

September 1999

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# U.S. Major Pharmaceuticals

## The Issues

Reason for Report: Industry Update

# Industry

### Investment Highlights:

- **The pharmaceutical industry for the bulk of 1999 has under-performed relative to the broader market. From our perspective this is the result of three factors weighing on the group: 1) diminishing change in earnings growth rates for the pharmaceutical industry relative to the change in S&P earnings growth rates; 2) relative sparseness of expected new product launches in 2000-2001 as compared to 1996-1999; and 3) the potential for reform of the Medicare system. The most important of these factors in our view is the first one listed. This report reviews these three factors in detail.**
- **Currently the valuation of the group relative to the S&P (on a trailing twelve-month P/E basis) is at a 28% premium with Pfizer, and 20% without Pfizer. This is below the levels seen from 1958-1982, and toward the bottom end of the range for the 1980s. Therefore, despite the group's recent strength, its relative valuation continues to be attractive. The risk to this relative valuation, however, continues to be the potential for upward revisions in S&P earnings forecasts.**
- **From a technical perspective, the DRG index is currently at 364 and has demonstrated support in the 335-345 range and resistance at the 380-382 level. Presently, the group appears to be bracketed in a trading range and is approaching the upper limit of that range.**
- **To break out of the range, the time rate of change in S&P earnings growth needs to moderate relative to that of the pharmaceutical group, which would be a catalyst for continued rotation of money into the sector. We are currently looking for this to happen late this year or early next year.**
- **Therefore we appear to be at a crossroads of where the group could go. If the economy slows down and there is a rotation into the group, then the high multiple, high growth names will likely lead the group to higher valuations. If this does not occur, then the low multiple names will likely outperform. We currently favor stocks that either offer compelling value, are counter-cyclical in that they still have new product launches sitting in front of them in the near term, or both. We believe these names will likely perform well on a relative basis in either economic scenario outlined above. Our top-picks are Bristol-Myers (\$70 3/8, BMY, A-1-1-7) and Warner-Lambert (\$66 3/8, WLA, B-1-1-7).**

## Introduction

The U.S. pharmaceutical industry has now seen more than two quarters of stock price under-performance relative to the broader market. The purpose of this report is to review the factors that are the cause of this under-performance and to elaborate on our reasoning as to why the situation may change later this year or in early 2000.

From our perspective the three primary factors weighing on the group are: (1) superior acceleration of earnings growth for the S&P as compared to the drug group; (2) relative sparseness of the industry's pipeline compared to the last few years, which is compounded for certain companies by patent expirations in the coming years; and (3) the fear of and confusion surrounding potential Medicare reform.

Despite these factors, the fundamentals for the industry are strong, and we expect earnings to be largely in-line or better than expectations over the next several quarters.

### U.S. Large Cap Pharmaceuticals EPS Expectations

Company	3Q:99E	4Q:99E	1999E	2000E
American Home Products (A-2-2-7)	\$0.48	\$0.46	\$1.77	\$2.01
% change y/o/y	3%	4%	-1%	14%
Bristol-Myers Squibb (A-1-1-7)	\$0.54	\$0.51	\$2.05	\$2.31
% change y/o/y	15%	15%	14%	13%
Eli Lilly (A-2-2-7)	\$0.62	\$0.61	\$2.28	\$2.65
% change y/o/y	17%	22%	18%	16%
Merck (A-2-2-7)	\$0.64	\$0.67	\$2.46	\$2.75
% change y/o/y	14%	16%	14%	12%
Pfizer (A-2-1-7)	\$0.22	\$0.23	\$0.83	\$0.97
% change y/o/y	30%	25%	24%	17%
Pharmacia & Upjohn (B-3-2-7)	\$0.47	\$0.50	\$1.80	\$2.04
% change y/o/y	15%	11%	14%	15%
Schering-Plough (A-2-1-7)	\$0.34	\$0.34	\$1.41	\$1.64
% change y/o/y	18%	20%	20%	17%
Warner-Lambert (B-1-1-7)	\$0.48	\$0.53	\$1.95	\$2.35
% change y/o/y	38%	35%	35%	20%

Source: Merrill Lynch Research Estimates

## U.S. Issues

### Macro Issue – Lower Relative Earnings Acceleration

In the fourth quarter of 1998, a marked reversal in the relative time rate of change in earnings growth of the drug group versus the S&P occurred, in that the change in earnings growth of the S&P exceeded that of the large cap pharmaceutical group. The change in S&P earnings growth is likely to be at parity or exceed that of the drug group until the fourth quarter of this year or into 2000. If upward S&P earnings revisions continue to be made, this time line may be pushed back. Therefore the group could continue to suffer from “competition for money” in the near term as investors place bets in sectors with better near term earnings acceleration.

Our belief is that, in general, the drug group should outperform the overall market when the sequential or time rate of (i.e. Q2:98 vs. Q1:98) change in the growth rate for the drug group compares favorably to that of the S&P 500. We attempt to illustrate this point in the table below. To calculate the sequential change in growth rate (or “ $\Delta$  growth rate”), we simply take the difference of a given quarter’s earnings growth rate and the preceding quarter’s earnings growth rate. We then compare the sequential change of the earnings growth for the drug group with that of the overall market. As seen in the table below, a negative “Difference” number for the drug group is generally correlated with stock price under-performance by the drug group - as defined by the DRG index. While this correlation is not strictly accurate in numerical terms, it seems to be quite suggestive directionally.

In our view, the key variable in predicting when the drug group should begin to outperform the S&P lies in the performance of S&P 500 earnings over the next several quarters. In the table below, we used the First Call mean for the S&P 500 earnings per share. The relative slowing of S&P 500 earnings growth that the Street is expected to see in Q4:99 suggests that the drug group could begin to outperform in that quarter. The risk to this forecast, as mentioned above, is that we continue to see upward revisions to S&P earnings forecasts, which would push a potential reversal out in time.

We therefore are not expecting a major rotation into the group until later this year. We believe a change in relative earnings growth acceleration favoring the drug group will be needed to push it out of its current trading range.

Relative Change in Growth Rates for the Drug Group

	Q2:98	Q3:98	Q4:98	Q1:99	Q2:99	Q3:99E	Q4:99E
<b>EPS Growth</b>							
U.S. Drugs	19%	20%	20%	16%	13%	16%	16%
S&P 500	3%	-5%	1%	10%	9%	20%	13%
<b><math>\Delta</math>Growth rate</b>							
U.S. Drugs	4%	1%	1%	-4%	-3%	3%	0%
S&P 500	2%	-8%	6%	9%	-1%	10%	-7%
Difference	2%	9%	-5%	-13%	-2%	-7%	7%
<b>Price Change</b>							
DRG	5%	-4%	19%	5%	-7%	-4%*	?
S&P 500	2%	-13%	23%	5%	8%	-5%*	?
DRG relative	2%	9%	-3%	0%	-16%	1%*	+

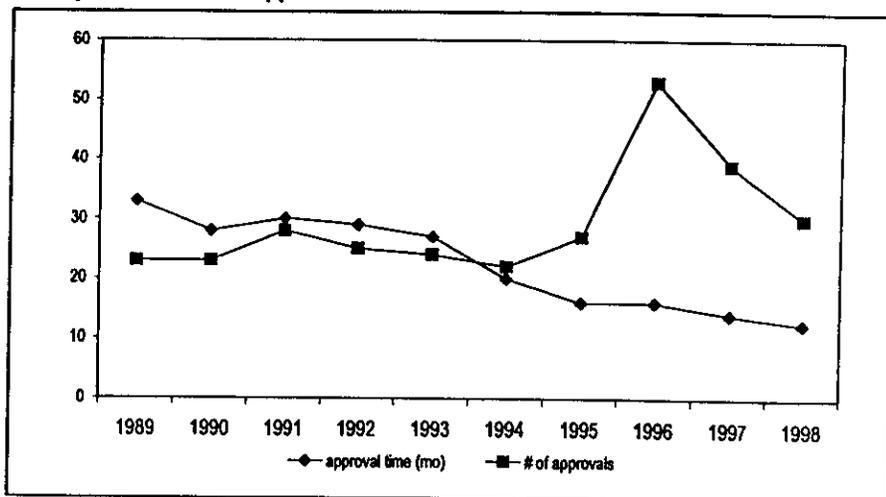
Source: Merrill Lynch Research Estimates and First Call  
 \* prices and estimates as of 9/01/99

## Sparseness - Inflated New Product Delivery Followed by Slowdown

### The FDA

The reforms in the mid 90's made to the FDA approval process shortened approval times from 2-3 years down to 6-12 months. This change resulted in a virtual doubling of new product launches (from all companies globally) in 1996 versus 1995, and a 50% increase in 1997 over 1995. This one-time artificial acceleration of product flow into the marketplace is being followed by a slowdown of approvals to levels seen before the reforms were enacted.

