

# LDI Specialty Drug News

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## Drug Safety Legislation Clears House

**The House of Representatives has voted to give the FDA more power to monitor the side effects of medicines after they reach the market.**

The vote gives the FDA authority to require post-approval studies of new medicines and to order additional warnings. The legislation also authorizes fines of \$250,000 for running false or misleading consumer-directed advertisement for prescription drugs.

The new powers for the FDA were included among several measures meant to improve the government's drug safety oversight, increase transparency of clinical trials and raise the fees manufacturers pay to speed reviews of new medicines.

The legislation comes on the heels of complaints of how the FDA handles serious side effects that come to light after drugs come to the market place. The agency has been criticized for being slow to respond to problems such as those related to Vioxx.

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The House is expected to vote on the full measure in July. Lawmakers then must reconcile the House legislation with a similar version that the Senate passed in May. The measure will then be sent to George W. Bush to sign into law.

Pharmaceutical Research and Manufacturers of America President, Billy Tuazin, said in a statement, "The legislation passed will preserve, and even strengthen, the FDA's ability to do its job. Patients will continue to have timely access to innovative therapies, and they can

be assured that the medicines they receive are reviewed under the most rigorous standards in the world today."

*\*Source: Washington Post*



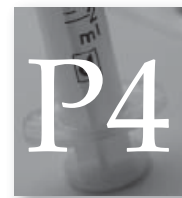
**Oral On-cologics-  
"Smart Pills" Hit the Market**



**Priority Review of Breast Cancer Drug**



**FDA Approves New Orphan Drug**



**Drug Listing by Disease/Condition**

# Oral Oncologics – “Smart Pills” Hit the Market

**The new “smart pills” attack tumors before they can grow and spread, giving hope to cancer patients that they can lead longer, more productive lives.**

That’s the aim of the oral oncologics, the new targeted therapies that increasingly are hitting the market and promise to tame run-away cells – theoretically making cancer a maintenance disease.

However, if cancer is categorized as a chronic disease it also means never having to stop taking medication. This has payers, physicians and patients concerned.

While new therapies create another treatment option for physicians the cost of those medications can be staggering. Tykerb (lapatinib) was recently approved by the FDA for treatment of late-stage breast cancer. The average annual cost of Tykerb will be in the neighborhood of \$35,000. Tykerb is used after a patient fails Herceptin (trastuzumab), so even though it’s an oral medication, it’s second line to the in-

fused drug. Among orals, one can be second-line therapy following another; for example, Sprycel is taken after a patient fails on Gleevac. This results in multi-level therapy options where before if one therapy didn’t work then it was on to radiation, transplants or nothing.

In 1995, only six oral cancer drugs were available. Today more than a dozen are on the market and the pipeline keeps filling. While it is a relatively small population who is using these drugs, they would have traditionally been treated with infused chemotherapy,

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and probably would not have survived. A lot of the oral drugs are improving survival rates so it is a new and growing category that is making a major impact on specialty drug spending.

Whether oral oncologics will advance survival rates and make cancer – the number two killer in the US

– a treatable chronic disease, can’t be answered yet, although early evidence does point to disease control.

*The following shows a select list of FDA-approved oral oncologic agents and their average cost:*

Trade Name	Indication	First FDA Approval	Cost
Sprycel	Chronic myeloid leukemia	2006	\$25,000 per course of treatment
Tarceva	Pancreatic cancer, Non-small cell lung cancer	2004	30/150mg \$3,400 (one month supply)
Iressa	Non-small cell lung cancer	2003	\$10,000 per course of treatment
Gleevec	Gastrointestinal stromal tumor, chronic myeloid leukemia	2001	\$40,000 est. per therapy course
Tykerb	Metastatic breast cancer	2007	150 tablets - \$3,339 (one month supply)
Revlimid	Multiple myeloma	2006	\$32,000 per course
Sutent	Kidney cancer, Gastrointestinal stromal tumor	2006	\$4,000 per 6 week course/\$38,000 annually
Thalomid	Multiple myeloma	2006	\$44,000 per course
Temodar	Brain tumors	2005	5/250mg \$1,910; \$11,000 per course
Zolinza	Cutaneous T-cell lymphoma	2006	\$45,000 per course

\*Source: *Biotechnology Healthcare*

# FDA Approves New Orphan Drug for Treatment of Pulmonary Arterial Hypertension

On June 15, 2007, the FDA approved Letairis (ambrisentan) for treatment of pulmonary arterial hypertension (PAH), a rare, life-threatening condition characterized by continuous high blood pressure within the arteries of the lungs.

John Jenkins, M.D., Director of FDA's Office of New Drugs stated that "Letairis represents a valuable addition to the treatment alternatives for this orphan disease. It is similar to an existing drug, but offers the potential for fewer drug interactions".

In PAH, the small arteries in the lungs become narrowed or blocked, which in turn makes the heart pump harder. In time, the overworked heart muscles become weak and lose the ability to pump enough blood through the lungs. People with PAH experience shortness of breath, fatigue, chest pain, dizziness and fainting. PAH currently affects approximately 100,000 people in the United States.

The safety and effectiveness of Letairis was demonstrated in two international clinical trials. Letairis significantly improved physical activity capacity compared to placebo. It also delayed the worsening of the condition.

