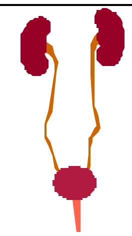
Urinary Incontinence

New Therapies Expanding The Market

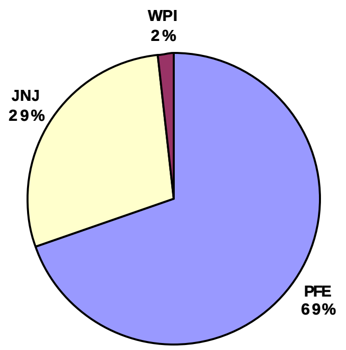


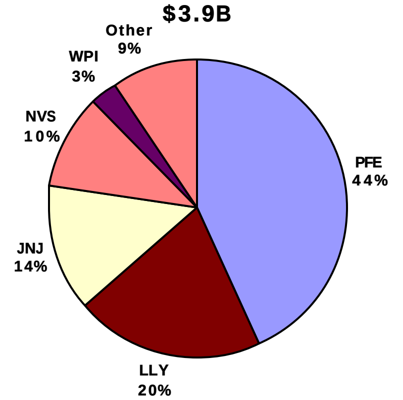
23% CGR 2003-08

DEFINITION / BACKDROP

Urinary incontinence (UI), the loss of bladder control or the leakage of urine, results from numerous causes, including pelvic muscle instability, pregnancy, surgery, urinary tract infections, and certain foods and medications. Urinary incontinence includes urge incontinence (characterized by a frequent desire to urinate) and stress incontinence (characterized by weak bladder muscles). Overactive bladder encompasses both increased urinary frequency and urge to urinate. More than 13MM Americans suffer from some form of urinary incontinence, and 18MM+ from overactive bladder. Pharmacologic therapies, pelvic muscle rehabilitation, and surgery are most frequently used to treat urinary incontinence and overactive bladder. Currently available pharmaceutical treatments address symptoms of urge incontinence but side effects are an issue. Stress and mixed incontinence account for over half of incontinence sufferers, providing a ready market for new therapies.

Urinary Incontinence Category Market Share By $ Sales





PARTICIPANTS

Pfizer's Detrol/Detrol LA (tolterodine) franchise should continue to lead the overactive bladder/urge incontinence market through 2008, driven by the strong clinical profile of Detrol LA. J&J's Ditropan XL dollar share could decline given that newer therapies, including Watson Pharmaceuticals' Oxytrol, Indevus' Trospium, Novartis' Enablex, and Yamanouchi/GlaxoSmithKline's Vesicare, may offer fewer side effects. Eli Lilly's Duloxetine, for stress and mixed urinary incontinence, should be a major force in this market.

MAJOR TRENDS & ISSUES

– The UI and overactive bladder patient populations are large, but difficult to penetrate given lack of effective therapies and embarrassment over the consequences of the ailments.

– New drug therapies with improved side-effect profiles have brought many patients into the treatment stream. The move from generics to new treatments has "re-branded" the category.