### History of New Product Approvals for the U.S. FDA

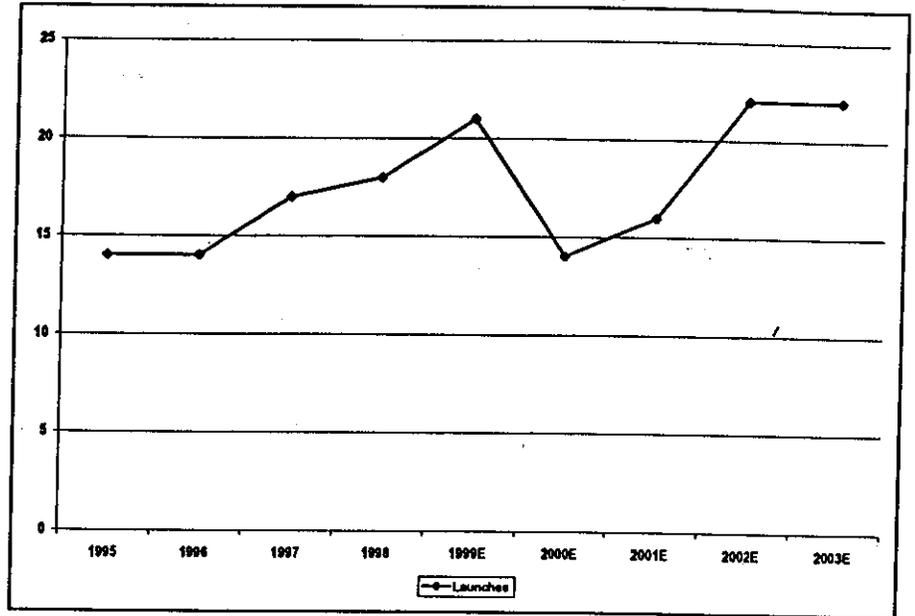


Source: U.S. FDA

### U.S. Company Launches

For the U.S. companies in particular the picture is slightly different; new product launches increased steadily from 1995, when 14 new products were launched, through to a peak of 21 this year (1999). Moving into next year we are looking for a marked decrease from 21 new products this year down to 14 in 2000 followed by 16 in 2001. The U.S. firms should then move into a new product launch upswing in 2002 and 2003, where we are currently projecting 22 new product launches in each of those years.

**Expected Launches by U.S. Large Cap. Pharmaceutical Companies**



Source: Merrill Lynch Research

For some U.S. companies the acceleration of product approvals by the FDA has created new product delivery gaps in their pipelines. In particular it is very noticeable that Merck will not be launching any new products in 2000 and that Lilly will not have any internally developed new product launches in either 2000 or 2001.

Revenue growth for a new product is greatest in the first 2-3 years after launch. According to IMS, sales growth of new products in the first year after launch is (on average) 150%, followed by 31.8% in the second and 27.7% in the third. Therefore the greatest impact after launch, given that the launch year is not typically profitable, is in years two and three. This speaks to the earnings growth strength that we have seen and expect to see in the group through the end of this year. Further strength in earnings growth in 2000 and 2001 will be mitigated by product patent expirations and an earnings deceleration for certain companies, such as that faced by Merck. In addition, we anticipate a slowdown in the introduction of "blockbuster drugs" which looks to have potentially peaked in 1999 and will fall to half that rate by 2001.

We therefore believe that earnings growth for the group (on average) may have peaked in 1998 and could slow down in 1999-2001.

**U.S. Drug Group EPS**

	1997	1998	1999	2000	2001
U.S. Group Average EPS Growth with AHP & PNU	7%	18%	16%	15%	15%
Group Average EPS Growth without AHP & PNU	15%	22%	19%	16%	15%

Source: First Call

In the table below, we have laid out the new U.S. product launches by year for the major U.S. pharmaceutical companies. What is apparent is the acceleration in the 1996-1999 time period, resulting from faster FDA review times and perhaps increased innovation. A relative slowdown in the 2000-2001 period should be reversed in 2002-2003 as new technologies and licensing efforts begin to pay off. However, we would expect some attrition to occur for some of the earlier stage products, which could be offset by additional licensing activity and/or acquisitions. We make the following observations on the individual companies:

**American Home Products:** One of the strongest near-term pipelines in the industry; six launches in the next 12-18 months should result in significant sales and earnings acceleration. Launches in the out years look to be tapering off.

**Bristol-Myers Squibb:** Three significant launches in 1999 (Avandia, Orzel, Tequin) should be followed by one of the industry's most significant launches in 2000 (Vanlev). Early stage research productivity appears to be picking up, as seen by the robust product line-up that should be launched in 2002/03.

**Eli Lilly:** An apparent gap in 2001 could be filled with faster-than-expected development of some products, but there is significant pressure to ramp up sales ahead of a 2004 Prozac patent expiration. We believe the out-year pipeline at Lilly is robust.

**Merck:** Launched six products in the last 12-18 months, but only Vioxx and Singulair appear to have billion-dollar potential. The pipeline is relatively thin particularly when compared to Merck's revenue base and the level of R&D spending. Substance P for depression appears to be the largest opportunity, but launch is not anticipated until 2002. In the near term, Merck faces a new product introduction gap in 2000 and significant patent expirations in 2000/01.

**Pfizer:** Launched several large products from 1997-1999E, a good mix of external (Aricept, Lipitor, and Celebrex) and internal (Viagra, Trovan) efforts. Future launches are evenly spaced, but the magnitude of those products is relatively small compared to Lipitor, Celebrex, and Viagra. We would expect more licensing activity to bolster the launch picture as this has been their profile in the past.

**Pharmacia & Upjohn:** Vestra and Zyvox are the most interesting products to be launched in the near/intermediate term. Launch profile in later years appears robust and could be supplemented by the recent acquisition of Sugen. New product launches should be incremental as the company does not have any major products facing patent expiration in the next 5 years. Noticably, none of the products to be launched appear to have billion-dollar potential.

**Schering-Plough:** Most successful launches have been and should continue to be in the asthma/allergy (Claritin line) area and in anti-infectives (Intron A/Rebetron). Asmanex and PEG Rebetron have high revenue potential. Launches in later years thin out.

**Warner-Lambert:** Currently in a lull after successful launches of Lipitor, Rezulin, and Celexa. Relpax co-promotion fills the 1999 gap. Pregabalin in 2001 should be the next billion-dollar opportunity. Agouron acquisition filled in early stage pipeline nicely.

**Major U.S. Company New Product Launches**

	1995	1996	1997	1998	1999E	2000E	2001E	2002E	2003E
<b>AHP</b>	Riabro Premphase	Lodine XL	Elavox Alesse Synvisc Benefix Acel-Imune	Rotashield Bonyl Neumega	Rapamune Protonix Sonata Roz	Fiumist Refacto	rhBMP-2	CMA-676	
<b>BMJ</b>	Glucophage Serzone		Avapro	Plavix Avalide Orzel Tequin			Max-K	GMK Vaccine Protease In.	Melatonin ag. TAS 103 Antifungal Zidovudine Orma
<b>LLY</b>	Reopro	Humalog Zyprex Ganzar		Evista Humalog Mix.	Arkos	Oxaliplatin		R-fluoxetine Glycopeptide MTA Tomoxetine (357)	Duloxetine MDR APC PKC inhibitor
<b>MRK</b>	Ecosamid Hyzaar Cozaar Trusopt Varivax	Vaqa	Comvax	Singulair Cosopt Propecia Maxalt Aggrastat			Candidas MK-826	SHR-9199 MK-869	Rota. Vacc.
<b>PFE</b>		Zylet	Epior Atropid	Viaagra Trovan	Calebrex Tikosyn Relpax	Zeldox	Valdecoxib Voriconazole Darifenacin	Inhaled Insulin	Droloxifene
<b>PNU</b>	Fragmin Genotropin Caverject	Camptosar Xalatan	Mirapex Rescriptor	Detrol	Vestra Lunelle Glyset Pletal Epirubicin	Aromasin Trelstar Zyvox Pegvisomant	Almotriptan SnE12	Tipranavir Antimicrobial NSAID glauc. SU-101 SU-5146 TPO	Insulin sens. Dopamine ag. K chan. (ED) LED LEP
<b>SGP</b>	Unidur	Claritin D-24 Claritin Syrup Cedax Vanc. AQ-DS	Nasorex Claritin Redi. Fareston	Rebetron Integrelin Prandin	Temodal Asmanex	Desloratidine Vasomax PEG Intron A	PEG Rebetron Ziracin Melacine Anti-estrogen	Caelyx Tenovil	Chol. Abs. Inh. p53
<b>WLA</b>		Cerebyx Procambid	Epior Rezulin Estrostep Fempatch	Omnicef Celexa	Relpax	Clinafloxacin FemHRT	Pregabalin Prinomestat NNRTI	Igmesine Conivaptan	Zenerastat P.I. 2nd Viracept Remune RhV Protease
<b>Total</b>	14	14	17	18	21	14	16	22	22
<b>Excl. co-promotes</b>	14	14	15	16	15	14	15	22	22
<b>Pot. blockbusters</b>	6	3	4	6	6	4	3	3	3