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The most common side effects included swelling of legs and ankles, nasal congestion, sinusitis and flushing.

Letairis will be available in 5-milligram and 10-milligram once-daily tablets.

*\* Source: U.S. Food and Drug Administration*

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## Priority Review of Breast Cancer Drug

The FDA announced on June 19th that it is giving "fast track" priority review of an experimental cancer drug. The agency could reach a decision on approval in as little as six months. The typical review period is 10 – 12 months.

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The drug is Bristol-Myers Squibb's ixabepilone. The drug is a semi-synthetic version of a compound isolated from an African soil sample.

The FDA grants priority review to those drugs that are considered to be potentially significant compared to existing therapies. Bristol-Myers is seeking approval for ixabepilone to treat breast cancer patients who have not responded to prior treatment with chemotherapies.

Data submitted from a clinical trial demonstrated that ixabepilone and chemotherapy were significantly better than chemotherapy alone. In the study, 35 percent of those receiving the experimental drug in combination with chemotherapy had at least a 50 percent reduction in tumor size. This compared with 14 percent of patients who received chemotherapy alone.

Ixabepilone belongs to a new class of drugs called epothilones, which stop cells from properly dividing.

*\*Source: Reuters*

# Specialty Medication Listing by Disease/Condition

## AIDS/HIV

Daunoxome  
Doxil  
Intron A  
Roferon-A  
Serostim  
Taxol  
Fuzeon

## Alpha1 - Proteinase Inhibitor Deficiency

Aralast  
Prolastin  
Zemaira

## Antihemophilic Agents

Antihemophilic Factor  
Advate  
Alphanate  
Bioclote  
Helixate FS  
Hemofil M  
Humate P  
Hyate C  
Koate DVI  
Kogenate FS  
Monarc M  
Monoclate P  
Recombinate  
ReFacto

## Anti-nausea

Aloxi  
Anzemet  
Emend  
Kytril  
Zofran

## Asthma

Xolair

## Cancer/Related

Adriamycin  
Adrucil  
Alkeran  
Aredia  
Avastin  
BiCNU  
Blenoxane  
Busulfex  
Campath  
Camptosar  
Cerubidine  
Cosmegen  
Cytarabine  
Cytosan  
Depocyt

Doxil  
DTIC-Dome  
Eligard  
Ellence  
Erbitux  
Ethyol  
Faslodex  
Fludara  
Gemzar  
Gleevec  
Herceptin  
Hycamtin  
Idamycin  
IFEX  
Intron A  
Leucovorin  
Leukine  
Leustatin  
Lupron Depot  
Lupron Depot-Ped  
Mesnex  
Mustargen  
Mutamycin  
Mylotarg  
Navelbine  
Nexavar  
Nipent  
Novantrone  
Oncaspar  
Ontak  
Paraplatin  
Platinol AQ  
Proleukin  
Rituxan  
Roferon-A  
Sutent  
Tarceva  
Taxol  
Taxotere  
Temodar  
Thyrogen  
Toposar  
Trelstar Depot  
Trelstar LA  
Trisenox  
VePesid  
Vinblastine  
Vincasar  
Vumon  
Xeloda  
Zanosar  
Zoladex  
Zometa

## Contraceptives

Depo-Provera

## Crohn's Disease

Remicade

## Dystonia

Botox  
Myobloc

## Factor IX Concentrates

Alphanine SD  
Benefix  
Mononine  
Profilnine SD  
Proplex T  
Bebulin VH

## Gaucher's Disease

Ceredase  
Cerezyme  
Zavesca

## Growth Hormone Deficiency

Genotropin  
Humatrope  
Norditropin  
Nutropin  
Nutropin AQ  
Saizen

## Hematologics

Arixtra  
Aranesp  
Epogen  
Fragmin  
Innohep  
Lovenox  
Neulasta  
Neumega  
Neupogen  
Procrit

## Hepatitis C

Copegus  
Infergen  
Intron A  
Pegasys  
Peg-Intron  
Rebetron  
Roferon-A

## Hormone Deficiency

Delatestryl  
Delestrogen  
Depo-Estradiol  
Depo-Testosterone

## Hunter Syndrome

Elaprase

## Primary Immunodeficiency

Carimune NF  
Gamimune N  
Gammagard S/D  
Gammar-P  
Gamunex  
Iveegam EN  
Panglobulin  
Panglobulin NF  
Polygam S/D  
Venoglobulin-S

## Miscellaneous

Alferon-N  
Milrinone  
Zincard

## Multiple Sclerosis

Avonex  
Betaseron  
Copaxone  
Novantrone  
Rebif  
Tysabri

## Osteo/ Rheumatoid/ Psoriatic Arthritis

Enbrel  
Humira  
Hyalgan  
Kineret  
Orencia  
Remicade  
Supartz  
Synvisc

## Osteoporosis

Forteo  
Miacalcin

## Psoriasis

Amevive  
Enbrel  
Raptiva  
Remicade

## Respiratory Syncytial Virus

Synagis

## Rh Hemolytic Disease

BayRho-D  
Micro-Rhogam  
Rhogam  
WinRho-SDF