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SALES OF GENERIC DRUGS IN THE U.S.A.

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July 1985

SALES OF GENERIC DRUGS IN THE USA

Background on Generic Drugs

When a new drug is discovered, it is given a brand or trade name. The drug company has exclusive rights to that product for seventeen years. When the patent expires, other drug companies may manufacture that drug under another brand name or under the drug's generic name. These drugs are often less expensive than the original drug.

All states within the U.S. now permit pharmacists to dispense a generic drug instead of a brand name product if the doctor approves. However, not all drugs are available from more than one manufacturer, and not all generic drugs are "therapeutically equivalent" (behave the same way in the body).

Therapeutic equivalence is the major problem with generic drugs. Pharmaceuticals are termed chemically equivalent if they meet chemical and physical standards established by the government or other regulatory agency. The drugs are said to be biologically equivalent if they yield similar concentrations of the drug in the blood and tissues. They are designated therapeutically equivalent if they provide equal therapeutic benefits under clinical trial. Pharmaceutical preparations that are chemically equivalent, are not always biologically equivalent or therapeutically equivalent and are said to differ in their

bioavailability. Dosage forms of a drug made by different manufacturers and even from different lots of a preparation from a single manufacturer sometimes differ in bioavailability.

Biological non-equivalence of drug preparations is a particularly acute problem because bioavailability of a preparation in man has not always correlated with laboratory tests. Biological non-equivalence of pharmaceuticals of practical importance has been detected among a number of important drugs, especially patients on maintenance drugs, e.g. cardiac, antihypertensives, and diabetics. These patients can have severe adverse reactions to the drugs when switched from one company's drug to another if the drugs are not therapeutically equivalent. Also, several antibiotics have been found to differ in bioavailability.

The question of whether a patient is better off with a brand name or a generic product is a difficult one. Use of a generic product often results in less expense for the patient. The substantial savings yielded by using a generic drug is an important benefit for many patients, especially senior citizens on a fixed income. On the other hand, by using a generic product, the patient may receive a preparation of inferior quality compared to the brand name drug or of uncertain bioavailability. The Federal Drug Administration does establish standards which manufacturers must meet before they are approved

for marketing. Unfortunately, meeting these standards does not insure bioavailability.

Many generic companies now not only meet, but surpass the FDA standards. Some major pharmaceutical companies have now gone into the generic market. The price of drugs from these companies is usually slightly higher than the smaller generic companies' prices, but the advantage is that the major pharmaceutical companies have higher standards and usually guarantee a product of superior quality.

The FDA publishes a list of drugs which can be safely substituted. Also, many state agencies publish books which list drugs which they have tested and found to be bioequivalent.

The U.S. Generic Drug Market

The total amount spent on prescription drugs in the U.S. last year was $21 billion dollars. Approximately 28 per cent of all prescriptions written in the U.S. are for generics.[1]

In October of 1984, the Federal government passed the ANDA (Abbreviated New Drug Application)/Patent Restoration Act. This act makes it easier and faster for a generic company to have their product approved by the FDA. The act provides the legislative basis for the approval of abbreviated drug applications which do not contain full clinical data establishing

their safety and efficacy. Instead, all that a generic applicant has to show is that it has manufacturing capabilities, the product is properly labeled, and the product is bioequivalent to the pioneer product. In effect, this accelerates the approval process for generic drugs once the original product loses patent protection.

This means that about twenty per cent of those products approved since 1962, many with annual sales in excess of $100 million dollars, will become available at a lower cost within a very short period of time.

This act will also protect certain drugs which were approved after 1962 from generic competition from two to ten years depending on their dates of approval and types of applications approved. The law also provides for the extension of certain patents in order to restore some of the effective patent life lost in the process of obtaining FDA pre-market approval.

The ANDA/Patent Restoration Act will give the consumer the opportunity to buy more drugs in generic form which will include many of the big selling drugs. In recent months, ANDA's have been filed for more than two hundred off-patent drugs and the FDA seems inclined to process them quickly.