Source: Company Reports and Merrill Lynch Research Estimates  
 Note: Shaded compounds have billion-dollar potential (our estimate)

## Patent Expirations

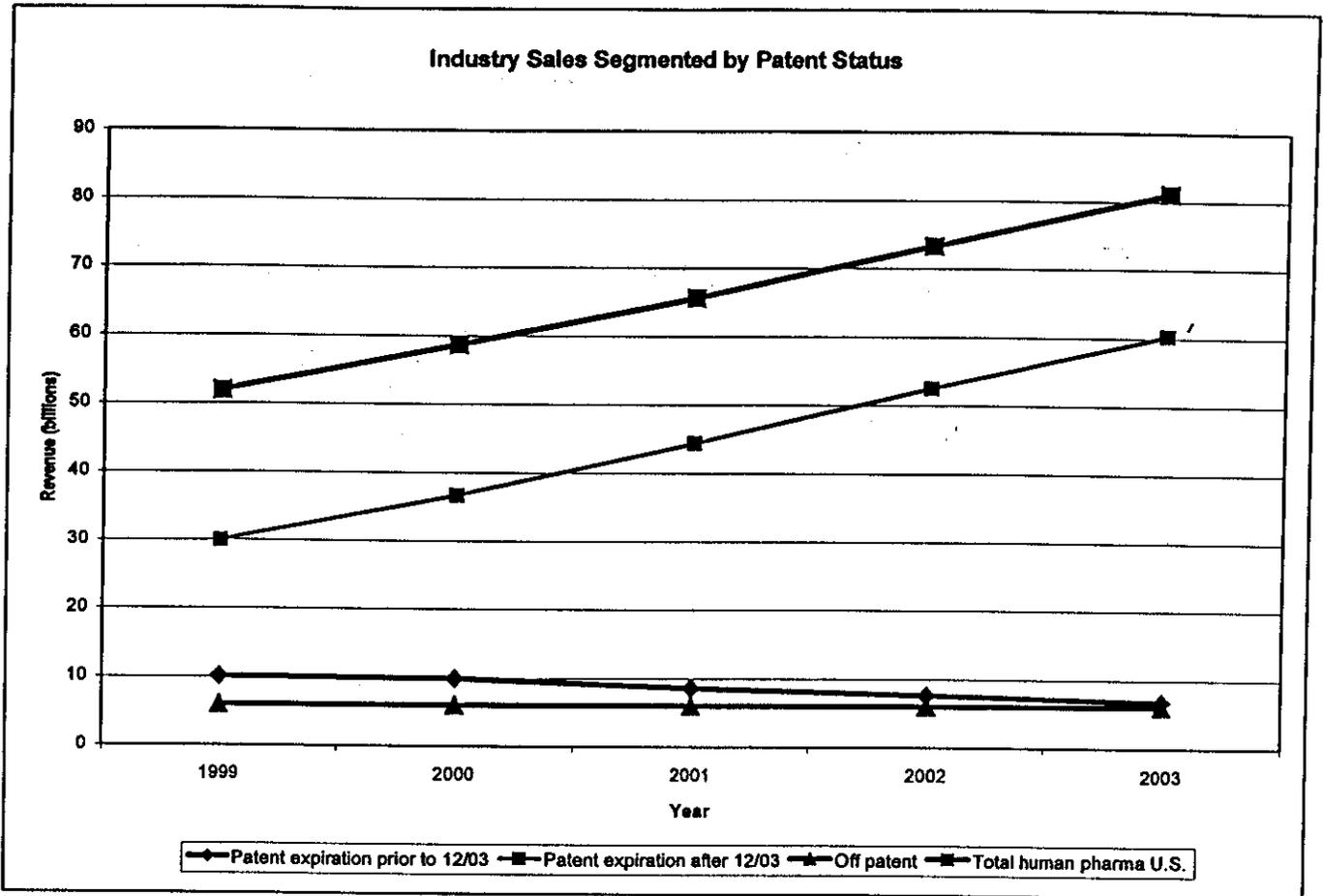
The two factors discussed above, relative deceleration of earnings growth and sparseness of pipelines, are exacerbated by upcoming patent expirations. Our belief however, which is supported by the analysis below, is that this is more of a perception issue and one that is company-specific, not industry-specific.

Large capitalization United States Pharmaceutical companies have generally engineered consistent earnings growth and share appreciation through growing sales of their proprietary medicines. Concerns regarding coming U.S. patent expirations and increasing generic competition have negatively impacted certain stocks. With stiff generic competition it is typical to see revenues for a given product fall to 25-30% of its pre-expiration level. In particular, Merck will be facing a number of product patent expiration in the 2000-2001 time frame. Pharmacia & Upjohn, on the other hand, should not see any generic competition to major products.

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## U.S. Sales and Patent Expiration Analysis

We performed an evaluation of overall group revenue segregated by the maturity of the products. Total U.S. revenue for the eight U.S. large cap pharmaceutical companies was divided between off-patent products, products losing patent protection prior to year end 2003, and products whose exclusivity is protected beyond 2003. The following chart summarizes the results.



Source: Merrill Lynch

## Upcoming U.S. Patent Expirations 1999-2003

	1998 U.S. Sales (\$MM) / % of Total Pharma	U.S. Patent Expiration Date
<b>American Home Products</b>		
Ziac	\$156 / 1.9%	Mar-00
<b>Bristol-Myers Squibb</b>		
Glucophage	\$855 / 7.6%	Mar-00*
Buspar	\$490 / 4.3%	May-00*
Stadol	\$82 / 0.7%	Aug-01
Monopril	\$175 / 1.5%	Dec-02
Serzone	\$221 / 2.0%	Mar-03
<b>Eli Lilly</b>		
Prozac	\$2,272 / 26.4%	Feb-01/Dec-03
<b>Merck</b>		
Mefoxin	\$45 / 0.3%	Aug-99
Vasotec	\$1,010 / 6.6%	Feb-00*
Pepcid	\$1,003 / 6.6%	Oct-00*
Prinivil	\$590 / 3.9%	Dec-01*
Mevacor	\$595 / 3.9%	Jun-01*
<b>Pfizer</b>		
Cardura	\$322 / 2.6%	Oct-00
Procardia XL	\$713 / 5.8%	Sep-03
Unasyn Oral / IV	\$141 / 1.2%	May-99 / Nov-99
<b>Pharmacia &amp; Upjohn</b>		
Rogaine 5%	\$151 / 2.3%	Dec-01
<b>Schering-Plough</b>		
Vanceril	\$144 / 2.0%	Dec-99
Vancenase	\$262 / 3.6%	Dec-99
Lotrisone	\$143 / 1.9%	Oct-00
Elocon	\$59 / 0.8%	Sep-01
Claritin	\$1,304 / 17.8%	Jun-02/Apr-04**
<b>Warner-Lambert</b>		
Neurontin	\$443 / 7.9%	May-00*
Accupril	\$236 / 4.2%	Oct-02
Cerebyx	\$5 / 0.08%	2003

Merrill Lynch

\* Denotes previous/imminent filing for a six month pediatric exclusivity extension

\*\* Loratidine composition of matter patent expires in 2002; desloratidine composition of matter patent expires in 2004.

Group-wide, \$10.1 billion of projected 1999 U.S. revenue is derived from drugs that will lose their exclusivity by the end of 2003. This represents 19.4% of total U.S. pharmaceuticals revenue. When Prozac (use patent expires in December of 2003) is excluded that number decreases to \$7.8 billion, or 15.0% of 1999 revenue. Products with exclusivity beyond 2003 account for \$30.1 billion in sales, or 57.9% of domestic pharmaceuticals revenue. Excluding Prozac those numbers improve to \$32.4 billion and 62.4%, respectively.

**Our analysis reveals that aggregate industry top-line growth will continue despite significant patent expirations in the U.S.** Revenues derived from products losing patent protection by the end of 2003 decline at an annual rate of 6.3%. The five-year growth rate for revenue derived from products with exclusivity beyond 2003 is 21.6%. This more than offsets the decline in sales of drugs newly exposed to generic competition, yielding overall long-term domestic sales growth of 13.2%. The total revenue for the older group of drugs is dwarfed by the revenue increase due to newer agents. Through 2001 we estimate newer product revenues will increase by over \$14 billion, 43% more than the total 1999 projected sales of patent-losing drugs. Furthermore, revenue on medicines losing patent protection drop by only \$3.3 billion in 2003 when compared to 1999, according to our estimates, a number more than doubled by one year of growth in sales of newer products. (\$2.4 billion of the remaining \$6.8 billion in 2003 industry revenue from the older group of drugs is derived from Prozac, whose use patent expires in 12/03).