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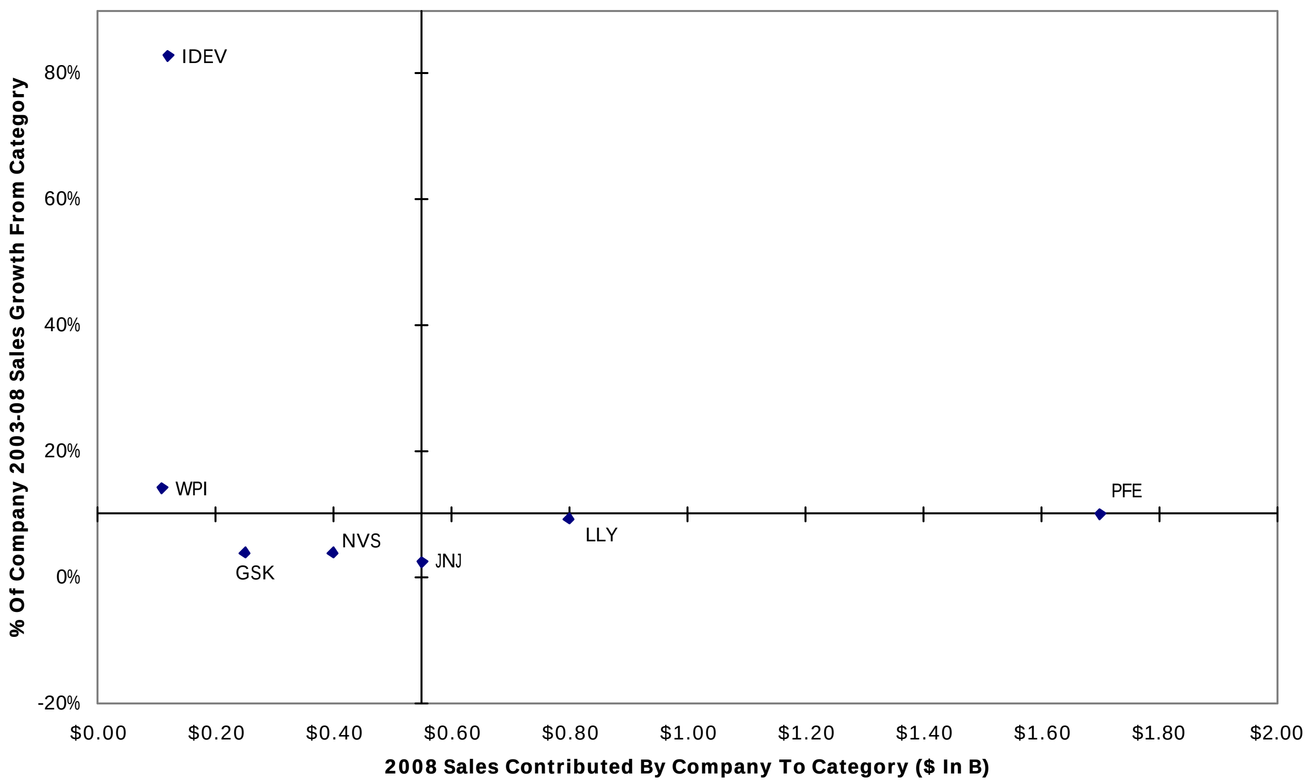
- Branded products for urge incontinence and overactive bladder, led by Pfizer's Detrol LA and JNJ's Ditropan XL, appear comparable in terms of effectiveness and side effects. Oxytrol's (Watson) improved side-effect profile and twice-weekly patch delivery system provide a differentiated alternative to oral anticholinergic therapies.
- Yamanouchi/GlaxoSmithKline's Vesicare, Novartis' Enablex, and Indevus' Trospium may improve upon the tolerability of current agents, although their mechanisms are similar. Head-to-head comparison studies will be required to claim superiority. Trospium appears most differentiated based on a lower CNS side-effect profile, but the current twice-daily dosing regimen will be a hurdle.
- Eli Lilly's Duloxetine could double the potential market by targeting a new patient population of stress and mixed incontinence sufferers.
- Our scatter plot shows that through 2008, Pfizer should dominate the incontinence market. Indevus should see the majority of its sales growth from this category.

Urinary Incontinence



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ESTIMATED U.S. MARKET FOR URINARY INCONTINENCE (STRESS + URGE) DRUGS*

