

Applying “Value Based” Pricing to Regenerative Medicine Based Pharmaceuticals

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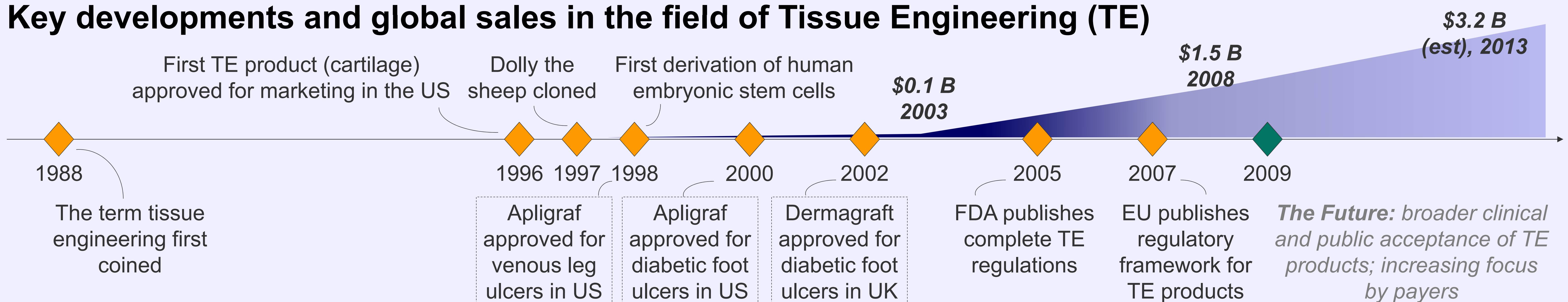
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Introduction

Over the last decade, attention has turned towards regenerative medicines and the potential benefits of tissue engineered (TE) products. Advances in stem cell technology have resulted in development of both autologous (individual patient-derived) and allogeneic (human-derived) products. Allogeneic regenerative medicines are likely to be marketed “off-the-shelf” similar to conventional biopharmaceutical products. This analysis will focus on the challenges they will face as they seek market access and undergo the process of pricing and reimbursement (P&R) in the absence of direct references. Our assessment includes a review of the P&R strategy employed by anti-TNFs when they entered the market and a case study contrasting the P&R approaches of two similar allogeneic skin products, Dermagraft and Apligraf.

Key developments and global sales in the field of Tissue Engineering (TE)



