

Biological and Generic Biological field notes: Another look at the pending market dynamics

TEVA,AMGN,HOSP,J&J

- Debate over generic biological coming to market is about the amount of exclusivity the brand manufacturers (AMGEN, J&J) will have before the generic biosimilars (TEVA, HSP, RPCI) can come to market.
- The House voted on 8/3/09 to pass a provision as part of the overall Healthcare Reform Package to allow 12 years of exclusivity to brand manufacturers despite President Obama's plea for only 7 years and Senator Waxman's plea for only 5 years
- Branded category leaders (Amgen, Genentech, Genzyme) and other biotech companies with margins from 75% will be safe for 12 years from generic competition and health care cost decline for new biological drugs (for example Amgen's Denosumab).
- Share shift to generic biological from branded manufactures is coming soon. Thus companies such, as Teva, and the other few companies with biologic manufacturing capabilities, will be able to produce the older biological and sell them as soon as the FDA approval pathway is established. There is intense lobbying underway for a shorter timeframe of exclusivity.
- Trend for Big Pharma and the Biotech's is that the new biological will get at least 12 years before copies can be made. Regular drugs (made from chemicals) only get 5 years of exclusivity versus the proposed 12 years for biological (made from proteins). from regional and 3rd-4th tier brands (expected to grow in 2H09 as economy stagnates).

- Unit demand in the emerging markets abroad is outpacing US regions... benefiting branded biotech's weighted in these markets (**AMGEN, DIACHSU** and **J&J**).

Contacts report that demand for branded manufactures and generic biological (1in 5 of all prescriptions in WAG is TEVA) continued to build throughout the front half of the year with expectations that sales penetration will continue as aging population counterbalance unemployment rates and economic weakness in the US. Overall demand for drugs has increased with Amgen and TEVA set to launch new DTC (Direct to Consumer) campaigns in the near future remained relatively flat compared to last year.

Why do you care?

Can the FDA approve generic biological? Will congress approve a public and private option?

The result is patient health care goes down. This will affect market share, margin and revenue expectations for leading branded manufacturers.

For example a leading biotech company now has a per average health care cost of \$3000 per month.

If everyone switches to Biological it will only be 10% of the cost or \$300.

Buy and Bill Model : Doctor buys and bills patient or insurance company (only for injectibles) Doctors by law are not to supposed to promote the spread (used to be paid on awp (average wholesale price). Now they have changed the reimbursement rate to average selling price * 6% for doctors. This applies on to injectibles (doctors only)

Specialty pharmacies (Caremark) are the new growth market. Certain ailments require specialty drugs.

Other trends are PBM's (WAG, WMT, TGT, CVS)

The new trend is to open health clinics within the mass merchandisers' stores to get patients to fill prescriptions while shopping within that store.

.Wal-Mart and Target are spearheading the health clinics. Walgreen's has begun to fight back and has begun to open the same in select Walgreen's stores in order to thwart the competition. There will be no samples given from the practitioners in the clinics. The practitioners are also generally not physicians but rather RN practitioners or physician assistants with prescription writing authority.

Mail order as a whole is up however. Further, Walgreen's has had success-switching patients back from mail order based upon personal service. When questions arise about generics or deviations from the originating physician's prescription, Walgreen's pharmacists have been able to regain customers based on face-to-face conveyance of product knowledge. Consequently pricing issues facing the retail pharmacy from mail order are overcome by personal service. However, patients have said that they like the convenience of mail order, especially in times of inclement weather or for elderly patients.