	2003	2004E	2005E	2006E	2007E	2008E	CGR	Comment
U.S. Population/Prescriptions (000's)								
Overactive Bladder Sufferers	19,634	20,262	20,890	21,517	22,163	22,827	+3%	- 18MM+ Americans with overactive bladder
% Growth	+3%	+3%	+3%	+3%	+3%	+3%		
% With Urge & Stress Symptoms	100%	100%	100%	100%	100%	100%		
Urge/Urge Predominant UI Sufferers	19,634	20,262	20,890	21,517	22,163	22,827	+3%	- Includes portion of patients with mixed UI
% Growth	+3%	+3%	+3%	+3%	+3%	+3%		
% Incontinence Pts Seeking Treatment	38%	38%	41%	44%	47%	49%		- Patients seeking treatment increase with better
Incontinence Pts Seeking Treatment	7,366	7,695	8,565	9,454	10,350	11,071	+8%	diagnosis, availability of newer treatments
Drug Therapy Market Share	44%	45%	48%	51%	53%	54%		- Drug therapy market share expected to climb
Incontinence Pts Placed On Drug Tx	3,209	3,461	4,090	4,811	5,461	6,016	+13%	significantly with introduction of Duloxetine
Drug Therapy Retention Factor	47%	50%	52%	52%	53%	54%		- Newer products with fewer side effects and longer
Incontinence Pts Compliant With Tx	1,504	1,741	2,139	2,514	2,899	3,273	+17%	duration and new products for stress incontinence
% Incontinence Pts Compliant With Tx	8%	9%	10%	12%	13%	14%		
Number of Scrips Filled/Year	**15,837**	**18,296**	**22,318**	**26,082**	**30,023**	**33,848**	**+16%**	**- Newer products for urge incontinence and**
% Growth	**+5%**	**+16%**	**+22%**	**+17%**	**+15%**	**+13%**		**2005 introduction of Duloxetine for SUI**
Detrol LA (PFE) Market Share	**40%**	**43%**	**41%**	**38%**	**36%**	**35%**		**- Once-daily LA launched 1/01**
Prescriptions (000's)	6,382	7,865	9,117	10,019	10,887	11,723		- Improved side-effect profile compared to Detrol
Price Therapy/Day	$2.40	$2.50	$2.55	$2.60	$2.65	$2.70		
Detrol LA Sales ($MM)	**$545**	**$700**	**$830**	**$930**	**$1,030**	**$1,130**	**+16%**	
Duloxetine (LLY) Market Share			**10%**	**16%**	**21%**	**24%**		**- Eli Lilly expected to launch in Q1:2005**
Prescriptions (000's)			2,224	4,253	6,273	8,239		- Stress urinary incontinence; first in class product
Price Therapy/Day			$2.55	$2.60	$2.65	$2.70		
Duloxetine Sales ($MM)			**$200**	**$400**	**$600**	**$800**	**NA**	**-**
Ditropan XL (JNJ/AZA) Market Share	**28%**	**28%**	**24%**	**21%**	**19%**	**17%**		**- New treatments with lower side effects clip**
Prescriptions (000's)	4,512	5,185	5,363	5,479	5,644	5,804		- Launched 2/99 for overactive bladder
Price Therapy/Day	$2.40	$2.50	$2.55	$2.60	$2.65	$2.70		
Ditropan XL Sales ($MM)	**$379**	**$455**	**$480**	**$500**	**$525**	**$550**	**+8%**	
Oxytrol (WPI) Market Share	**2%**	**4%**	**4%**	**4%**	**4%**	**4%**		**- Oxybutynin patch; improved side-effect profile**
Prescriptions (000's)	331	752	967	1,136	1,263	1,389		- Marketed by Women's Health, GP Division & CSO
Price Therapy/Day	$2.15	$2.25	$2.35	$2.40	$2.40	$2.40		
Oxytrol Sales ($MM)	**$23**	**$55**	**$75**	**$90**	**$100**	**$110**	**+37%**	
Enablex (NVS) Market Share		**2%**	**4%**	**5%**	**5%**	**6%**		**- Sold by Pfizer to Novartis in Q1:2003**
Prescriptions (000's)		353	784	1,209	1,617	2,011		- NDA Q1:2003; H2:2004 launch assumed
Price Therapy/Day		$2.50	$2.55	$2.60	$2.65	$2.70		
Enablex Sales ($MM)		**$30**	**$70**	**$110**	**$150**	**$190**	**NA**	**- Side-effect profile clips potential**
Trospium (IDEV) Market Share		**1%**	**3%**	**3%**	**4%**	**4%**		**- NDA Filing 4/03; H2 2004E launch**
Prescriptions (000's)		125	577	879	1,078	1,270		U.S. trials positive on side effects/efficacy
Price Therapy/Day		$2.50	$2.55	$2.60	$2.65	$2.70		
Trospium Sales ($MM)		**$10**	**$50**	**$80**	**$100**	**$120**	**NA**	
Vesicare (YM-905) Market Share		**1%**	**3%**	**3%**	**4%**	**4%**		**- NDA Filing 12/02; H2:2004E launch**
Prescriptions (000's)		125	577	879	1,078	1,270		GlaxoSmithKline co-marketing in U.S.
Price Therapy/Day		$2.50	$2.55	$2.60	$2.65	$2.70		
Vesicare Sales ($MM)		**$10**	**$50**	**$80**	**$100**	**$120**	**NA**	
Detrol (PFE) Market Share	**8%**	**5%**	**3%**	**2%**	**1%**	**1%**		**- Continued conversion to LA**
Prescriptions (000's)	1,199	907	654	405	405	405		
Price Therapy/Day	$2.40	$2.50	$2.60	$2.80	$2.80	$2.80		- Price increases bolster switch to Detrol LA
Detrol Sales ($MM)	**$102**	**$80**	**$60**	**$40**	**$40**	**$40**	**-17%**	
Generic Oxybutynin Market Share	**14%**	**9%**	**6%**	**5%**	**4%**	**4%**		**- Share decline with launch of new UUI therapies**
Prescriptions (000's)	2,161	1,700	1,400	1,270	1,225	1,225		
Oxybutynin Generics Sales ($MM)	**$28**	**$22**	**$18**	**$17**	**$16**	**$16**	**-11%**	
Other Therapies Sales ($MM)	**$18**	**$19**	**$10**	**$13**	**$14**	**$14**	**-5%**	**- Other generics (flavoxate, imipramine, etc.)**
U.S. Incontinence Drug Sales ($MM)	**$1,095**	**$1,381**	**$1,843**	**$2,260**	**$2,675**	**$3,090**	**+23%**	**- Improved treatments, better compliance**
% Growth	**+17%**	**+26%**	**+33%**	**+23%**	**+18%**	**+16%**		**(Market sales include generics)**

Source: SG Cowen estimates, IMS Monthly Prescriptions.