The largest promoters of generic drugs are the third party programs, which come about when an insurance company (third party) pays for the patients' prescriptions. Also, a good number of drug chains encourage the dispensing of generic drugs on which the gross profit ratio is apt to be higher than on the brand name drugs.

Approximately two hundred fifty drugs with a total sales value of $4 billion dollars have entered or will soon enter the off-patent pool. According to some analysts, by 1990 the generic market will account for $8 billion dollars in sales, comprising forty per cent of the total U.S. drug market.[2]

In 1984, generic prescriptions increased almost two per cent over the previous year. The top thirty generics account for almost ten per cent of all new prescriptions. Total prescriptions filled rose to 1,533,620,000 in 1984 which is a 1.7 per cent increase over total prescriptions in 1983. The 1.7 per cent increase in the total number of prescriptions filled (1984 vs 1983) compares with a 1 per cent rise in the total number of prescriptions filled (1983 vs 1982). Refills in 1984 grew 2.1 per cent over 1983, while new prescriptions were up only by 1.2 per cent. Branded new prescriptions rose 1.2 per cent (1984 vs 1983), while new generic drugs showed a gain of 1.9 per cent over the same period.

Prescription Volume in 1984 Compared to 1983

	1984	1983	% Increase
New Prescriptions	751,627,000	742,399,000	1.2
Branded	665,192,000	657,551,000	1.2
Generics	86,435,000	84,848,000	1.9
Refills	781,993,000	765,735,000	1.7
Total Prescriptions	1,533,620,000	1,508,134,000	1.7

Source: Pharmacy Times - April 1985 Edition.

Importing Pharmaceuticals

All foods and medicines manufactured in or imported into the United States are subject to approval by the FDA. The FDA inspects manufacturers and facilities, tests products, establishes standards, approves licenses of manufacturers under its jurisdiction, and establishes labelling policies. Because of its high standards, the FDA is respected by the United States consumer. Therefore, generic medicines which undergo the same rigorous examinations as brand name drugs have found wide acceptance by the population.

Foreign companies must meet the same requirements for product registration as American companies. There are two additional requirements for imported pharmaceuticals. First, there is a customs quarantine and a quality statement by an independant laboratory which has been approved by the FDA. The second requirement is the examination of three batches of the drug per year under stress stability conditions.

There is a definite trend toward increased pharmaceutical industry competition from new sources. As most people in the industry know, there are frequent complaints about over-regulation in the US. Despite this feeling of over-regulation, we see increasing competition from foreign companies, especially the Japanese. We expect a growing presence by these firms not only in product development, but in

establishing their own on shore manufacturing and marketing.

The US remains the most attractive pharmaceutical market in the world. All things being equal, where there is promise, competition is certain to follow.

While half of the new drug patents issued in the US are granted to foreign firms, there are presently very few foreign generic companies importing into the US. This may be due to the fact that generics are priced very low to begin with and the cost and restrictions of importing make it difficult to compete with American drug companies. However, quite often, the raw materials used to manufacture the generics are imported from overseas.

The Top Generic Drugs in the US

Of the top fifteen generic drugs (new prescriptions), almost one-half (seven drugs) are antibiotics. Antibiotics account for 12.61 per cent of the nation's prescriptions. All told, drug stores dispensed 133 million prescriptions for antibiotics, amounting to $936 million dollars in acquisition costs.[3] Under pressure from generics and mandatory substitution laws, many brand name drug manufacturers have in many instances lowered their prices.

In addition, thirteen of the top fifteen generic drugs had over one million prescriptions written for. With respect to

generically written prescriptions, the following chart is based on prescriptions dispensed by the pharmacists instead of prescriptions prescribed by the physician. This reflects the importance of the retail pharmacist's decision making authority regarding multiple source drugs. This is especially important since every state within the US now has some form of substitution law which allows the pharmacist to dispense a generic drug at his discretion if the doctor okays it.

The data listed in the following tables are for prescriptions filled in retail pharmacies only. They do not include drugs dispensed in hospitals. These tables show which drugs pharmacists dispensed pursuant to the doctors prescriptions.