**We believe that the patent expiration story will not negatively effect the industry as a whole.**

**It will however, remain problematic for selected companies.**

- **High Exposure**

**Merck:** Total domestic pharmaceutical revenue for Merck is projected at \$9.4 billion in 1999, \$2.5 billion (26.5%) of which will come from the sale of drugs losing exclusivity prior to 2003. Revenue from patent-losing drugs drops by \$2.1 billion in 2003 as compared to 1999, stunting the five-year growth rate for total U.S. pharmaceuticals sales (7.6%) through 2003. Absolute sales of domestic drugs are projected to increase by \$2.4 billion dollars in 2003 over 1999 levels. Sales of fresher drugs are projected to add \$4.5 billion to 1999 sales by 2003, 47% of this increase is projected to be offset by dropping revenue on more mature drugs.

- **Moderate Exposure:**

**Bristol Myers Squibb:** Total domestic pharmaceutical revenue for BMY is projected at \$8.4 billion in 1999, \$2.3 billion (28%) of which will come from the sale of drugs losing exclusivity prior to 2003. Revenue from patent/exclusivity-losing drugs actually is projected to increase by \$270 million in 2003 as compared to 1999. This increase results from rising Glucophage sales. Marketing exclusivity expires in March of 2000. A six-month pediatric extension has been filed which would likely forestall actual entry of generic competition until September of 2001. BMY also plans to file an NDA for a fixed dose Glucophage-sulfonylurea combination tablet, as well as a once-a-day formulation. Approvals could come in late 2000 giving BMY 9 to 12 months to convert the market. The five-year growth rate for total U.S. pharmaceuticals sales is projected at 13.7% through 2003, with 220 basis points of that increase due to increased Glucophage sales. Other patent-losing drugs have decreasing sales over this period. Absolute

sales of domestic drugs are projected to increase by \$4.9 billion dollars in 2003 over 1999 levels. Sales of fresher drugs are projected to add \$3.6 billion to 1999 sales by 2003.

**Pfizer:** Total domestic pharmaceutical revenue for Pfizer is projected at \$9.4 billion in 1999, \$1 billion (11.1%) of which will come from the sale of drugs losing exclusivity prior to 2003. Revenue from patent-losing drugs drops by \$850 million in 2003 as compared to 1999, decreasing the five-year growth rate for total U.S. pharmaceuticals sales to 15.9% through 2003. Absolute sales of domestic drugs are projected to increase by \$6 billion dollars in 2003 over 1999 levels. Sales of fresher drugs are projected to add \$6.6 billion to 1999 sales by 2003, 13% of this increase is projected to be offset by falling revenue on more mature drugs.

**Schering Plough:** Total domestic pharmaceutical revenue for SGP is projected at \$5 billion in 1999, \$600 million (11.9%) of which will come from the sale of drugs losing exclusivity prior to 2003. Revenue from patent losing drugs drops by \$390 million in 2003 as compared to 1999, decreasing the five-year growth rate for total U.S. pharmaceuticals sales to 14.6% through 2003. Absolute sales of domestic drugs are projected to increase by \$3.2 billion dollars in 2003 over 1999 levels. Sales of fresher drugs are projected to add an additional \$3.7 billion to 1999 sales by 2003, 10.5% of this increase is projected to be offset by dropping revenue on more mature drugs. The real patent risk faced by SGP involves Claritin. U.S. Claritin sales in 1999 are projected at \$1.6 billion, 21.1% of Schering's total ethical drug revenue, and 17.8% of total company revenue. The composition of matter patent on loratidine is currently set to expire in June 2002. Schering will file for a six-month pediatric extension, which will push this date out to December 2002. Four other patents currently protect this franchise, 1) desloratidine (loratidine metabolite) composition of matter patent - April 2004, 2) loratidine manufacturing patent - 2008, 3) loratidine-pseudoephedrine 24-hour combination patent - 2012, and 4) desloratidine use patent (licensed from Sepracor) - 2014. Five generic companies have filed aNDA's against the 2004 patent and two of the five have filed against the tablet (2002 composition of matter patent) in addition to the 2004 patent. Schering management has expressed confidence in the validity of their defense of this patent. Our current estimation allows for Claritin to enjoy exclusivity into 2004, on the basis of that patent.

**Warner Lambert:** Total domestic pharmaceutical revenue for Warner is projected at \$5.4 billion in 1999, \$1 billion (18.3%) of which will come from the sale of drugs losing exclusivity prior to 2003. Revenue from patent losing drugs drops by \$320 million in 2003 as compared to 1999, decreasing the five-year growth rate for total U.S. pharmaceuticals sales to 15.3% through 2003. Absolute sales of domestic drugs are projected to increase by \$3.1 billion dollars in 2003 over 1999 levels. Sales of fresher drugs are projected to add \$2.9 billion to 1999 sales by 2003, 10.9% of this increase is projected to be offset by dropping revenue on more mature drugs. The largest patent issue for Warner involves Neurontin, an anti-convulsant used for treatment of epilepsy and pain syndromes. Neurontin generated \$514 million in 1998 revenue while 1999 revenue is projected to grow 58% to \$811 million. Patent protection is due to expire in May of 2000, however WLA has filed for a six-month pediatric extension which will likely push the entry of generic players out to 2001. Warner will also introduce 600mg and 800mg tablets with an effort toward converting prescriptions to these forms, which carry 3 years of marketing exclusivity.

- **Low Exposure:**

**American Home Products:** AHP derives only a small part of revenue from products approaching patent expiration. With only \$221 million in projected 1999 revenue, representing 2.5% of the U.S. pharmaceuticals business, coming from such drugs, AHP is immune from the threat of increasing generic competition.

**Eli Lilly:** Only one Lilly drug is vulnerable to the patent issue before 2004. Prozac has a composition of matter patent due to expire in February of 2001 and a use patent which expires in December of 2003. We are assuming that the use patent will be upheld after the expiration of the 2001 patent, and Prozac will remain a proprietary product through the end of 2003. Any challenge to the exclusive use of Prozac by generic manufacturers prior to 2004 will be met with stiff Lilly legal action, which we believe would delay an earlier generic entrant through this timeframe. In this way Lilly can avoid any impact of patent expirations prior to 2004.

**Pharmacia & Upjohn:** PNU derives just over 2% of its projected 1999 U.S. pharmaceuticals revenue from products due to lose protection before 2004, rendering it immune to the patent issue.

## Sales and Patent Model (U.S. Only)

## American Home Products

Product Patent Status	1999	% Chg.	2000	% Chg.	2001	% Chg.	2002	% Chg.	2003	% Chg.
Patent expiration prior to 12/03	\$221	41.9%	\$212	-4.1%	\$202	-5%	\$191	-5%	\$176	-8%
% of total human pharma (U.S.)	2.5%		2.2%		1.8%		1.5%		1.3%	
Off patent	\$2,323	-7.3%	\$2,356	1.4%	\$2,400	2%	\$2,442	2%	\$2,497	2%
% of total human pharma (U.S.)	41.9%		37.6%		32.6%		29.3%		27.8%	
Patent expiration after 12/03	\$1,360	103.9%	\$2,171	59.7%	\$3,269	51%	\$4,211	29%	\$4,875	16%
% of total human pharma (U.S.)	24.5%		34.7%		44.5%		50.6%		54.2%	
<b>Total Human Pharma (U.S.)</b>	<b>\$5,543</b>	<b>11.1%</b>	<b>\$6,262</b>	<b>13.0%</b>	<b>\$7,353</b>	<b>17.4%</b>	<b>\$8,323</b>	<b>13.2%</b>	<b>\$8,991</b>	<b>8.0%</b>

## Bristol-Myers Squibb

Product Patent Status	1999	% Chg.	2000	% Chg.	2001	% Chg.	2002	% Chg.	2003	% Chg.
Patent expiration prior to 12/03	\$2,345	25.8%	\$2,671	13.9%	\$2,581	-3.4%	\$2,714	5.2%	\$2,617	-3.6%
% of total human pharma (U.S.)	28.0%		27.9%		24.2%		22.2%		19.7%	
Off patent	\$1,078	7.7%	\$1,157	7.3%	\$1,238	7.0%	\$1,294	4.5%	\$1,328	2.6%
% of total human pharma (U.S.)	12.9%		12.1%		11.6%		10.6%		10.0%	
Patent expiration after 12/03	\$2,979	25.0%	\$3,609	21.2%	\$4,503	24.8%	\$5,680	26.1%	\$6,604	16.3%
% of total human pharma (U.S.)	35.6%		37.7%		42.2%		46.5%		49.7%	
<b>Total Human Pharma (U.S.)</b>	<b>\$8,359</b>	<b>19.2%</b>	<b>\$9,571</b>	<b>14.5%</b>	<b>\$10,658</b>	<b>11.4%</b>	<b>\$12,212</b>	<b>14.6%</b>	<b>\$13,279</b>	<b>8.7%</b>

## Eli Lilly

Product Patent Status	1999	% Chg.	2000	% Chg.	2001	% Chg.	2002	% Chg.	2003	% Chg.
Patent expiration prior to 12/03*	\$2,299	1.2%	\$2,345	2.0%	\$2,392	2%	\$2,440	2.0%	\$2,440	0.0%
% of total human pharma (U.S.)	37.4%		33.7%		30.2%		27.3%		24.1%	
Off patent	\$859	0.3%	\$830	-3.4%	\$784	-5.4%	\$745	-5.1%	\$710	-4.7%
% of total human pharma (U.S.)	14.0%		11.9%		9.9%		8.3%		7.0%	
Patent expiration after 12/03*	\$2,720	23.7%	\$3,348	23.1%	\$4,199	25.4%	\$5,131	22.2%	\$6,323	23.2%
% of total human pharma (U.S.)	44.2%		48.1%		53.0%		57.5%		62.5%	
<b>Total Human Pharma (U.S.)</b>	<b>\$6,149</b>	<b>10.8%</b>	<b>\$6,967</b>	<b>13.3%</b>	<b>\$7,925</b>	<b>13.7%</b>	<b>\$8,923</b>	<b>12.6%</b>	<b>\$10,116</b>	<b>13.4%</b>

\*Prozac composition of matter patent expires in 2/01; use patent expires in 12/03. The use patent expiration has been used for this analysis.

