

## MAIMON WORKING PAPERS No. 3 JANUARY 2022

**WITHOUT A CLUE: THE NATIONAL PHARMACEUTICAL COUNCIL AND IMAGINARY COST-EFFECTIVENESS CLAIMS**

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**Abstract**

*A continuing feature of those who subscribe to the approximate information meme in health technology assessment, the construction of non-empirically assessable value claims for pharmaceutical products, is their insistence that the standards of normal science do not apply in formulary decisions. Apparently, the National Pharmaceutical Council (NPC) shares this belief. A recent commentary supported by the NPC illustrates the absurdity of this position where it is argued that to assess the presence of uncertainty in imaginary value claims, there should be a concerted effort to incorporate alternative assumptions in competing model structures. This is complete nonsense as the result it a plethora of competing imaginary claims as aides to formulary decisions.*

**INTRODUCTION**

A recent publication in *Health Affairs Forefront* supported by the National Pharmaceutical Council (NPC) raises concerns about decisions regarding the value of prescription drugs <sup>1</sup>. Apparently, the NPC in supporting this study subscribes, along with the authors, to the belief system, or meme, now dominant in health technology assessment. The NPC should know better <sup>2</sup>. This meme, held as a belief system for some 30 years, rejects hypothesis testing, the standard of normal science, in favor of inventing value claims for pharmaceuticals in the guise of approximate information <sup>3</sup>. As epitomized in the recent CHEERS 22 guidance for creating imaginary value claims and supporting their publication in leading academic journals, the NPC joins many respectable organizations, such as the Institute for Clinical and Economic Review (ICER) in advocating value claims for pharmaceuticals which are entirely imaginary, lacking by definition (and intent) the possibility of empirical evaluation <sup>4</sup>. The NPC and the authors of this commentary represent a unique feature of health technology assessment not shared by the physical sciences and the mature social sciences such as education, psychology and economics, a deeply held belief that formulary decisions are well served by invented non-evaluable value claims. The notion of progress, the discovery of new, yet provisional facts, in therapy impact through a process of conjecture and refutation, the product of over 300 years of scientific endeavor since the foundation of the scientific revolution of the 17<sup>th</sup> century are, by ignorance or design, rejected <sup>5</sup>.

**CREATION OF UNCERTAINTY**

While it may seem somewhat odd that we can talk about the uncertainty of value claims when the claims are assumption driven and entirely imaginary, this is certainly a concern of imaginary model

builders in an effort to obscure the fact that the modeled claim is somewhat dubious. Strenuous efforts have been made to evolve from one way, to multiway sensitivity analyses to the ultimate uncertainty peak of probabilistic sensitivity analysis, to create a defensible smokescreen for the believer and, presumably, the more critical outside observer. Indeed, there are actually guidelines for constructing imaginary claims by those who should know better, including a textbook primer by leaders in the field, for inventing claims and report uncertainty <sup>6</sup>. But, according to the NPC and the authors we can do more! The starting point is the 'keys under the lamppost problem' where it is easier to describe a range of possibilities for assumptions represented by numbers than it is to characterize uncertainty for 'qualitative' assumptions. No mention is made, it might be noted, that the person looking for her/his keys is usually represented as intoxicated. Qualitative assumptions, apparently, can include pathways to include in a disease progression model or how to impute information about one drug with limited data from another drug.

To illustrate this distinction, which is weird as an assumption is an assumption, they undertook a pilot study which compared 20 model inputs where expert panels introduced their preferred assumptions and compared these to the assumptions preferred by ICER by ICER in a model report on the treatment of ovarian cancer. While some assumptions were held by both parties the results, most surprisingly, found that different assumptions produced different modeled results. The result was that in 11 cases the alternative assumptions produced more effective cost-effectiveness ratios for one panel, while the second panel's preferred assumptions produced nine ratios that were more favorable than ICER's. A most surprising result which, unfortunately, goes to a key point: the belief in modeled assumption driven imaginary value claims can, obviously, produce potentially an infinite number (infinity is not a number) of competing model claims with no basis for judging one against the other <sup>7</sup>; a situation that would certainly energize formulary decision making.

#### UNCERTAINTY RECOMMENDATIONS

The recommendations are (i) groups such as ICER should promote consideration of multiple possibilities for qualitative assumptions (good luck!) ; input from outside parties should be facilitated to inform characterizing uncertainty; and (iii) technology assessment documentation should comprehensively report uncertainty's influence on cost-effectiveness results and value-based prices.

To be reasonable, this is complete nonsense. Locked into the approximate information belief system, the 30 year meme, the NPC and authors fail to see that the entire assumption driven modeling is a charade that defies the standards of normal science, including the axioms of fundamental measurement, to produce value claims that, by design, fail to be credible, evaluable or replicable <sup>8</sup>. This is well documented although NPC and ICER choose to ignore it.

NPC and the authors fail to recognize the problem of induction (David Hume, 1748), although this has been a central problem (now resolved by Popper in the 1930s) in philosophy there is a quaint belief that we can judge the merits of an assumption, its realism, by reference to past observation: (i) the future is unknown and (ii) in logic we cannot claim that because past futures have resembled past

pasts that future futures will resemble future pasts. Thus: all swans are white! Choosing one assumption over another is in the mind of the model builder; you cannot in logic justify its inclusion ahead of other assumptions. Any attempt to differentiate assumptions on any criteria is a waste of time.

The fact that preference scores have only ordinal properties is conveniently overlooked, indeed ICER is a firm believer in the ordinal preference score that has mystical ratio properties (even with negative preferences). This means the QALY is an impossible mathematical construct and the entire edifice of incremental cost-per-QALY modeling and cost-effectiveness claims collapses <sup>9</sup>. There is a certain Titanic feel when the NPC supports a study on modeled impossible uncertainty when the entire assumption driven assumption exercise is a waste of time. To compare one modeled cost-effectiveness claim to another is not only absurd by the notion of cost-effectiveness as a blanket term has no meaning in the belief system that supports imaginary claims.

## CONCLUSION

If the NPC wishes to actually support formulary decision making, rather than encouraging imaginary speculation, then it should focus on the standards of normal science and fundamental evidence where value claims are evaluable, single attributes with ratio or interval properties. It is doubtful if this will happen.

## REFERENCES

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