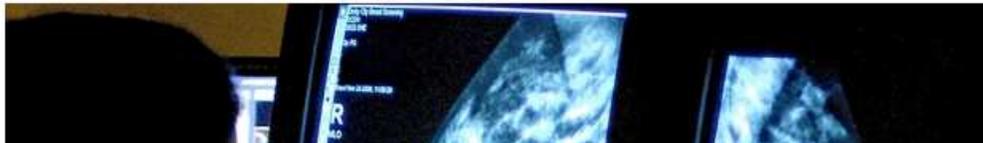
Andrew Ward



### Cancer

## NHS to rein in cost of Cancer Drugs Fund

Experts to announce results of review aimed at cutting costs of fund launched by Cameron in 2011, which has hugely overspent



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## Value: Real World Points

Yes, innovative drugs and biologics, including in immunotherapy for cancer, are expensive; for a variety of reasons.

## Value: Real World Points

Question for Managed Care Medical Directors as *financial considerations increasingly creep into medical necessity determinations:*

*Would you absolutely abide by the processes, the decision-makers, and the decisions of/at your managed care company in making a coverage and medical necessity determination directly for one of your loved ones or for you? YES or NO*

**The QALY as the Main Policy-Setting Paradigm??? :**  
*Use of the QALY is producing results that are inconsistent and reduce patient access to innovative treatments such as those we are discussing today (European Commission, Oct 2014)*  
**(European Commission Report)**

Ariel Beresniak, chief executive of Data Mining International and ECHOUTCOME Project Leader said: “The research provides robust scientific evidence that QALYs produce hugely inconsistent, wrong results, on which important decisions are being made. Agencies such as NICE should abandon QALY in favour of other approaches. European HTAs currently looking to adopt the NICE model must seriously reconsider.”

# The QALY → Valuation Gone Wrong for 30 Years

## 2002

- **DATAMONITOR Report: “Cancer Survival: UK at the Bottom of the League”**
- **Guardian “UK survival rates worst in Europe”**
- **Daily Mail: “Cancer patients in Britain have a far worse chance of surviving than those in any country in the developed world, a shocking study reveals today.”**