**Sales and Patent Model (U.S. Only)**

<b>Merck</b>										
<b>Product Patent Status</b>	<b>1999</b>	<b>% Chg.</b>	<b>2000</b>	<b>% Chg.</b>	<b>2001</b>	<b>% Chg.</b>	<b>2002</b>	<b>% Chg.</b>	<b>2003</b>	<b>% Chg.</b>
Patent expiration prior to 12/03	\$2,508	-5.3%	\$2,207	-12.0%	\$1,549	-29.8%	\$851	-45.0%	\$400	-53.0%
% of total human pharma (U.S.)	26.5%		21.2%		14.3%		7.5%		3.4%	
Off patent	\$106	-12.0%	\$106	0.0%	\$106	0.0%	\$105	-1.0%	\$104	-1.0%
% of total human pharma (U.S.)	1.1%		1.0%		1.0%		0.9%		0.9%	
Patent expiration after 12/03	\$6,766	23.5%	\$8,025	18.6%	\$9,081	13.2%	\$10,200	12.3%	\$11,245	10.2%
% of total human pharma (U.S.)	71.6%		77.0%		83.7%		90.4%		94.5%	
<b>Total Human Pharma (U.S.)</b>	<b>\$9,449</b>	<b>14.3%</b>	<b>\$10,429</b>	<b>10.4%</b>	<b>\$10,845</b>	<b>4.0%</b>	<b>\$11,287</b>	<b>4.1%</b>	<b>\$11,900</b>	<b>5.4%</b>

<b>Pfizer</b>										
<b>Product Patent Status</b>	<b>1999</b>	<b>% Chg.</b>	<b>2000</b>	<b>% Chg.</b>	<b>2001</b>	<b>% Chg.</b>	<b>2002</b>	<b>% Chg.</b>	<b>2003</b>	<b>% Chg.</b>
Patent expiration prior to 12/03	\$1,037	11.9%	\$835	-19.5%	\$449	-46.3%	\$261	-41.8%	\$191	-26.9%
% of total human pharma (U.S.)	11.1%		7.8%		3.7%		1.9%		1.2%	
Off patent	\$0		\$0		\$0		\$0		\$0	
% of total human pharma (U.S.)	0.0%		0.0%		0.0%		0.0%		0.0%	
Patent expiration after 12/03	\$7,727	32.5%	\$9,204	19.1%	\$10,974	19.2%	\$12,709	15.8%	\$14,393	13.2%
% of total human pharma (U.S.)	82.4%		85.8%		90.5%		92.7%		93.8%	
<b>Total Human Pharma (U.S.)</b>	<b>\$9,375</b>	<b>27.0%</b>	<b>\$10,726</b>	<b>14.4%</b>	<b>\$12,128</b>	<b>13.1%</b>	<b>\$13,706</b>	<b>13.0%</b>	<b>\$15,347</b>	<b>12.0%</b>

<b>Pharmacia &amp; Upjohn</b>										
<b>Product Patent Status</b>	<b>1999</b>	<b>% Chg.</b>	<b>2000</b>	<b>% Chg.</b>	<b>2001</b>	<b>% Chg.</b>	<b>2002</b>	<b>% Chg.</b>	<b>2003</b>	<b>% Chg.</b>
Patent expiration prior to 12/03	\$56	7.2%	\$57	3.0%	\$58	1.0%	\$58	1.0%	\$59	1.0%
% of total human pharma (U.S.)	2.2%		1.9%		1.6%		1.4%		1.3%	
Off patent	\$854	8.7%	\$893	4.6%	\$917	2.7%	\$943	2.8%	\$959	1.7%
% of total human pharma (U.S.)	33.7%		30.3%		25.5%		22.8%		20.6%	
Patent expiration after 12/03	\$1,042	60.3%	\$1,426	36.9%	\$2,000	40.3%	\$2,410	20.5%	\$2,805	16.4%
% of total human pharma (U.S.)	41.1%		48.4%		55.7%		58.3%		60.4%	
<b>Total Human Pharma (U.S.)</b>	<b>\$2,536</b>	<b>19.0%</b>	<b>\$2,949</b>	<b>16.3%</b>	<b>\$3,592</b>	<b>21.8%</b>	<b>\$4,131</b>	<b>15.0%</b>	<b>\$4,647</b>	<b>12.5%</b>

**Sales and Patent Model (U.S. Only)**
**Schering Plough**

Product Patent Status	1999	% Chg.	2000	% Chg.	2001	% Chg.	2002	% Chg.	2003	% Chg.
Patent expiration prior to 12/03*	\$600	-12.5%	\$480	-19.9%	\$355	-26.1%	\$269	-24.3%	\$212	-21.3%
% of total human pharma (U.S.)	11.9%		8.4%		5.5%		3.7%		2.6%	
Off patent	\$437	-19.4%	\$352	-19.5%	\$274	-22.2%	\$211	-23.1%	\$164	-22.3%
% of total human pharma (U.S.)	8.7%		6.1%		4.2%		2.9%		2.0%	
Patent expiration after 12/03*	\$3,763	35.9%	\$4,648	23.5%	\$5,539	19.2%	\$6,468	16.8%	\$7,431	14.9%
% of total human pharma (U.S.)	74.9%		81.1%		85.4%		88.3%		90.0%	
<b>Total Human Pharma (U.S.)</b>	<b>\$5,021</b>	<b>19.9%</b>	<b>\$5,730</b>	<b>14.1%</b>	<b>\$6,485</b>	<b>13.2%</b>	<b>\$7,328</b>	<b>13.0%</b>	<b>\$8,260</b>	<b>12.7%</b>

**Warner-Lambert**

Product Patent Status	1999	% Chg.	2000	% Chg.	2001	% Chg.	2002	% Chg.	2003	% Chg.
Patent expiration prior to 12/03	\$997	46.9%	\$1,057	6.0%	\$968	-8.4%	\$802	-17.1%	\$677	-15.6%
% of total human pharma (U.S.)	18.3%		17.5%		14.7%		10.8%		7.9%	
Off patent	\$331	-9.4%	\$312	-6.0%	\$310	-0.5%	\$310	-0.1%	\$309	-0.1%
% of total human pharma (U.S.)	6.1%		5.2%		4.7%		4.2%		3.6%	
Patent expiration after 12/03	\$3,696	31.6%	\$4,235	14.6%	\$4,859	14.7%	\$5,652	16.3%	\$6,636	17.4%
% of total human pharma (U.S.)	68.0%		70.3%		73.9%		76.0%		77.8%	
<b>Total Human Pharma (U.S.)</b>	<b>\$5,436</b>	<b>28.8%</b>	<b>\$6,028</b>	<b>10.9%</b>	<b>\$6,579</b>	<b>9.1%</b>	<b>\$7,433</b>	<b>13.0%</b>	<b>\$8,525</b>	<b>14.7%</b>

**Industry Totals**

Product Patent Status	1999	% Chg.	2000	% Chg.	2001	% Chg.	2002	% Chg.	2003	% Chg.
Patent expiration prior to 12/03	\$10,062	5.5%	\$9,864	-2.0%	\$8,553	-13.3%	\$7,587	-11.3%	\$6,772	-10.7%
% of total human pharma (U.S.)	19.4%		16.8%		13.0%		10.3%		8.4%	
Off patent	\$5,988	-3.0%	\$6,004	0.3%	\$6,030	0.4%	\$6,048	0.3%	\$6,071	0.4%
% of total human pharma (U.S.)	11.5%		10.2%		9.2%		8.2%		7.5%	
Patent expiration after 12/03	\$30,053	31.9%	\$36,667	22.0%	\$44,424	21.2%	\$52,463	18.1%	\$60,311	15.0%
% of total human pharma (U.S.)	57.9%		62.5%		67.8%		71.5%		74.4%	
<b>Total Human Pharma (U.S.)</b>	<b>\$51,870</b>	<b>18.6%</b>	<b>\$58,661</b>	<b>13.1%</b>	<b>\$65,566</b>	<b>11.8%</b>	<b>\$73,344</b>	<b>11.9%</b>	<b>\$81,065</b>	<b>10.5%</b>

\* Claritin (loratadine) composition of matter patent expires in June 2002; desloratadine composition of matter patent expires in April 2004. The 2004 date has been used for this analysis.

