

HEPATITIS C ACTION & ADVOCACY COALITION (HAAC)

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August 1, 2001

HAAC ALERT

GOOD NEWS: Schering-Plough To Market Unbundled Ribavirin

BAD NEWS: Prohibitive Pricing & Attempts To Block Generic and Compounded Alternatives Likely

Schering-Plough has received FDA approval to market Rebetol (ribavirin) separately from Rebetron (ribavirin and Intron-A packaged together in one kit). This is long overdue. Community and health care advocates have been fighting for separately available ribavirin for over three years.

People with hepatitis C must have access to ribavirin so that dosing and choice of interferon for combination treatment can be individualized to achieve the best possible results. But will the unbundling provide real access? Should we applaud Schering for its belated action?

Shortly after the Rebetron package was approved in June of 1998, the FDA issued a letter to Schering stating that the agency was willing to work with the company to unbundle ribavirin from the package. Schering could have done so at any time over the past three years. So why now?

SCHERING'S BOLD NEW PLAN

As much as we wish Schering's action were a response to the needs of patients, the timing of the unbundling has everything to do with market manipulation. The needs of people with hepatitis C don't figure into the equation. We're concerned that the company is playing out another strategy to hold patients and providers hostage to Schering's products. Consider the facts:

- ◆ Schering's exclusivity on ribavirin expires in December;
- ◆ A generic ribavirin is eligible to enter the market in January;
- ◆ Compounded ribavirin continues to be available by individual prescription through compounding pharmacies;
- ◆ Schering's pegylated interferon (PEG-Intron) was approved early this year as monotherapy;
- ◆ FDA approval of PEG-Intron + ribavirin combination therapy is expected as early as this month; and;
- ◆ FDA approval of Roche's brand of pegylated interferon (Pegasys) as monotherapy is expected soon.

PRICING

Schering is likely to set an exorbitant price for Rebetol (ribavirin) while charging very little mark-up in their combination kits (the "convenience" packaging). This would discourage off-label use of Rebetol with other interferons. Any price higher than the \$225 for an average month's supply charged by compounding pharmacies is unacceptable and should be met with public outcry.

At \$18,000 a year *before* adding in the ribavirin, PEG-Intron has already set the price bar ridiculously high. With this new strategy, Schering can claim to be helping patients by providing separate ribavirin, while actually making it prohibitively expensive to use with any other interferon. Institutions and third-party payers (the VA, Medicaid, HMOs, private insurers) may refuse to pay the higher price of separately packaged Rebetol.

The result? Patients will be forced to use Intron-A or PEG-Intron for combination therapy whether or not that is the best option for their individual treatment needs.

ACTIONS TO BLOCK GENERIC AND COMPOUNDED RIBAVIRIN

Compounded ribavirin has been available by individual prescription since July of 1999. Yet Schering has not sued any of the compounding pharmacies. If the company had filed suit against a compounding pharmacy and lost, they would have no standing to challenge a generic manufacturer in the courts on the same patent infringement issues.

We're concerned that Schering is likely to block a generic ribavirin from receiving a marketing license when the company's exclusivity on ribavirin expires in December. Once Schering has been notified that a generic manufacturer has applied to the FDA, the company can sue the generic maker for patent infringement. After that, regulations force the FDA to delay issuing any generic license until 30 months have elapsed or the case is settled, whichever comes first. Based on Schering's history of extensive litigation, the company may drag the matter out in court as long as possible to delay the FDA from issuing that generic license. Schering may use similar litigation to try to shut down access to compounded ribavirin as well.

The result? People with hepatitis C who might achieve better results from combination treatment with Pegasys or another interferon will be left with little alternative but to use Schering's Rebetol in combination with Schering's PEG-Intron.

THE BOTTOM LINE

In essence, Schering's likely strategy is to abuse the intent of the patent infringement provisions to extend its exclusivity on ribavirin, while setting the price of unbundled ribavirin so high as to put combination treatment with other interferons out of reach of most patients. The strategy is clever, cruel, and manipulative.

Community pressure is needed to ensure equitable access to treatment and allow patients and their providers to choose the best treatment option. We must develop community strategies to counter Schering's latest manipulations. Working together and with members of Congress, the FDA, the Federal Trade Commission, the Veterans Administration and third-party payers, we can put treatment choice where it belongs – in the hands of people living with hepatitis C.

Please start by sharing this alert with patients and providers.

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HAAC receives no money from any pharmaceutical company or pharmacy, including those mentioned in this alert. Our goal is to help folks like us in the HCV community make informed choices and have the access and flexibility to choose the treatment that will best meet their individual needs.