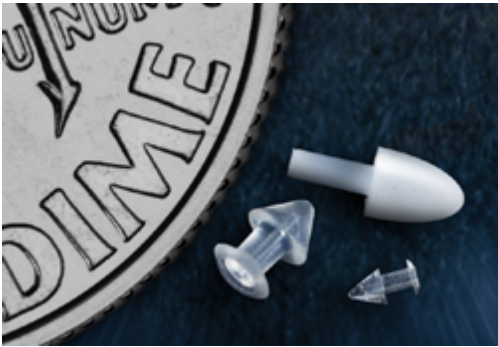


Medical Manufacturers Drawn to Fast Growth of Combination Products

Mark Paulsen



Combination products are a rapidly growing segment of the healthcare market that has attracted the interest of a growing number of medical device manufacturers. A combination product is comprised of two or more regulated components (i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic) that are physically, chemically, or otherwise combined or mixed and produced as a single entity.

This new category of FDA approved drug eluting medical devices holds great promise for advancing patient care compared to traditional drug delivery methods. Combination products provide controlled release of the active pharmaceutical ingredient (API). This allows API concentrations to be consistently maintained within an optimal therapeutic range. These drug eluting devices also allow for a targeted delivery of the API. Targeting permits higher therapeutic dosage to be delivered while minimizing side effects.

In many cases, existing drugs have been shown to exhibit greater efficacy at lower cost when delivered as a combination product. This is significant because historically only five out of 10,000 compounds investigated reach clinical trials. Of these, only one will be approved for human use. Early results suggest that many abandoned drugs may be safe and effective when manufactured and delivered as a combination product. As a result, medical device manufacturers are focusing on developing devices that employ new ways of introducing drugs into the body. The cost of device development is considerably less than drug discovery, and the potential upside of improving existing products and producing better patient outcomes is very attractive.

The growth rate of the combination product sector is outpacing both the pharmaceutical and medical device sectors of the healthcare industry. Transdermal

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combination products alone are on track to achieve \$20B in revenue by 2014. Advances in silicone rubber technology are a key component in the rapid market expansion for combination products. Silicone is uniquely well suited for manufacturing drug eluting devices. This has given rise to companies like ISSAC Medical in the U.S, who are among the vanguard of a new generation of silicone medical device manufacturers that are also licensed drug manufacturers.

Many are calling combination products the future of medicine. If they are right, the future is happening right now.

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[1] <http://www.issacmedical.com>