



US Health Care Reform: Impact on Biologic Drug Development and Partnering

By Peter Molloy

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What happened on March 22, 2010?

- The House passed the Health Care Reform package (est. around 2,700 pages of legislation)
 - Signed by the President into Law on March 23
 - Law includes Pathways for Biosimilars Act (HR1548)
 - Ostensibly to allow generic biologics (“Follow On Biologics” or FOB) a way to market which does not currently exist
 - Reality is it gives biologics innovators 12 years of market exclusivity post-registration
 - Different to Hatch-Waxman Act
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Why is FOB legislation needed?

- Generic biologics are only “Bio-similar”
 - “Bio-equivalence” doesn’t work
 - Complex molecules, post-translational modification
 - Minor changes in manufacturing process, cell lines or other variables can unpredictably change efficacy or side effects
- Issues to be resolved FDA
 - FDA requirements in terms of clinicals for generics?
 - How will a biologic will be deemed “similar”?
 - How exactly will the FDA enforce the Act?
 - What is a biologic?
 - All these questions make life problematic for generics, not easier

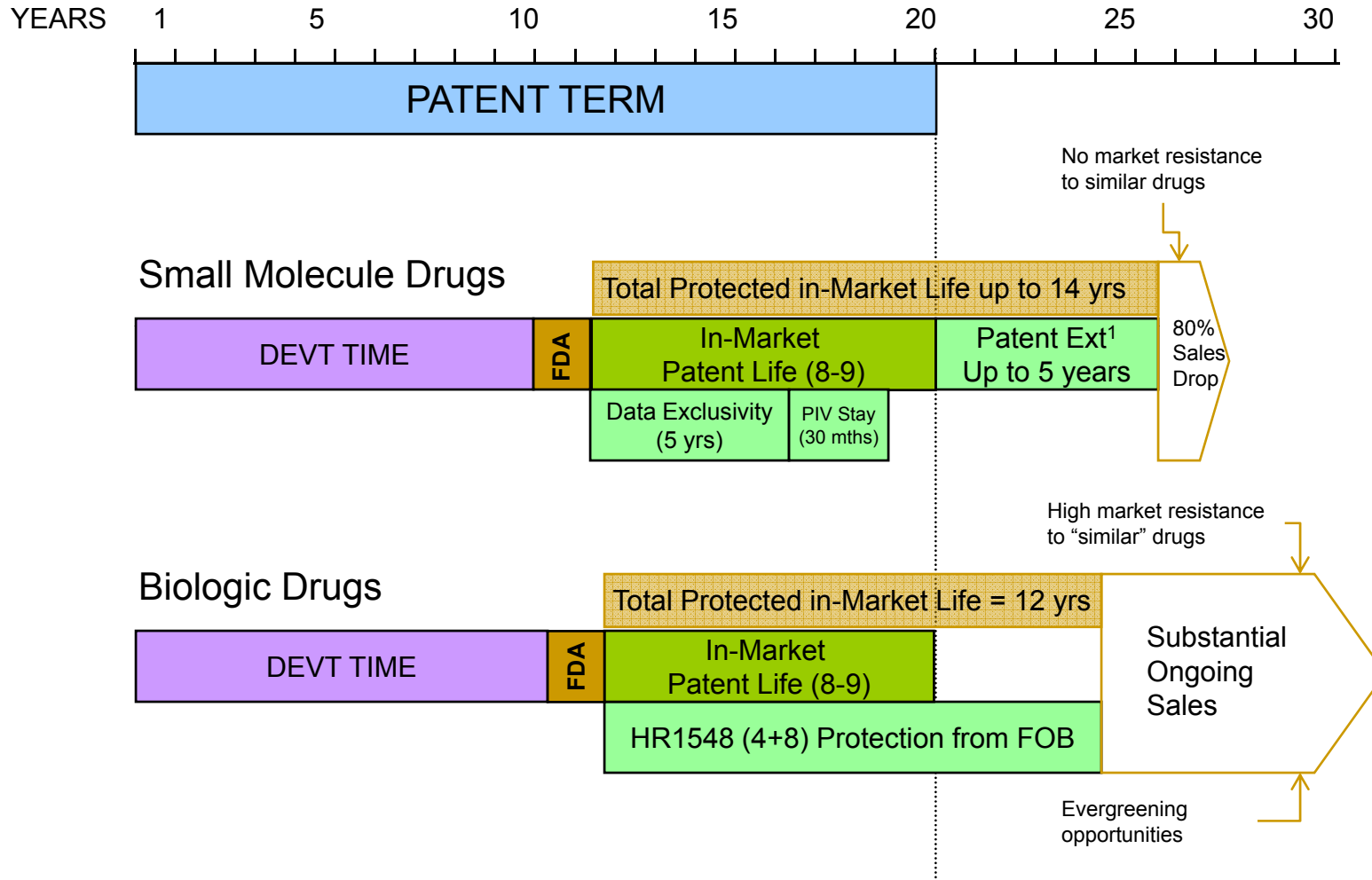
“The goal is to have no clinically-meaningful differences in safety, purity, or potency, but the complexities of biologic drugs leave significant room for variability in FOBs that may be considered “biosimilar.”?”