The Top 15 Prescribed Generic Drugs (New Rx's)

Rank	Generic Drug	Use	Equivalent Brand Name
1	Amoxicillin	Antibiotic	Trimox, Amoxil Polymox, Wymox
2	Ampicillin	Antibiotic	Amcill Pollycillin Tetracillin
3	Penicillin VK	Antibiotic	Pen Vee K Ledercillin
4	Tetracycline	Antibiotic	Achromycin Sumycin
5	Prednisone	Cortisone deriv.	Meticoren
6	Erythromycin stearate	Antibiotic	Erythrocin
7	Hydrochlorthiazide	Antihypertensive Diuretic	Hydrodiuril Esidrex
8	Phenobarbital	Anti-convulsent	None
9	Nytroglycerin	Anti-anginal	Nitrostat
10	Erythromycin Base	Antibiotic	E-mycin
11	Acetaminophen/codeine	Analgesic	Tylenol/codeine
12	Hydrocortisone cream	Topical cortisone for allergic skin	Hytone rashes
13	Doxycycline	Antibiotic	Vibramycin
14	Thyroid	Hormone	None
15	Digoxin	Anti-arrythmic	Lanoxin

Source: Pharmacy Times - April 1985 Edition

The Top 15 Prescribed Generic Drugs (Refills)

Rank	Generic Drug	Use
1	Hydrochlorthiazide	Antihypertensive
2	Thyroid	Hormone
3	Phenobarbital	Anti-convulsent
4	Tetracycline	Antibiotic
5	Dipyridamole	Anti-arrythmic
6	Furosemide	Diuretic
7	Nitroglycerin	Anti-anginal
8	Prednisone	Cortisone deriv.
9	Acetaminophen/codeine	Analgesic
10	Erythromycin	Antibiotic
11	Isosorbide dinitrate	Anti-anginal
12	Amoxicillin	Antibiotic
13	Hydrocortisone	Skin rashes
14	Ampicillin	Antibiotic
15	Amitriptyline	Anti-depressant

Source: Pharmacy Times - April 1985 Edition

The Top 15 Prescribed Generic Drugs (New + Refills)

Rank	Generic Drug	Use
1	Hydrochlorthiazide	Antihypertensive
2	Thyroid	Hormone
3	Phenobarbital	Anti-convulsent
4	Tetracycline	Antibiotic
5	Amoxicillin	Antibiotic
6	Dipyridamole	Anti-arrythmic
7	Furosemide	Diuretic
8	Penicillin VK	Antibiotic
9	Erythromycin	Antibiotic
10	Acetaminophen/codeine	Analgesic
11	Ampicillin	Antibiotic
12	Prednisone	Cortisone
13	Amitriptyline	Anti-depressant
14	Isosorbide	Anti-anginal
15	Hydrocortisone cream	Skin rashes

Source: American Druggist - February 1985 Edition

As is evident, drugs used to treat acute conditions such as colds, sore throat infections, and pain rank high on the list of new prescriptions. Drugs used to treat chronic conditions such as high blood pressure and heart disease are lower down on the list of new prescriptions but higher on the list of refilled prescriptions.

The decision to use a generic product is based on a number of factors, including the pharmacist's professional judgement. Therefore, it is expected that generic drug products will grow significantly in the future.

Pharmacists will probably encounter a significant demand for many of the newer or soon to be generic products. Most of the products in demand will be for chronic use affecting major markets and currently generating a high volume of prescriptions for most pharmacies.

Following, is a table of some major drugs whose patents have recently expired or will expire soon. The off-patent status of these drugs will make a major dent in the generic drug market.

Major Drug Patent Expirations In The US : 1984-1987

Product	Manufacturer	Rank	Patent Expires
Inderal	Ayerst	1	1984
Valium	Roche	4	1985
Motrin	Upjohn	9	1985
Keflex	Dista	11	1987
Aldomet	Merk Sharp Dohme	12	1984
Ativan	Wyeth	22	1986
Diabinese	Pfizer	23	1984
Minipress	Pfizer	32	1987
Haldol	McNeil	57	1986

Source: American Drug - July 1985 Edition.

