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VALUE IN HEALTH

Beyond AWP . . . Way Beyond

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First of all, congratulations and kudos to the ISPOR Drug Cost Standards Task Force, led by Joel Hay and Jim Smeeding. Their combined report represents several years of hard work and recognition that there were a number of important aspects to the question of drug costing that merited full exploration and explication. Producing this well-coordinated series of reports is a real accomplishment and a major contribution to our field.

Many people think that costing drugs is mainly about getting the accounting details right. Though several of these reports do pay close attention to such detail, the overview and the societal perspective articles focus more heavily on the economic costs, that is, the opportunity costs, of producing drugs. It provides an important, fascinating, and underdiscussed set of considerations around what the real costs of drugs are. Getting this right can be very important in CEA. As we all know, the intervention drug cost is usually the main driver of the "ΔC" in the ICER's numerator.

A key consideration in the societal perspective report is that new drugs are generally priced at monopolistically determined levels due to patent protection rather than at marginal-cost-of-production levels. The short-term resource cost of production is thus well below the market price, and, depending on the nature of the decision to be made, it may only be the marginal resource cost that is relevant to the societal perspective. The remainder of the drug price really goes toward "producer surplus" or alternatively can be considered a return on past R&D costs or simply as "transfer" to the producer, but in none of these views is it a short-term resource cost. So, are the societal costs of new drugs really overstated in most analyses, leading to ICER's that are too high? Should pharma be asking all the societal decision-makers for recounts on drugs they have recently turned down? It's not quite that simple, of course, but reading the reports is worth the trip on this question. You will read about a "limited societal" perspective and more.

There are a couple of issues embedded here that are worthy of comment. First, as you would expect, the societal perspective report discusses the need to consider R&D costs as part of societal costs in the long term as an aspect of dynamic efficiency. Somewhat overlooked is the role of expectations of producers, who are increasingly making R&D investment decisions based on the likelihood that the drug will pass muster as being cost-effective. Raising or lowering those hurdles will affect R&D decisions and must be considered in discussions of dynamic efficiency.

Though really a sidebar to the overall report, the notion of patent buyouts is an interesting thought exercise. The idea here is that there may be mechanisms by which the government could "buy out" a drug patent, say, shortly after FDA approval, reward the producer for the innovation in a market-determined way, and then allow the drug to be produced and sold by all comers, as if generic, thus reducing the market price to marginal cost levels and enabling more widespread and potentially socially optimal use much earlier than usual. There are a number of considerations here, and I recommend reading Michael Kremer's article (referenced in the societal report) for those who are interested in thinking more about how this might work. Personally, I am most dubious about the feasibility of funding such buyouts in political economy sense. Some buyouts would involve multibillion dollar payments to drug makers for the "expected future value" of a drug. Will that be acceptable politically? More importantly, which governments are going to pitch in for these buyouts? All countries would benefit from them, but what is each one's fair share? The potential for free ridership here seems enormous, even worse than under our current system.

The subsequent reports take different perspectives: those of the managed care payer, the US government payer, the industry, and several countries, representing the international perspective. All of them are well done and make important points. If you cannot read them all in one sitting, take them along as plane/train/bus reading. The following comments are offered simply as potential points of reflection as you read them.

The managed care payer report is excellent. Interestingly, it includes the recommendation that the drug cost used in budget impact and CEA models net out patient copays. This clearly makes sense for budget-impact models. But what does it mean for CEA results? That the higher the patient copay, the more cost-effective a drug will be? It implies that an MCO can provide highly cost-effective care by making a patient pay the whole drug cost. Try pitching that one to an employee benefits group.

The report by the US Government Payers Subgroup is a tour de force of public program regulations around pricing, and I would highly recommend it for anyone who needs to bone up on the how Medicare, Medicaid, VA, and other program pricing regulations have evolved recently. Just one caveat: government being what it is, the report is acronym rich; I stopped counting at 25.

The industry report provides a needed emphasis on value versus cost comparisons, transparency, and credibility in evaluation of drug therapy. The international report not only shares a helpful sampling of how drug prices are determined in some representative countries but also reviews some controversies in international economic evaluations.

Taken all together, one comes away with two impressions. First, drug costing is indeed "complicated," as noted in the overview report. Second, it seems abundantly clear—as if it wasn't already—that CEA results are likely to vary significantly from one perspective to another, based on drug costing alone. Although having a centrally carried out CEA by a national authority may seem efficient in some ways, the potential for its results to be inapplicable to many local situations seems very high.

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