*- Dr Gregory Glover
Pharmaceutical Law Group*

Why BIO loves the FOB legislation

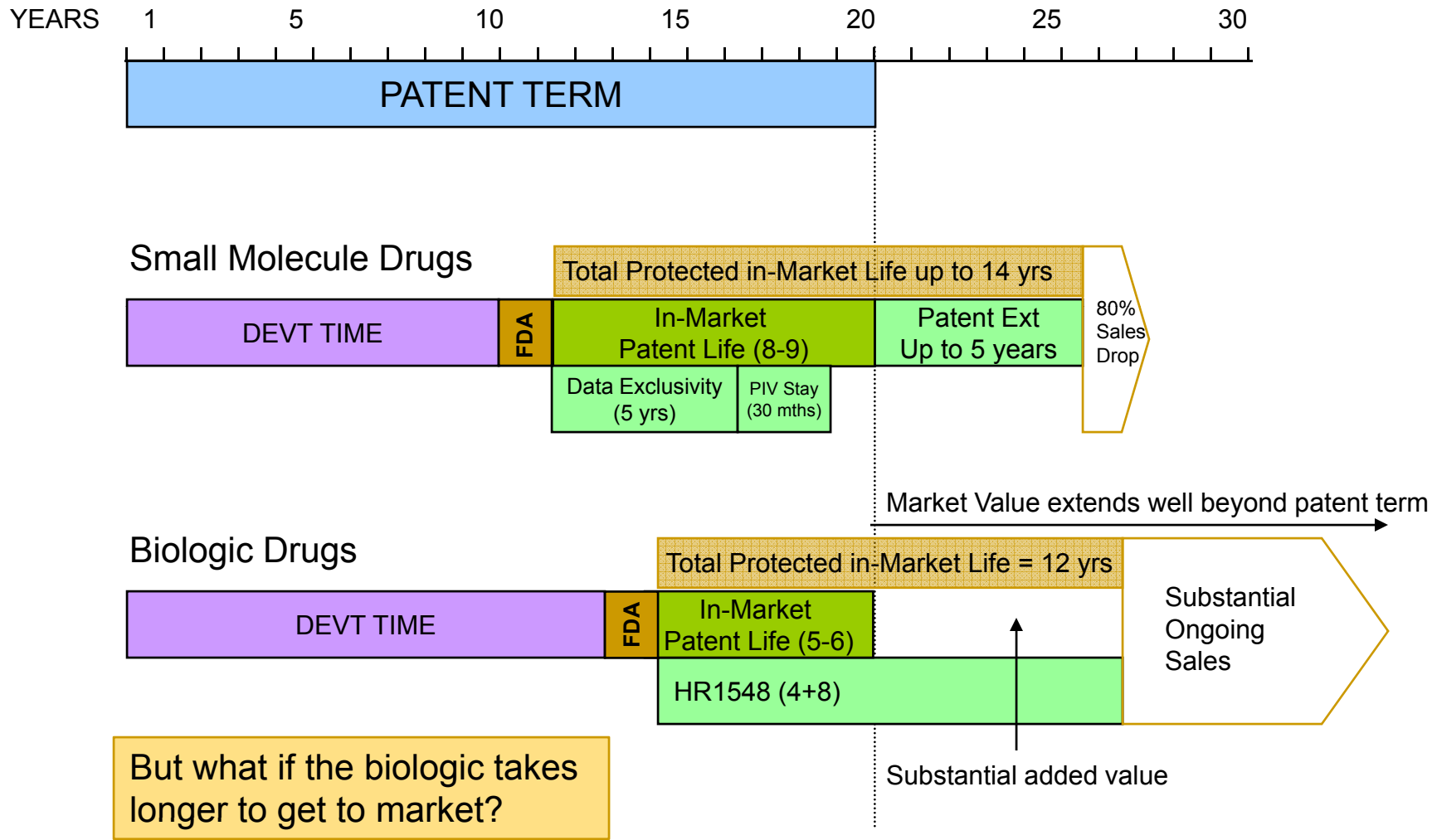
- Very positive for biologics biotechs
 - 12 years market monopoly regardless of patent life
 - 4 years of data plus 8 years on sales
 - Regardless of (in parallel to) patent life
 - Unlike Hatch-Waxman which is a patent extension
 - Ongoing and probably new barriers to entry for FOB generics
 - Both at FDA and marketing level
 - No patent challenge incentives like ‘paragraph IV’ in Hatch-Waxman
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The new deal-making value chain

