



integrated pharmacy services

# LDI Specialty Drug News

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## Generic Insulin Controversy

**Diabetes. It's a common disease that is unfortunately on the rise. In some areas of the United States it is considered an epidemic. Heart disease and kidney failure follow in its path so it is imperative that diabetics stay true to their treatment regimens.**

In the recent debates regarding biogenerics, insulin is at the top of the list. The drug is expensive and indispensable in the treatment process. Scientists agree that creating generic insulin would be easier than creating most other biologic equivalents.

Six years ago the FDA was to release guidelines for approval of generic insulin. This past February the agency announced that guidance would not be forthcoming, at least not for a while. Several days after that an-

*Biologics are typically 20 times more expensive than traditional drugs. The market accounted for \$32.8 billion in 2005.*

nouncement Congress reacted with proposed legislation that forced the FDA's hand. Eleven governors contacted the FDA demanding that it ease the way for production and

sale of generic insulin. Named the Access to Life-Saving Medicine Act, it would expand Waxman-Hatch to include biologics. The act does recognize that because biotech drugs are produced from living cells, their generic versions are more chemically complex than traditional medications. The proposed law therefore,

establishes stipulations for case-by-case approvals.

Sara Radcliffe, VP for scientific and regulatory affairs of the Biotechnology Industry Organization (BIO), which represents the industry said, "No one is arguing that there is no potential value in financially available forms of insulin. The issue is safety and effectiveness. The complexity of biopharmaceuticals is far greater than that of other drugs. While insulin relies on small non-glycosylated proteins, it doesn't mean that it is simple to create an insulin product."

Several drugmakers are currently in the process of developing generic versions of biopharmaceuticals because patents on brand drugs have expired, or will soon. In this country the insulin market is dominated by Eli Lilly (Humulin), Novo Nordisk (Novolin) and Sanofi-Aventis



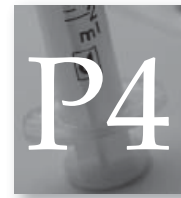
**Discarding Unused Drugs: Are They Toxic To Our Environment?**



**Imatinib Treatment for Advanced Gastro-intestinal Tumors**



**Ask the LDI Clinical Pharmacist**



**Drug Listing by Disease/Condition**

**-continued, Generic Insulin Controversy** (Lantus). Humulin and Novolin have already lost much of their patent protection so these companies have a vested interest in creating new products.

According to Barr Laboratories, a large generic manufacturer, Novo Nordisk should be more worried because the science behind biologics is not as complex as brand manufacturers say it is. "We have the knowledge necessary to understand and deal with it", says Bruce Downey, Chairman. "At this point, given the political pressure, it's just a matter of time."

Insulin is among the most readily accessible biopharmaceuticals to generic substitution, say scientists. But there is no standard approval pathway for generic versions of biologics. Unanticipated responses, such as reactions to the generic versions are a real concern.

For example, Eprex, a European antianemia biologic that Johnson & Johnson markets, had a problem after a minor manufacturing change. Several patients developed an allergic reaction to the product because of the rubber stoppers used in the syringes. Johnson & Johnson has corrected the problem but it does highlight how volatile even small changes to the process can affect the drug.

This example exemplifies what the controversy surrounding generic biologics comes down to: the chemical complexity of drugs derived from living organisms and the unforeseen consequences implied by such complexity. That and money, of course.

Biologics are typically 20 times more expensive than traditional drugs. The market accounted for \$32.8 billion in 2005. It's no surprise that this represents the fastest-growing section of the prescription drug market. It is predicted this figure will exceed \$60 billion by 2010. People in this country spend \$3.3 billion a year on insulin alone most of which is covered by Medicare, Medicaid and health plans. If generic versions of insulin become available the cost could drop by as much as 25%.

Given that drug compliance is key when dealing with the often devastating effects of diabetes, there is no one that should be denied access to the drugs because they are too expensive. \*Source: Drug Topics

## Discarding Unused Drugs: Are They Toxic To Our Environment?

It's a typical scenario. You're cleaning out a medicine cabinet and come across bottles of unused medication. If you're like most people, you flush them. Gone. Forgo. Or, are they?

At a recent convention in Atlanta, the officials from the U.S. Fish and Wildlife Service

announced the launch of SMARxT Disposal, a national consumer awareness program. Evidence is growing that many drugs are ending up

in our drinking water. For example, the U.S. Geological Survey found traces of 22 pharmaceuticals ranging from acetaminophen to fluoxetine to warfarin in Boulder Creek in Boulder, CO. Other studies have found traces of drugs in fish. A program set up in the state of Oregon revealed that in a two-month period 45, 5 gallon containers of unused medications were collected at pharmaceutical return sites. What would the impact have been had these medications been flushed, poured down the drain or just tossed in the trash?

