On numbers and access to medicines – CBO figures on the PAAG Act are not that convincing

11 November 2011

by Rachel Chu

Will the proposed Preserve Access to Affordable Generics (PAAG) Act actually generate the $4.8 billion savings over 10 years that the Congressional Budget Office suggests it will? How realistic are its assumptions about generic competition or healthcare costs over the next ten years?

The CBO's savings estimate of a new bill restricting the use of patent settlement agreements which reward generic manufacturers for delaying market entry and avoid litigation under the ANDA approval pathway is exaggerated. It assumes that savings from increasing generic competition would outweigh the savings that would have otherwise been generated from the introduction of innovative pharmaceutical products. In doing so, it makes key assumptions about the behaviour of both the generic and research-based pharmaceutical industries which do not capture the full reality. Therefore, estimates on the savings to healthcare spending as a result of banning so-called "pay for delay" agreements are likely overstated.

The Preserve Access to Affordable Generics Act (S.27), introduced in October 2011, would make illegal patent settlement agreements which pay generic companies a fee to settle drug patent litigation in return for agreeing to withhold marketing their generic drugs until the end, or shortly before, the expiration of the patent under dispute.

Generic competition and savings to healthcare spending

The majority ($4 million) of the savings that the CBO expects to follow from the Act is based on the idea that, "limiting [patent settlement] agreements would result in earlier generic entry into the market and... lower drug prices".[1] Although it expects that fewer generic companies would challenge patents in order to enter the market, it only estimates that this would offset savings from the Act by $0.3 billion. Effectively, the CBO anticipates that generic competition would continue to be as robust as it is today, while also occurring earlier than it currently does.

This overlooks the fact that generic rivals actually benefit from a relatively early market entry under a settlement. According to the Generic Pharmaceutical Association (GPhA), in 100 percent of settlement agreements the generic drug enters the market before the expiration of the patent under dispute (and this has occurred for 16 of the 22 first-time generic medicines that are entering

[1] http://www.cbo.gov/ftpdocs/125xx/doc12544/s27.doc.pdf, p.9

the market in 2011).[2] Furthermore, generic manufacturers gain profits and, importantly, certainty about the market entry process.

The CBO may have severely underestimated the importance of these three factors. In particular, it does not consider the extent to which the ability to avoid the costs and risks of litigation improves incentives for generic manufacturers, both first-time and secondary rivals. If the rewards from settlements impact incentives to a high degree, the offsetting costs of $0.3 million from reduced generic challengers would actually be much higher. Sixteen of the generic drugs that have entered the market this year could likely still be embroiled in litigation, and this could mean fewer generic competitors over the long-term.

Pharmaceutical innovation and rising healthcare costs

If cost, timing and risk constraints negatively impact incentives for generic companies, they certainly impair incentives for the research-based industry to introduce innovative products to the market. The pharmaceutical industry relies on patents and other intellectual property rights for its business more than any other knowledge-intensive industry, and having to engage in litigation introduces uncertainty as to the strength of a company's patents and its ability to exploit them in the market. As the CBO itself recognises,[3] such a weakening of pharmaceutical patents would likely decrease profits for the research-based industry, and as such reduce incentives to invest in research and development of new, life-saving therapies and devices.

However, the CBO estimate fails to incorporate the negative implications of the Act for pharmaceutical R&D (i.e. the loss of the ability of patent holders to influence ANDA-based litigation) on long-term healthcare costs.

Indeed, both path-breaking therapies like personalised medicines and anti-cancer treatments, as well as incremental innovations that improve and expand existing drug classes, introduce significant efficiencies in healthcare spending. Advances in formulations, delivery systems and dosage forms in second and third generation drugs reduce treatment costs as well as indirect costs such as hospital stays, doctors visits and loss of productive working time. For example, use of torasemide instead of original loop diuretic furosemide in the treatment of cardiac heart failure (CHF) created annual hospital savings of $700,000 for CHF admissions and $1.3 million for cardiac events.[4]

The point is, such innovations are an important component of curbing rising healthcare costs. While it is difficult to estimate the extent to which deterioration of patents as a result of the Act

[2] http://www.gphaonline.org/media/press-releases/2011/gpha-ftc%E2%80%99s-misguided-policy-patent-settlements-would-be-costly-consumers-a
[3] http://www.cbo.gov/ftpdocs/125xx/doc12544/s27.doc.pdf, p.9
[4] http://www.who.int/intellectualproperty/submissions/Pharmacoevolution.pdf, p.11

would reduce savings from pharmaceutical innovations over the next ten years, nevertheless the CBO estimate did not factor it in sufficiently.

The bottom line is that if the incentives of generic competitors and research-based innovators – which both facilitate savings to healthcare spending – are equally deterred by the Preserve Access to Affordable Generics Act, the estimate of $0.3 billion in offsetting costs from industry is likely too low. As such, the $4.8 billion savings that the CBO anticipates as following from the Act are probably exaggerated.