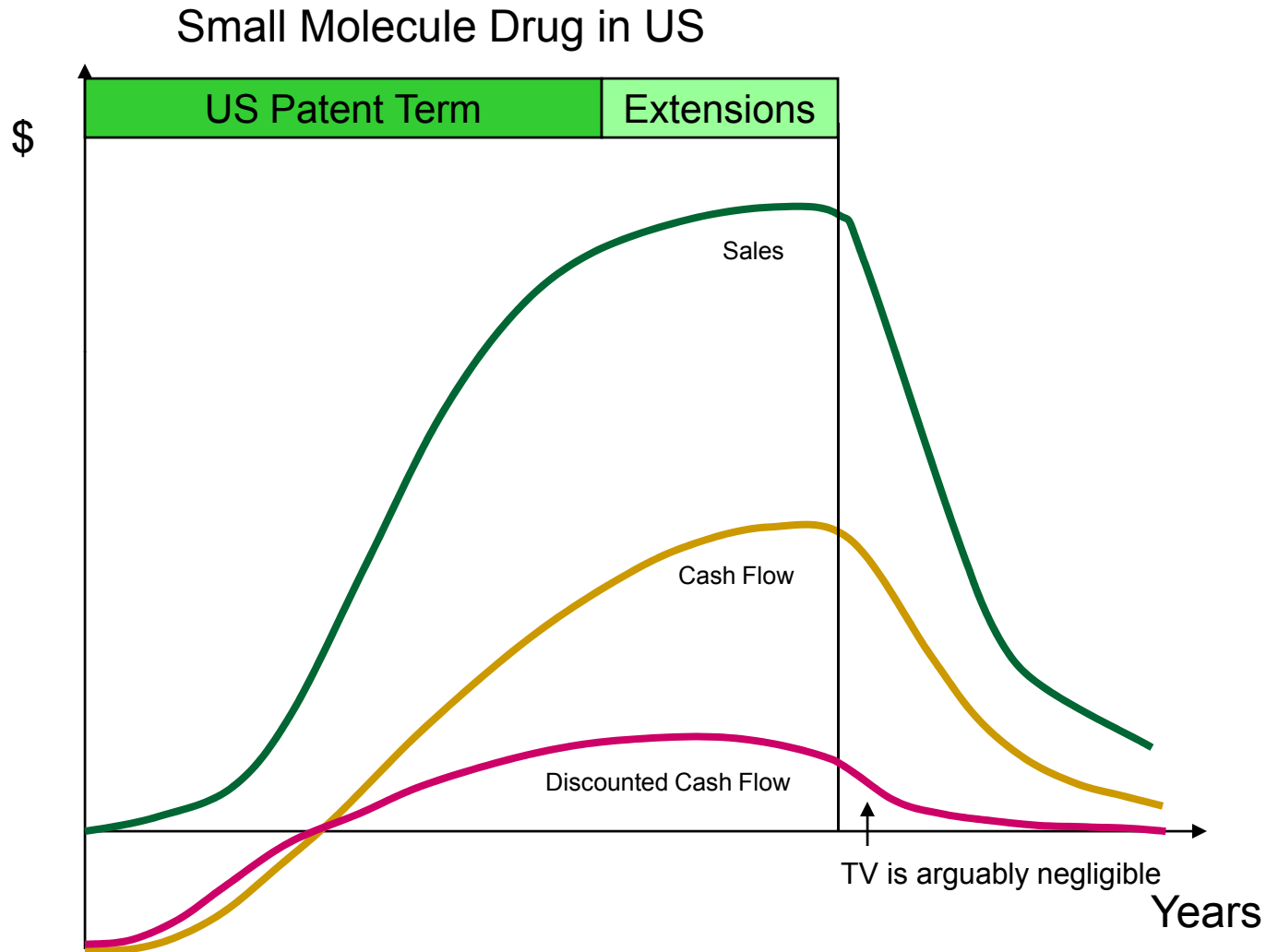


¹ Hatch-Waxman allows up to 5 years extension to maximum 14 years total protected in-market life. Similar provisions exist in EU (SPC).