So how does one safely dispose of unused prescription drugs or OTC

medications? The federal government advises that consumers should crush solid medications or dissolve in water and combine them with an undesirable substance, such as kitty litter or used coffee grounds. The medication should then be placed in a sealed bag or container before disposing in the trash. The

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FDA has ruled that some medications are safe to flush, however, check with a pharmacist before doing so. Your local pharmacy may have a collection box for unused medications that are taken to a hazardous waste site for incineration.

The American Pharmaceutical Association and government officials are working toward better disposal solutions. Among them are establishment of a take-back program in which drugs are taken back to central locations. Another option is reverse distributors. The firms facilitate the return of drugs to manufacturers for credit.

Another way to impact this growing issue is to address the prescribing practices that lead to medication waste. There is no way to solve disposal problems without the concept of pollution prevention.

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## Imatinib (Gleevec) Treatment for Advanced Gastrointestinal Stromal Tumors

**A recent randomized European trial indicated that patients who are being treated with Imatinib for advanced gastrointestinal stromal tumors (GIST) ran a risk of rapid disease progression if the treatment was interrupted. The results of the study were published in the March 20th Journal of Clinical Oncology.**

Imatinib can provide tumor control and prolong overall survival in up to 90 percent of patients with advanced GIST. Side effects of Imatinib are usually mild but are often chronic and include fluid retention, nausea, vomiting, muscle cramps, rash and headaches. The standard treatment of GIST is to administer Imatinib until the tumor progression or recurrence develops. Patients who are experiencing side effects often request treatment interruption if their cancer is under control. However, clinical studies were previously unavailable to determine if the interruption is safe.

The randomized trial assigned 58 patients who had taken Imatinib for more than one

# Ask the LDI Clinical Pharmacist

*Do you have a question regarding specialty medications? At LDI our Clinical Department is available to answer your questions.*

Almost every day it seems a new specialty medication gains FDA approval. As an employer, case manager, underwriter or claims manager, the information available on these drugs can be overwhelming or it can be hard to find. In some cases, there is a fine line between off-label use or treatment protocols.

*Some of the common questions our clinical department answers are:*

- Is a particular drug considered a specialty medication or is it a traditional drug?
- Is a HCPCS (J Code) a physician billed considered specialty?
- What type of monitoring is needed during RSV season to ensure that a baby is receiving the proper dosage of Synagis?

*Another function of our Clinical Department is monitoring treatment therapies such as:*

- Care planning and growth assessments every six months for growth hormone therapy.
- Medication adherence monitoring for patients receiving Hepatitis C therapy.

LDI would like to be your resource when you need answers to your specialty drug questions. Please e-mail your questions to our Clinical Department at [smh@ldipbm.com](mailto:smh@ldipbm.com).

**Imatinib, continued** - year and whose disease was under control to either continuation of the treatment or interruption. Of the 26 who continued treatment, 8 had disease progression. In the patients who interrupted treatment, 26 of the 32 patients experienced disease progression. This outcome caused the trial to be stopped and it was recommended to physicians to restart treatment.

Of the 26 patients that restarted treatment, 24 again achieved tumor control. No difference in overall survival rates were seen in either group. The final result of the trial concluded that for GIST, interruption of Imatinib is not recommended.\*Source: National Cancer Institute

*For more information regarding LDI's Specialty Newsletter, please contact us:*

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## Tykerb Gets FDA Approval for Treatment of Breast Cancer

Tykerb (GlaxoSmithKline) in combination with Xeloda (Roche) has been approved for treating advanced or metastatic breast cancer. Tykerb, given once-daily, is an oral therapy used to combat breast tumors that overexpress human epidermal receptor type 2 (HER2) in patients who have already received treatment with Herceptin (Genentech).

Tykerb targets tor proteins on cells. These revery important to growth and divi-inhibits the growth proteins thereby targeted therapy.

“This is the fu-cancer therapy”, Boehnke Michaud, the University of Anderson Cancer Center. “Over the past 10 years, we have been able to improve rates of survival and duration of life for women with metastatic breast cancer through the development and availability of new drugs.

“This is the future of cancer therapy”, says Laura Boehnke Michaud, Pharm, D., at the University of Texas M.D. Anderson Cancer Center. “Over the past 10 years, we have been able to improve rates of survival and duration of life for women with metastatic breast cancer through the development and availability of new drugs.

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ture of says Laura Pharm, D., at Texas M.D.

Tykerb is available in 250 mg tablets. Current AWP pricing is \$24.17 per tablet. Doses of Tykerb can range from 500 mg per day to 4500 mg per day depending upon individual needs. \*Source: Drug Topics

# 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  
Monoclote 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