



the medical Review

H.P Acthar: A New Revenue Stream

H.P. Acthar Gel is a natural form of adrenocorticotrophic hormone (ACTH) originally synthesized in the 1940s. The drug is used mostly in children to treat infantile spasms, intractable seizures and opsoclonus myoclonus-ataxia syndrome. Opsoclonus myoclonus-ataxia syndrome (OMAS) is a rare disorder associated with the childhood brain tumor neuroblastoma. OMAS manifests itself with abnormal eye movements, muscle jerking, difficulty walking, rage attacks and psychomotor retardation. In early 2007, H.P. Acthar Gel could be obtained from a variety of pharmacies and its average wholesale price per 5 ml vial was \$2,069. Treatment continues indefinitely for these patients.

\$29,086.25. With no other avenue to obtain the drug, payors are forced to reimburse Curascript at these much higher prices.

In March 2008, Questcor issued a press release that noted "On August 27, 2007, Questcor implemented a new strategy and business model for its principal product, H.P. Acthar Gel. As a result of the new Acthar strategy and business model, net sales of Acthar were \$26.9 million for the fourth quarter of 2007, as compared to \$3.1 million in the fourth quarter of 2006, and \$48.7 million for the year ended December 31, 2007, as compared to \$12.1 million for the year ended December 31, 2006."

For patients without or denied coverage, Questcor provides Acthar for free through the National Organization for Rare Disorders (NORD). How magnanimous of them...

In August 2007 Questcor, the sole manufacturer of the drug, elected to stop selling the Acthar to wholesalers and its sole distributor of the drug became Curascript. Simultaneously, the average whole price of the same 5 ml vial increased to

Off-Label Drug Use*

The FDA provides a barrier to market entry and use of unproven and unsafe products. Once a drug is approved for a specific indication, the FDA has little involvement in overseeing how the drug is then used. Although off-label prescribing—the prescription of a medication in a manner different from that approved by the FDA—is legal and common, it is often done in the absence of adequate supporting data. Off-label uses have not been formally evaluated, and evidence provided for one clinical situation may not apply to others.

label use accounted for approximately 21% of prescriptions. The highest rates of off-label use were for anticonvulsants (74%), antipsychotics (60%), and antibiotics (41%). In an examination of off-label prescribing of 160 common drugs, off-label use was also found to account for 21% of all prescriptions, and most off-label drug uses (73%) were shown to have little or no scientific support. Atypical antipsychotics and antidepressants were particularly likely to be used off-label without strong evidence. Off-label use is widespread for many biologics (such as bevacizumab [Avastin]).

Evaluations have shown that off-label use is common but often not supported by strong evidence. A 2003 report showed that for the 3 leading drugs in each of the 15 leading drug classes, off-

Given the lack of supporting data justifying most off-label use, these claims should be carefully reviewed prior to reimbursement.

TOP 10 MOST EXPENSIVE HEALTH CONDITIONS (IN BILLIONS OF DOLLARS)

- Heart conditions: \$76
- Trauma disorders: \$72
- Cancer: \$70
- Mental disorders, including depression: \$56
- Asthma/COPD: \$54
- Hypertension: \$42
- Type 2 diabetes: \$34
- Joint diseases, includes osteoarthritis: \$34
- Back problems: \$32
- Normal childbirth: \$32

Note: Based on 2005 data for visits to doctors' offices, clinics, and emergency departments, and for hospital stays, home health care, and prescription drugs.

Source: Agency for Healthcare Research and Quality

The average manufacturer cost for a cochlear implant is \$20,000

THE BOTTOM LINE



Summer 2008
Volume 5, Number 2

The Medical Review
is a publication of
Advanced Medical Strategies

Written, designed and edited by
the AMS Public Relations Team
except * excerpted from *NEJM Volume*
358: 1427-1429



7 Kimball Lane
Building A
Lynnfield, MA 01940

Phone: 781.224.9711
Fax: 781.224.9713

E-mail: info@mdstrat.com

Find us on the web at:
www.mdstrat.com



Consider adding language addressing
coverage of off-label drug use.

The Kanzius Machine: A Future Cancer Cure?

John Kanzius is a former businessman and radio technician under treatment for leukemia. His cytotoxic chemotherapy led to his desire to find treatment that could kill cancer cells without destroying surrounding healthy cells and causing side effects. He invented the Kanzius machine, a device that uses radio waves to target malignant cells and break them down.

First, he discovered that radio waves could be sent from one box to another which could create enough energy to activate gas in a fluorescent light. He noted that he could pass his hands between the two boxes and nothing happened to the tissue. He then discovered that metal heats up when exposed to radio-waves which could be a potential mechanism for targeting cancer cells. The metal (such as copper, gold or carbon) can be injected into the tumor then exposed to the radiowave creating enough heat to

completely eradicate the tumor. The tissues that are not exposed to metal would not be heated and remain unaffected by the radio waves.

This method has only been applied to solid, localized tumors. The ultimate goal is to treat cancer that has metastasized to other parts of the body. This could be achieved by targeting microscopic cells with a specific antibody that implants into the tumor cell. The antibody does not bind to normal cells. The antibody contains the metallic particles which also embeds in the tumor. The patient is then exposed to the radio waves with only the microscopic cancer cells destroyed.

This invention is currently under animal research at the University of Pittsburgh and M.D. Anderson. Human trials are not expected for another four years, but preliminary animal data appears promising.

Drug Average Wholesale Price...Fixing

The Connecticut attorney general's office has filed a lawsuit accusing pharmaceutical distributor McKesson Corp. of illegally inflating the average wholesale price (AWP) of more than 400 brand-name drugs. This has resulted in millions of dollars in unnecessary costs to state-funded health plans.

The lawsuit, filed in U.S. District Court in May 2008 alleges that McKesson conspired with drug-price publisher First DataBank to arbitrarily raise average wholesale prices from 20%

to 25% on a variety of drugs, while maintaining wholesale acquisition costs (WAC) at current levels. WAC is the price pharmacies and providers pay distributors to purchase particular drugs while AWP is, theoretically, what these providers charge payors and consumers for the drug. In reality, providers charge much higher rates than AWP. The net effect was to increase reimbursement profit margins for providers and pharmacies, which ultimately increased the use of McKesson as a distributor by those entities.

Brand-name prescriptions for the treatment of allergies, arthritis, cholesterol, acid reflux and anxiety are among the drugs named in the lawsuit. The suit accuses McKesson of violating state consumer-protection laws and the federal racketeering act. McKesson officials declined to answer questions about the charges, but in a company statement said the claims appear to be based on allegations made in a 2005 class-action suit filed in Massachusetts. First DataBank has not been named in the lawsuit.