## Other Issues

### ■ Aging Demographics

The leading edge of the baby boomers are now in their early 50's. Over time, the population of the U.S. is simply going to get older. As the population ages, healthcare utilization is rising. This is a long-term positive trend for the industry.

#### Projected U.S. Population (over 65)

Year	Over 65 est. Population (mn)	% of Total Population
1996	33,872	12.8%
2000	34,709	12.7%
2005	36,166	12.6%
2010	39,408	13.2%
2015	45,567	14.7%
2020	53,220	16.5%
2025	61,952	18.5%
2030	69,379	20.0%

Source: U.S. Census Bureau

### ■ Sales Force Saturation

Conversations with the major pharmaceutical companies support the notion that the U.S. market has reached saturation when it comes to the number of reps covering physicians. It stands to reason, as there has been a marked increase in the number of sales reps in the U.S. since 1994, yet the number of physicians has been relatively stable. New additions to sales forces are likely to be associated with new product launches - which in the near term look to be tapering off. With high levels of rep coverage, physicians will be looking for new product stories, new clinical data and new indications for the products being sold to justify the time spent with reps. Triage decisions will be made when it comes to deciding which company's reps will get the most time. This leads us to believe that we will see increasing differentiation between the "haves" and "have nots" in the physician's office whereby the reps that have value-added messages will have better leverage with their physician clients.

### ■ Branded Price Increases - Good News, Bad News

In 1998 total price increases for all pharmaceuticals was 3.2%. This compares to 1.9% in 1995, 1.6% in 1996, 2.5% in 1997. While these numbers pale in comparison to the volume increases (ranging from 7.8% in 1995 to 12.7% in 1998), they have recently been on the rise. The 1998 figure, however, is somewhat misleading because there was substantial erosion in generic pricing in that year. In particular, branded pricing at the retail level on average went up 4.8% in 1998, which is 3% above the change seen in the consumer price index (CPI) of 1.8%. The conclusion is that the pharmaceutical industry is one of the few industries that has substantial pricing power, which would on the surface appear to be a distinct positive. The negative aspect, however, is that there is a somewhat unspoken understanding between the branded pharmaceutical industry and the government that the industry would not exceed CPI plus 1-2%. The effect is to potentially draw additional unwanted scrutiny to the industry.

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**Components of Sales Growth, 1998**

Company	Volume	Price	Exchange
American Home Products	+3%	+1%	-2%
Bristol-Myers Squibb	+10%	+2%	-3%
Eli Lilly	+15%	+2%	-2%
Merck	+12%	+4%	-2%
Pfizer	+25%	+1%	-4%
Pharmacia & Upjohn	+7%	+2%	-3%
Schering Plough	+19%	+2%	-2%
Wamer-Lambert	+29%	-1%	-3%

Source: Company reports and Merrill Lynch Research

**■ Increased R&D Spending**

With an average of over \$9 billion in annual human pharmaceuticals sales for each of the major cap pharmaceutical companies based in the U.S. in 1998, sustaining growth is requiring increased R&D investment. Currently, we expect R&D spending growth to lag behind sales growth by roughly 1 percentage point in 1999. Companies with decelerating top-line growth may not be able to sustain this rate of investment, or will have to sacrifice earnings growth to do so.

## Medicare Reform

Investors still have vivid memories of sector under performance during the period of time in which President Clinton attempted to reform the entire U.S. healthcare system in the early 1990's. The group has come under some pressure with the ground swell of reform proposals that have been floated on Capital Hill and from the White House. We do not believe there will be any resolution to this issue in the near term, as the Democratic party is likely to maintain the Medicare issue for the upcoming 2000 elections. We have done some detailed sensitivity analysis on the impact of potential reforms, and on a worst case basis are not convinced that the impact will be that onerous, and in fact under the right conditions could be neutral to slightly positive.

### Medicare - The Facts

The Medicare eligible include the elderly (65 and over), the disabled, and those with end-stage renal disease and comprise roughly 39 million individuals in the U.S. Not surprisingly, because the Medicare population is generally older and sicker than the rest of the population, the drug utilization of this group is multiples higher than broader averages. According to the Health Care Financing Administration (HCFA), elderly persons represent 12.4% of the population but account for a third of drug expenditures. Also, given the political clout of this group, it is closely monitored by the politicians as well as the media.

While the Medicare program covers certain hospital and outpatient services, it does not include an outpatient drug benefit. With the technological revolution that is taking place in the development of safe and effective drug therapies, the absence of an outpatient prescription drug benefit is becoming a hindrance to providing comprehensive, effective treatment to certain components of this population.

According to the National Academy of Social Insurance, approximately two-thirds of the Medicare population have some form of prescription drug benefit. The remaining one-third or so have no outpatient drug coverage, presumably because they are unwilling or unable to purchase insurance or additional coverage. Bureau of the Census data indicate that in 1995, 10% of Medicare recipients were poor (annual income <\$7,309 for a single person or <\$9,212 for a couple) and 7% were near-poor (<\$9,316 and <\$14,618, respectively).

### Medicare Recipients' Drug Coverage

	% Of Beneficiaries with Supplemental Insurance	% of Supplementally Insured patients receiving a drug benefit	% of all Medicare Beneficiaries receiving a drug benefit
Employer Sponsored	33%	86%	28%
Medicaid	12	90	11
Medicare Risk HMO	7	95	7
Individually Purchased (Medigap)	29	29	8
All Other	3	89	3
Switched Coverage During the Year	8	80	6
No Supplemental Insurance	8	0	0
<b>Total</b>	<b>100</b>	<b>N/A</b>	<b>65%</b>

Source: National Academy of Social Insurance, "A Medicare Prescription Drug Benefit," Michael E. Gluck.

**Price Impact**

We have looked at a few different scenarios including what we believe to be a worst case impact on pricing for Medicare reforms. The three scenarios we outline are:

- **Price reductions for all Medicare beneficiaries to Federal Supply Schedule (FSS) levels (Scenario #1).** In this scenario we assume that Medicare recipients get a 40% discount from the manufacturers price (approximately the same price that the Veterans Association would pay). Therefore, Medicare beneficiaries without coverage would see a 40% reduction in price. The two-thirds that have coverage would see a 25% reduction, assuming that their coverage is providing them with a 15% discount currently. We would view this as the worst case scenario.
- **Price reductions for Medicare beneficiaries without coverage to FSS levels (Scenario #2).** In this scenario we assume that 40% price cuts would be provided for the 1/3 of the Medicare population that currently does not have coverage. We would assume that this would be according to some income or other criteria that would not result in switching for those patients that are currently receiving coverage.
- **Price reductions for Medicare beneficiaries equivalent to that seen by large customers (Scenario #3).** This scenario assumes that Medicare beneficiaries not currently receiving coverage would receive coverage from private providers and therefore see price reductions for the drugs they receive equivalent to what large pharmaceutical customers are seeing today. We estimate that large customer discounts run in the range of 15-20%.

**Potential Pharma Sales Impact of a Medicare Drug Benefit**

	Scenario #1	Scenario #2	Scenario #3
Company Pharmaceutical Sales	100%	100%	100%
U.S. Component of Total Sales	60%	60%	60%
% Exposed to Medicare	33%	33%	33%
Sales Reduction due to Price Reduction for 1/3 Not Receiving Prescription Drug Coverage	-2.67% (40% Reduction)	-2.67% (40% Reduction)	-1.00% (15% Reduction)
Sales Reduction due to Price Reduction for 2/3 with Prescription drug Coverage	-3.27% (25% reduction beyond assumed existing 15% discount)	0.00% (No benefit provided)	0.00% (No benefit provided)
<b>Estimated Effect on Total Sales</b>	<b>-6.00%</b>	<b>-2.67%</b>	<b>-1.00%</b>

Source: Merrill Lynch

As can be seen from the table above we estimate that the worst impact to an average company would be a negative 5.9% to the top-line. More reasonable scenarios cause a negative impact of 1-3%. It is important to note, however, that these only consider the negative impact of price and do not consider that volumes are more than likely to go up.

**Volumes Go Up with Benefits**

It is our belief that when you either cut drug prices, provide a prescription benefit, or both, then volumes will go up with increased drug utilization. This could potentially make what is perceived to be a negative situation a positive or less negative one. In a paper entitled "Inadequate Prescription-Drug Coverage for Medicare Enrollees – a Call to Action" published March 4<sup>th</sup>, 1999 in the *New England Journal of Medicine* the authors (Stephen B. Soumerai and Dennis Ross-

Degnan) sight some interesting figures with regard to annual drug expenditures per individual as a function of whether or not a Medicare beneficiary lacks or has supplemental health care insurance. The following table summarizes the annual prescription drug spend per enrollee presented in that work.