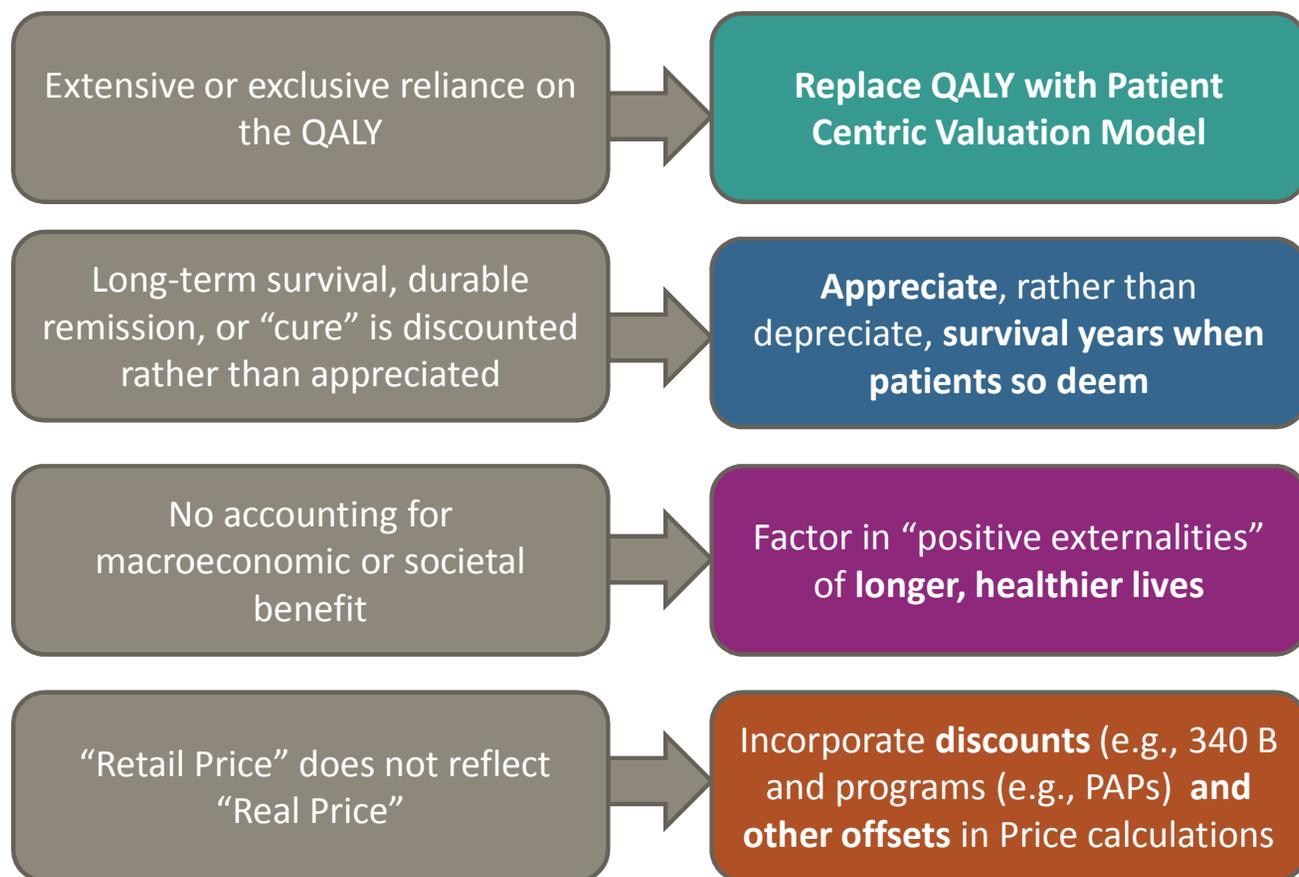
## 2013

- **Guardian: OECD finds Britain’s Cancer survival rates unacceptable**
- **OECD 2013 : “Overall an adequate level of resourcing is fundamental to improving cancer survival.” .....“All countries, however, should insure sufficient investment in cancer care facilities, professionals, diagnostic and therapeutic technologies, and medications.”**

## Value: “Real World” Points

- *Issue: IO has brought **a transformational change in mechanism of action and, in some patients, patterns of response requiring adaptation and development of a new response measurement system, the immune-related Response Criteria.** It was recognized early on that IO agents demonstrate distinct “kinetics” compared to cytotoxic agents as IO is a new paradigm in cancer treatment.*
- *Issue: Evaluation methods based upon FDA/EMA approval present a negatively biased indication for evaluation/valuation usually in a refractory disease and/or heavily pretreated population looking at a single specific indication.*
- *Issue: **As cost is integrated with greater weighting into policy-setting and decision-making processes that impact autonomy in prescribing and, thus, access for patients, the innovative IO agents require corresponding “real world” adjustments, refinements or retooling of existing valuation methodologies.***

## In Oncology: What Should the Valuation Methodology Look Like?



## Value: Real World Points

**Is not the major issue to be addressed and evaluated first.**

Which Stakeholder in the Cancer Care delivery system provides the most value in terms of benefit to patients per dollar extracted by that Stakeholder?

Provider

BioPharma Company

Payer/Managed Care Company



# Value in the Eye of the Beholder

## When Physician Policy-Maker Becomes Patient

**“I had come into the presence of a technological marvel, namely me. To be sure, the pacemaker is a wonderful miniature piece of high technology, my friend the surgeon a skilled worker in high technology, but the greatest of wonders is my own pump, my myocardium, capable of accepting electronic instructions from that small black box and doing exactly what it is told.....**

**I suppose I should be feeling guilty about this. In a way I do, for I have written and lectured in the past about medicine’s excessive dependence on technology in general and the resultant escalation in the cost of health care.**



## Value in the Eye of the Beholder

### When Physician-Policy Maker Becomes Patient

I have been critical of what I have called “halfway technologies” designed to shore things up and keep flawed organs functioning beyond their appointed time. *And here I am, enjoying precisely this sort of technology, eating my own words.”*



## Value in the Eye of the Beholder

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Lewis Thomas, MD:



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