** Patient population and scrips in 000's; sales in $MM.*

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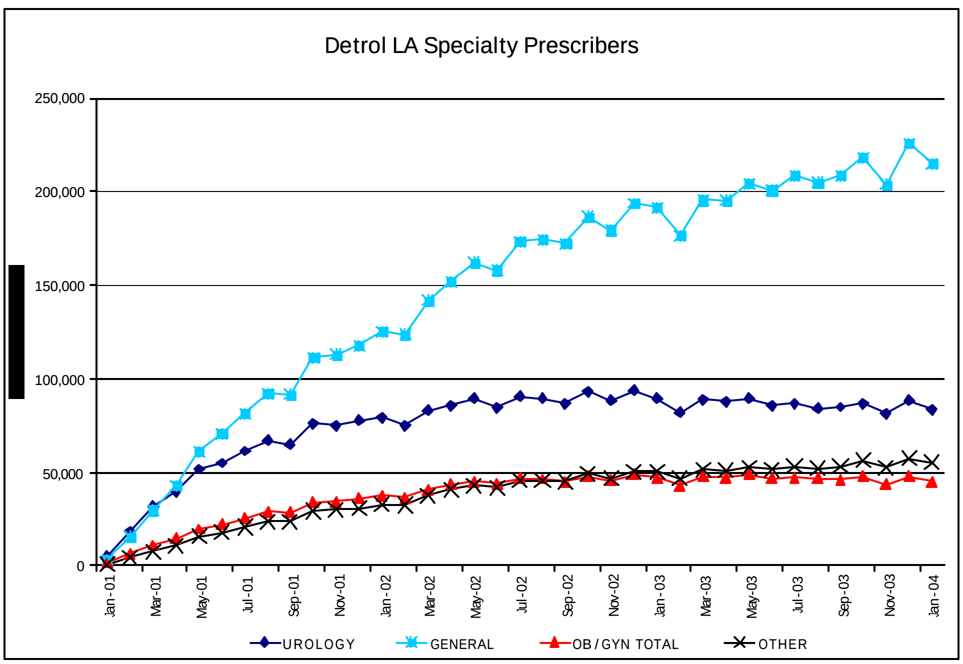
Detrol/LA and Ditropan XL Dominate The Treatment Market

Both Detrol/LA and Ditropan XL are advances over prior therapy due to their reduced incidence of side effects (particularly dry mouth) and improved dosing regimen. Immediate-release oxybutynin generally is dosed at 2.5mg two or three times daily. At the 5mg dose, up to 70% of patients discontinue use of immediate-release oxybutynin within six months due to side effects, particularly dry mouth. Detrol is dosed at 2mg twice daily, with no titration. Detrol LA is dosed at 2-4mg once-daily and Ditropan XL is dosed at 5-30mg once daily, with the dose titrated to efficacy and patient tolerance. In the clinical studies published in the package inserts, Detrol and Detrol LA show superior tolerability to Ditropan XL, with dry mouth incidence reported at 39.5% for Detrol and 23.5% for Detrol LA, versus 60.8% for Ditropan XL. On the efficacy front, the drugs appear similar in their reduction (17-22%) of urinary frequency, although Ditropan XL may be superior in terms of reducing incontinence episodes. Detrol, Detrol LA and Ditropan XL garnered 80%+ of new prescriptions in the incontinence market in 2003.

– Pfizer's Detrol Franchise Holding Steady

Detrol and Detrol LA have dominated the overactive bladder/urinary incontinence market. A wide-reaching patient and physician education program has increased treatment of incontinence and overactive bladder. Detrol is efficacious in reducing the number of micturitions and in increasing the volume voided per micturition, and Detrol LA has shown similar results with an improved dosing profile. The Detrol franchise continues to capture nearly 50% of new prescriptions, bolstered by once-daily Detrol LA. Detrol LA's NRx share decreased modestly to 41.0% in January 2004 from 41.5% in February 2003, and Detrol market share declined from 10.4% in February 2003 to 7.4% in January 2004, trimmed by the launch of Watson's Oxytrol. With Pfizer's primary care reps currently promoting Detrol LA in the U.S., the Detrol franchise has maintained strong penetration of the general practitioner market. In January 2004, nearly 54% of all Detrol LA prescriptions were written by general practitioners.



Source: SG Cowen, IMS Monthly Prescriptions

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