**Effect of Coverage Type on Drug Expenditures**

Medicare Beneficiary Health Status	Medicare Fee-for-service Coverage only	Medicare plus Individually purchased plan	Medicare plus employer sponsored plan
Excellent	\$169	\$243	\$296
% Change		44%	75%
Fair	474	688	777
% Change		45%	64%
Poor Health	529	787	1033
% Change		49%	95%

Source: "Inadequate Prescription-Drug Coverage for Medicare Enrollees – A Call to Action," *New England Journal of Medicine*, March 4, 1999 p722-727.

What is noticeable is that the level of drug expenditures increases with increasing coverage. While the supplemental coverage may not in all instances provide for a prescription drug benefit, those that do are likely to be providing the drugs under that coverage at lower prices than that obtained by fee-for-service only beneficiaries who are paying list price. This would suggest that the underlying volume and utilization increases dramatically when coverage is provided. Furthermore, the authors of the paper (cited above) point out that for low-income beneficiaries, annual drug expenditures increase as their coverage is supplemented.

Below is a table illustrating the components of U.S. pharmaceutical sales growth from 1987 through 1998. What is most interesting is the increasing volume component of sales growth during a period in which an increasing percentage of the population entered managed care. In that setting, drug prices are lower and the recipient is likely to have a benefit involving a small co-pay. In 1990, 26.1% of retail prescriptions were paid for by private managed care and 63.1% were paid for with cash, versus 64.9% and 24.7%, respectively in 1998.

**Components of U.S. Pharmaceutical Sales Growth**

Year	Price	Volume
1987	6.6%	8.9%
1988	8.5	3.0
1989	7.8	6.5
1990	8.4	6.1
1991	7.2	6.7
1992	5.9	3.0
1993	3.6	3.6
1994	1.8	4.8
1995	1.9	7.8
1996	1.6	10.1
1997	2.5	10.1
1998	3.2	12.7

Source: IMS

**All of this points to the potential for volumes to increase if a prescription drug benefit is provided.**

**Medicare Reform May Not Be a Negative**

The following scenarios are similar to those in the previous section. The major difference is that we have introduced volume increases into the equation since increasing coverage and/or lower prices lead to an increase in pharmaceutical utilization.

- **Price reductions for all Medicare beneficiaries to FSS levels (Scenario #4).** In this scenario we assume that Medicare recipients get a 40% discount from the manufacturers price. Therefore Medicare beneficiaries without coverage would see a 40% reduction in price. The two-thirds that have coverage would see a 25% reduction, assuming that their coverage is providing them with a 15% discount currently. For the one-third without coverage, we have assumed a 45% increase in volume. We estimated that the two-thirds with coverage would see a 10% increase in volume as a result of the lower price.
- **Price reductions for Medicare beneficiaries without coverage to FSS levels (Scenario #5).** In this scenario we assume that 40% price cuts would be provided for the 1/3 of the Medicare population that currently does not have coverage. Again, we estimated a 45% volume increase for these beneficiaries. We would assume that this would be according to some income or other criteria that would not result in switching for those patients that are currently receiving coverage. We would expect no volume or price impact in the two-thirds with coverage.
- **Price reductions for Medicare beneficiaries equivalent to that seen by large customers (Scenario #6).** This scenario assumes that Medicare beneficiaries not currently receiving coverage would receive coverage from private providers and therefore see price reductions for the drugs they receive equivalent to what large pharmaceutical customers are seeing today. We estimate that large customer discounts run in the range of 15-20%. We assumed that volume would increase by 45% in the one-third of the population without coverage. We would expect no volume or price impact in the two-thirds with coverage.

**Potential Pharma Sales Impact of a Medicare Drug Benefit**

	Scenario #4	Scenario #5	Scenario #6
Company Pharmaceutical Sales	100%	100%	100%
U.S. Component of Total Sales	60%	60%	60%
% Exposed to Medicare	33%	33%	33%
Price and Volume Change for 1/3 Not Receiving Prescription Drug Coverage	-0.87% (40% Price Discount+45% Volume Increase)	-0.87% (40% Price Discount+45% Volume Increase)	1.55% (15% Price Discount+45% Volume Increase)
Price and Volume Change for 2/3 with Prescription drug Coverage	-2.33% (25% discount beyond assumed existing 15% discount+10% volume increase)	0% (No discount or volume change)	0% (No discount or volume change)
<b>Estimated Effect on Total Sales</b>	<b>-3.20%</b>	<b>-0.87%</b>	<b>+1.55%</b>

Source: Merrill Lynch

Compared to the scenarios earlier in the report that did not consider the impact of

volume changes, the above scenarios highlight the fact that increased utilization that should result from decreased prices can make the impact on sales less negative, or perhaps even positive.

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### Different Degrees of Exposure

Because a drug benefit for the Medicare population involves only pharmaceutical sales in the U.S., we have provided the U.S. pharmaceutical sales for the companies in our universe in the table below. The higher the percentage of total company sales represented by U.S. pharmaceutical sales, the higher the exposure to a drug benefit for the Medicare population. We should point out that these percentages alone do not predict true exposure to Medicare reform. If a company has a high percentage of U.S. pharmaceutical sales but its main products are not heavily used by patients over 65 years of age, that company's actual exposure may be relatively low. The converse may also be true for some companies.

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#### Company Exposure to a Medicare Drug Benefit

Company	1998 U.S. Pharma Sales as a % of Total Company Sales / % of Pharma Sales
American Home Products	37% / 61%
Bristol-Myers Squibb	38% / 62%
Eli Lilly	60% / 64%
Merck	31% / 56%
Pfizer	55% / 67%
Pharmacia & Upjohn	26% / 37%
Schering-Plough	52% / 63%
Warner-Lambert	37% / 67%

Source: Merrill Lynch

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### Other Risks and Benefits

It must be realized that the analysis we have done is rather simplified, as we do not know the final form of Medicare reform that will be made into law. It is important to highlight other factors that may prove to be additional risks or benefits, including:

- **Potential phase-in of reforms.** Governmental programs are often phased in over time and are not implemented in one dramatic step. We could see a gradual increase in price discounts. Our scenarios have assumed a sudden one-time change in order to gauge the overall impact.
- **Prescription drug benefits may exceed budgets.** If the reforms include a prescription drug benefit and the financing for these benefits is not rock solid or well defined, there is a risk that a rise in drug utilization leads to drug coverage expenditures exceeding budgets. This could lead to further price reductions or additional regulation. This underscores the importance of the funding mechanisms for the various proposals being made.
- **Margin impact may be greater than top-line impact.** Given the high prices paid by Medicare recipients that currently pay out of pocket, this segment may be very (if not the most) profitable segment. This may amplify negative price effects. Gross margins, however, for a given product may improve with increasing volumes.

## The Key Proposals

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### Clinton

President Clinton announced his plan for Medicare reform on June 29<sup>th</sup>, and more details of the plan were made available on July 2<sup>nd</sup>. The main thrust of the plan is the inclusion of an optional drug benefit which would be made available to *all* Medicare recipients. The following details are available on the White House website at <http://www.whitehouse.gov>.

#### ■ Overview

Under Clinton's proposal, Medicare recipients would have the option to enroll in "Part D" of the program. These beneficiaries could immediately buy prescriptions at lower drug prices which private pharmacy benefit managers (PBMs) would be able to negotiate. The new benefit would have no deductible and would pay 50% of drug costs up to \$5,000 (or a \$2,500 payment from Medicare) when fully implemented. Most recipients would pay a monthly premium of \$24 in 2002 and \$44 in 2008 when the plan is fully implemented. Those with incomes below 135% of poverty would not pay for premiums or cost sharing, and those with incomes between 135 and 150 percent of poverty would pay a reduced premium. Enrollees that are already in Medicare managed care plans would receive their benefit as they do today. However, the plans would be paid directly for providing this coverage. Beneficiaries in the traditional fee-for-service program would get their benefits through PBMs. Medicare would contract out for this management through competitive bidding similar to that used in the private sector. Incentives would also be offered to retain and develop employer-provided retiree coverage.

#### ■ Design

As stated above, the key components of the design are (1) no deductible, (2) immediate and continuing discounts, (3) co-insurance, (4) a benefit limit or cap at \$5,000 in 2008. In general, all therapeutic classes of drugs would be included, except for those which are currently excluded under Medicaid, including drugs for weight loss, fertility treatments, cosmetic purposes or hair growth, cough or cold medications, vitamins and minerals, and non-prescription drugs. Smoking cessation drugs, however, would be covered under "Part D." Importantly, no formularies would be set up by the government. The private benefit managers could establish formularies, subject to the coverage requirements, as most private PBMs and private insurers do today. Benefit managers would be allowed to create incentives for generic substitution, also a practice used today by private plans. Beneficiaries would be guaranteed access to off-formulary drugs when medically necessary and have basic appeal rights where coverage is denied.