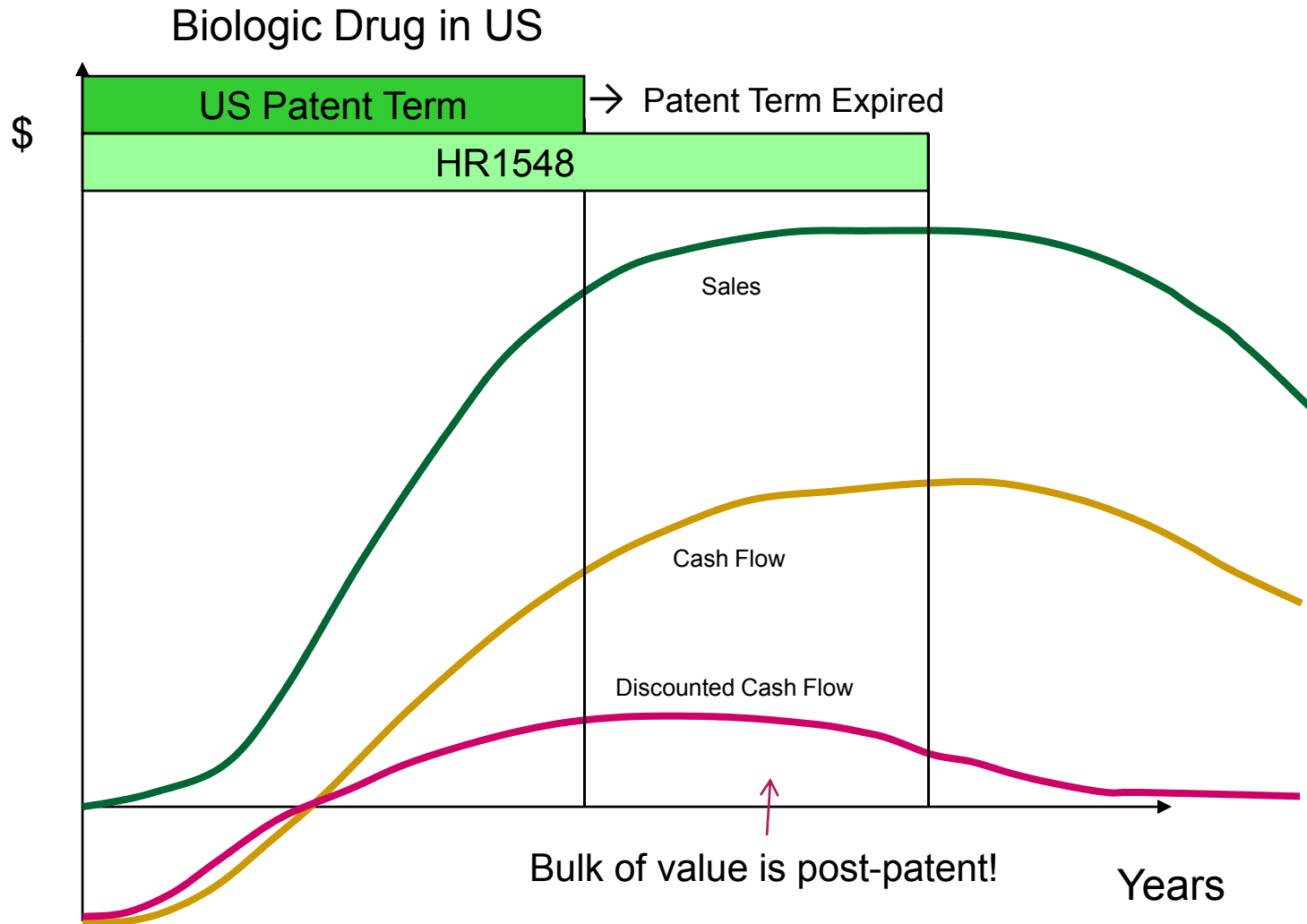
The new deal-making value chain



Deal the product life cycle not the patent



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Impact of the new legislation

- Patents and 'Time to market' may become less critical for biologics
 - Getting it right may be more important than speed
 - Drug candidates previously shelved due to patent age could be worth developing
 - Biologic drugs become more attractive to pharma
 - Increases number of biologics in development
 - Biologic markets get larger than small molecules (eventually)?
 - Changes valuations & deal negotiations
 - Biologic company valuations change
 - Should become more attractive to investors
 - Biologic drug licensing deals worth more
 - Importance of properly valuing in-market life in the deal
 - Don't negotiate only on patent life
 - Use/process patents, trade secrets are valuable in extending life cycle
 - Unlike small molecule deals, use patents may be 'useful'
 - Terminal value becomes an important part of the valuation
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