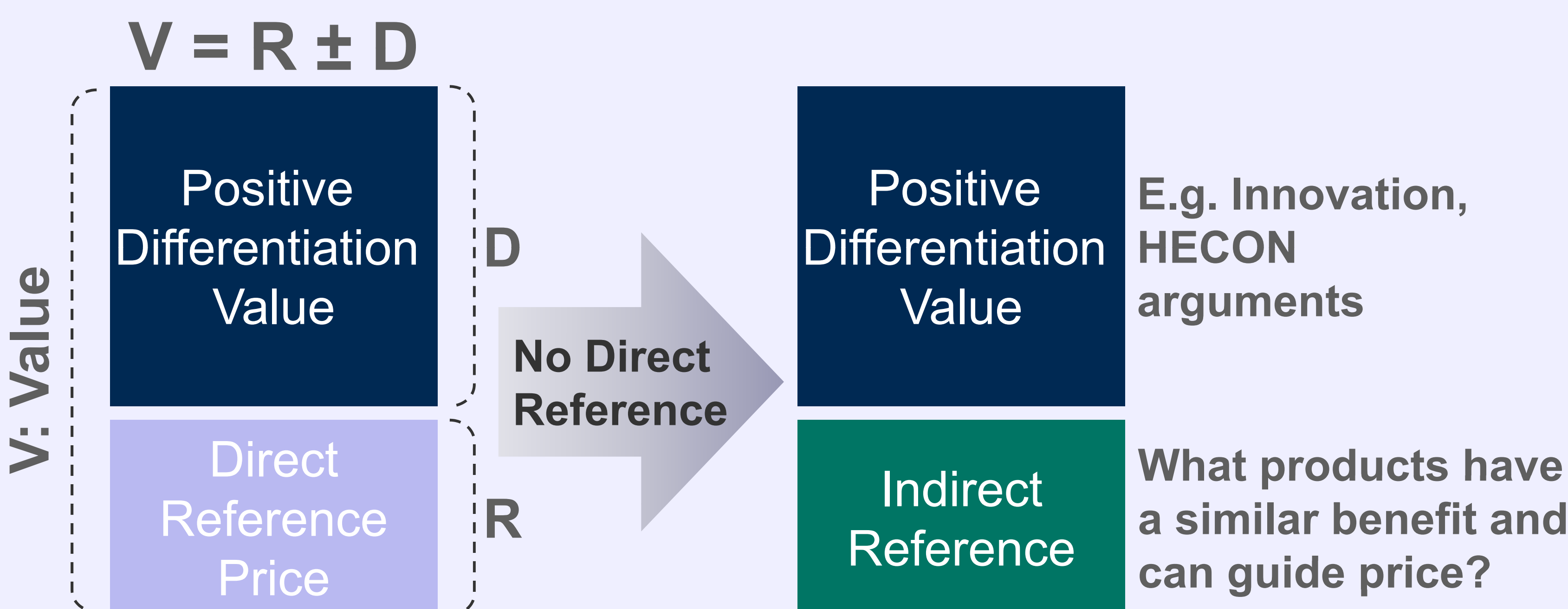
Methods & Results

Application of Value Based Pricing in the absence of direct references

Typical approach to value based pricing (VBP)

Manufacturers must have a keen grasp of VBP and how it applies to ensure that the value of TE products is appropriately recognized.

- Measuring differentiation from references is the crux of VBP and is a key challenge for innovative products lacking true direct references.
- Identifying appropriate indirect references is critical in communicating value to payers; these can include analogous innovations in other therapy areas as well as economic offsets.



VBP in the absence of direct references: the case of anti-TNFs

Remicade was the first anti-TNF α to enter the RA market and it developed a VBP strategy based on indirect referencing. Three key pricing tactics were employed by Remicade and can be used to inform VBP strategy for regenerative medicines:

- Appropriate Indirect Referencing:** Positioning as an adjunct to DMARDs and to delay/ avoid surgery made the cost of surgery a more appropriate indirect reference than a direct reference to DMARDs.

- Target Population Positioning:** Positioning later line reduced the patient volume and resulting budget impact.
- HECON argumentation:** Cost-offset and budget impact arguments supported reimbursement in target populations (e.g. positive NICE review for use following failure on two non-biologic DMARDs).

Remicade established a VBP using surgery avoidance as an indirect reference and positioning such that its budget impact could be justified with HECON arguments.

Case study: Value Based Pricing of Tissue Engineered chronic wound care products

Regenerative medicines will face similar challenges to the anti-TNFs in establishing a VBP in the absence of a direct reference. This is evidenced by the success and failure of Apligraf and Dermagraft, two TE chronic wound management products launched in the last decade.

	Dermagraft – Unsuccessful VBP	Apligraf – Successful VBP
Referencing	Inappropriate Referencing: Positioned as a dressing for diabetic foot ulcers with a total cost of treatment of ~£2000, Dermagraft was inappropriately referenced to conventional dressings. Without significant clinical differentiation, the incremental cost compared to this reference exceeded diabetes clinics’ willingness to pay.	Appropriate Referencing: Positioning as an adjunct to conventional wound care allowed indirect comparison to Regranex, a growth factor indicated for neuropathic diabetic ulcers. Apligraf was able to justify a 65%-230% premium to Regranex (depending on ulcer size) based on the strength of its differentiation.
Positioning	Inappropriate Target Population: Dermagraft’s clinical trials did not identify patient subgroups in which the product was most effective. This would have reduced the budget impact and provided a stronger argument to justify Dermagraft’s value.	Appropriate Target Population: Apligraf’s clinical trials targeted diabetic foot ulcer patients who responded poorly to conventional therapy, limiting its target patient population and resulting budget impact for payers.
HECON	Lack of HE argumentation: If a strong HECON case had been made, Dermagraft’s price may have been supported, allowing the product to remain on the market rather than being withdrawn.	HE argumentation: HE analyses for Apligraf demonstrating cost offsets associated with shorter treatment periods, fewer complications and fewer inpatient episodes are sufficient to support its VBP.

Conclusion

Value based pricing for innovative therapies in the absence of direct references requires careful analysis of patient populations in which the greatest value of innovation, clinical outcomes and economic advantages can be demonstrated. VBP strategy must take into account the funding available in each market and price/ volume trade-offs must be considered. Anti-TNFs exemplify the interplay between VBP and value based reimbursement, in which the strongest arguments are based on demonstrating clinical benefit relative to discrete patient populations in which HECON analyses can support budget impact. Allogeneic regenerative medicines will face significant challenges in establishing a value based price as they enter the market, and lessons learned from the successful pricing and positioning strategies employed by Remicade and Apligraf can infer challenges and opportunities for these novel and innovative therapies.