#### ■ Financing

The Part D benefit would be financed on a shared voluntary basis, similar to the structure of Part B. The new benefit would be operated as a separate part of the Supplemental Medical Insurance (SMI) Trust Fund, which would eliminate the bureaucracy that would be associated with a new trust fund. Part D costs and income would in no way affect Part B costs or premiums. In addition to cost sharing, beneficiaries would pay a premium of \$24 per month in 2002, rising to \$44 per month in 2008. Premiums would be collected in the same manner as Part B, as a deduction from Social Security checks for most beneficiaries. Beneficiaries would be notified of the annual premium in the same notice in which they learn about the Part B premium for the next year.

### ■ Enrollment

Beneficiaries would have one opportunity to sign up for the voluntary benefit, in either in the first year the benefit is offered (2002) or in their first year of Medicare eligibility. The one-time nature of the enrollment is important in reducing or eliminating selection bias; if enrollment were allowed on an annual basis, beneficiaries could select coverage only for years in which they expect high drug expenses. The exceptions are (1) beneficiaries who are covered by their employer while still working have a one-time opportunity to enroll after retirement, and (2) beneficiaries who are covered by employer-based retiree coverage have a one-time opportunity to enroll if the former employer drops coverage of prescription drugs for all retirees. In the first year of implementation, Medicare beneficiaries would be able to sign up for the benefit during an open enrollment period in November of 2001 (same enrollment time for Medicare+Choice plans). The Medicare program would conduct an educational campaign about the new benefit option during 2001.

### ■ Management, payments, and beneficiary protections

The drug benefit program would be contracted out with private sector entities, including PBMs, retail drug chains, health plans or insurers, states (through mechanisms established for Medicaid), or collaborations between entities. Private benefit managers would bid to manage the benefit for a particular geographic area and rules would be set to prevent a few managers from dominating the Medicare market. Competition for contracts would occur every two or three years and could involve any entity that meets a certain set of criteria. Importantly, all PBMs or other entities would be required to meet access and quality standards including:

- Inclusion of strategies to encourage appropriate use of medications
- Use of a medical panel with outside experts in creating a formulary
- Use of objective criteria in selecting drugs for the formulary
- Open and fair dealing with drug and biologic companies
- Publication of criteria for any cost containment measure that could affect patient care
- Submission of data about costs and utilization on a regular basis to help improve quality of care
- Compliance with standards for capacity and pharmacy availability to serve all beneficiaries in the geographic area
- Compliance with contractual requirements and consumer protections
- Continued access to discounted prices after beneficiaries have exceeded caps

Most of the risk for the cost and utilization of services under the benefit would be borne by the government. The PBM serving each geographic area would be paid a fee for managing the benefit, and would have some contractual incentives to control costs and utilization. The program would test the use of various arrangements such as bonuses to provide incentives to the benefit managers to manage the benefit effectively. Importantly, Medicare would not set prices for drugs. Discounts would be obtained by private benefit managers from pharmaceutical companies. The plan does not involve a rebate as seen in Medicaid, nor would a schedule for drugs (like the VA) be set up. Medicare+Choice plans would be required to provide a prescription drug benefit for all enrollees who have elected to participate in Part D. The government would explicitly subsidize the coverage.

### ■ Expanded Assistance

Low-income beneficiaries tend to have disproportionately high drug costs. According to AARP, beneficiaries with incomes below 100 percent of poverty spend an average of 8 percent of their incomes for drugs. Under Clinton's proposal, Medicaid would pay for the drug premiums and cost sharing for beneficiaries up to 100% of poverty. The proposal would create two new eligibility categories. Beneficiaries with incomes between 100 and 135 percent of poverty would receive full assistance for their drug premiums and their cost sharing. The Federal matching rate would be 100 percent. Beneficiaries with incomes between 135 and 150 percent of poverty would pay a partial, sliding scale premium based on their income. The Medicaid costs for this group would also be matched at 100 percent. States would be obligated to offer this expended protection.

### ■ Retaining employer-provided retiree drug coverage

Because some 30% of Medicare recipients currently have drug coverage through their employer, it would be important for the proposal make certain that current coverage is not lost or diminished. Under the policy, Medicare would provide a partial drug premium subsidy to employers whose retiree coverage is at least as good as the Medicare benefit. The Medicare contribution would be 67 percent per beneficiary of the subsidy that it would otherwise provide for Medicare Part B enrollees. This would allow Medicare to save 33% of its costs for each beneficiary in private employer-based retiree coverage. The incentive payment would operate through the health plan or PBM that administers the employer's drug benefit. Because the employer contribution to the drug benefit is tax-deductible, the proposal provides an additional incentive for employers to provide coverage, allowing employers to offer the same or more generous drug benefits at a significantly lower net cost.

Many questions remain about the details of the plan and how the benefit would be funded. Part of the funding would presumably be provided by the cost savings that drugs provide by lowering the need for expensive health care services. In our opinion, this concept would be a hard sell for President Clinton, as managed care companies are struggling to keep costs under control despite the benefits that prescription drugs might offer. In fact, these same organizations have in some part blamed the rapid growth of their drug bill for their financial woes. Regardless of what the feasibility and popularity of Clinton's plan will be, we believe that the Democratic party will elect to save Medicare reform as it applies to a drug benefit as a major platform for the next presidential election. Therefore, we would not expect Clinton's plan to become reality in the next year. We do, however, expect to hear some noise on other proposals, both new proposals and older ones. Some of the older plans have been outlined below.

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### Breaux/Thomas

The National Bipartisan Commission on the Future of Medicare, chaired by Sen. John Breaux (D-La.) and Rep. Bill Thomas (R-Calif.), failed in late March to achieve a supermajority of 11 votes needed to send reform recommendations to the president and Congress.

Under the premium support system proposed by the commission co-chairmen, Sen. John Breaux (D-La.) and Rep. Bill Thomas (R-Calif.), Medicare beneficiaries would select comprehensive health care coverage from either the government-run fee-for-service program or from a variety of private health plans, and would receive a federal contribution toward their premiums. The system seeks to blend government protections and market-based competition. The proposal would establish full coverage of outpatient prescription drugs to beneficiaries under 135

percent of the poverty level, which could total some 6 million recipients, according to Breaux. It would require that the government-run fee-for-service plan and all Medigap plans, which supplement Medicare, offer a "high option" plan that would provide prescription drug coverage.

The key points of disagreement of this plan seem to be where the poverty line should be drawn as well as how much, if any, of the program would be subsidized by the federal government. Apparently, time limitations prevented the committee from coming up with much detail for an actual drug benefit and how it might be funded.

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### **Kennedy**

The Access to Rx Medications in Medicare Act of 1999, proposed on April 20, 1999 by Sen. Edward M. Kennedy (D-Mass.) and others, proposes a program that would cover 80 percent of all costs for seniors with more than \$200 in annual spending on prescription drugs. Beneficiaries also would be subject to a 20 percent coinsurance payment under the bill. Funding could come from increasing the federal tobacco tax, using part of the projected federal budget surplus, or through savings generated from less frequent hospitalizations that would occur if prescription drugs were more widely available.

Under the bill, Medicare would contract with companies offering prescription drugs through a competitive bidding process. The contracting entities could include pharmaceutical benefit management companies, health insurers, or networks of wholesale and retail pharmacies. The companies would be reimbursed on a regional or national basis and would be reimbursed based on the number of seniors enrolled. Current Medicare+Choice plans would continue providing drug coverage, and would have their Medicare payments adjusted to account for any additional costs associated with the bill. All 10 types of Medigap plans also would be required to provide drug coverage that exceeds that offered under the bill (currently, just three types of Medigap plans offer coverage).

Providers would be required to offer an adequate drug formulary and to provide such services as an appeals process, online drug utilization review, and 24-hour counseling for seniors. The bill also would attempt to increase the number of employers offering prescription drug coverage as part of their health care benefits package by providing a capitated payment geared to the number of retirees with drug coverage. The benefit would be offered under Part B of the Medicare program.

The key shortfall of the Kennedy proposal relates to how the program would be funded. In addition, the pharmaceutical industry would certainly point out that the bill relies on the federal government to control prices, access to care, scope of benefits, and quality of care.

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### **Allen**

Tom Allen (D-Maine) introduced Sept. 25, 1998 legislation called the Prescription Drug Fairness for Seniors Act of 1998 (H.R. 4627) that would allow senior citizens who are Medicare beneficiaries to purchase prescription drugs from participating pharmacies at substantially reduced prices. That would be achieved by allowing pharmacies that serve Medicare beneficiaries to purchase prescription drugs at the low prices available to federal agencies under the Federal Supply Schedule, which could reduce prices for seniors by 40 percent.

The limitations of this plan stem from the fact that while the Act would make medicines cheaper, it would not necessarily improve access to drugs for the uncovered Medicare population. Pharmacies would benefit from the system, but the pharmaceutical lobby would obviously object to the Act on the grounds that price controls would stymie innovation.