Brand Name Versus Generic Drugs

The following survey conducted by Wyeth Laboratories of 2,603 doctors, shows doctors' attitudes towards prescribing generic drugs.

-How often does a doctor prescribe a generic alternative?

Sometimes	53.3%
Usually	21.8%
Rarely	20.7%
Never	4.2%

-How do doctors specify their desire for a brand name or generic product?

Dispense as written	51.0%
Substitution permitted	26.1%
Do not specify	24.6%

Replies surveyed total more than 100% due to multiple answers.

If the physician signs dispense as written, the pharmacist must dispense the exact drug as written by the doctor. If the physician signs substitution permitted or does not specify, the pharmacist may dispense any alternative drug which he feels is proper (laws may vary from state to state).

-Which drugs are doctors most likely to prescribe by generic names?

Drug	Usually	Sometimes	Rarely	Never
Penicillins (Ampicillin,Amoxicillin)	54.0%	22.0%	10.6%	13.4%
Thiazides (Hydrochlorothiazide)	33.6%	29.2%	15.5%	21.6%
Furosemides	11.0%	10.9%	21.0%	57.1%
Oral Cephalosporins (Keflex)*	12.1%	18.6%	24.7%	44.6%
Beta Blockers (Inderal)#	9.7%	10.9%	26.0%	53.5%

* - on patent through 1986 # - generic recently approved.

-Why would a doctor insist on a brand name product?

Product quality	76.8%
Habit	20.1%
Manufacturer	14.9%
Encourage research and development	14.7%
Professional representatives' influence	12.4%

-Replies surveyed total more than 100% due to multiple answers.

The top fifteen prescribed generic drugs comprise almost seventy-five per cent of all the generic drug prescriptions dispensed in the US and 8.5 per cent of all prescriptions dispensed. It is interesting to note that the top three generic drugs are all antibiotics which are used to treat acute conditions and the top three generic drugs of all prescriptions are used for chronic conditions. This is because refills account for 51 per cent of the total prescription business. Also, prescriptions for drugs used to treat acute conditions usually contain 0-2 refills per prescription, while drugs used to treat chronic conditions will contain 5-6 refills per prescription.

Approximate Quantities Sold of the Top Fifteen Prescribed Generic Drugs

The Top 15 Prescribed Generic Drugs (New Rxs)

Rank	Generic Drug	Number of New Rxs	% Generic New Rxs	%All New Rxs
1	Amoxicillin	13,052,000	15.1%	1.7%
2	Ampicillin	10,425,000	12.1%	1.4%
3	Penicillin VK	10,389,000	12.0%	1.4%
4	Tetracycline	7,285,000	8.4%	1.0%
5	Prednisone	4,783,000	5.5%	0.6%
6	Erythromycin stearate	3,955,000	4.6%	0.5%
7	Hydrochlorthiazide	3,810,000	4.4%	0.5%
8	Phenobarbital	1,886,000	2.2%	0.3%
9	Nitroglycerin	1,430,000	1.7%	0.2%
10	Erythromycin base	1,373,000	1.6%	0.2%
11	Acetaminophen/codeine	1,294,000	1.5%	0.2%
12	Hydrocortisone cream	1,142,000	1.3%	0.2%
13	Doxycycline	1,074,000	1.2%	0.1%
14	Thyroid	990,000	1.1%	0.1%
15	Digoxin	941,000	1.1%	0.1%

Source: Pharmacy Times - April 1985 Edition.

The Top 15 Prescribed Generic Drugs

New Rxs and Refills Combined

	Generic Drug	# of Tablets in millions	Usual # of Tablets per Rx
1	Hydrochlorthiazide	700	100
2	Thyroid	40	100
3	Phenobarbital	81	90
4	Tetracycline	292	20
5	Amoxicillin	520	20
6	Dipyridamole	436	100
7	Furosemide	182	50
8	Penicillin VK	416	40
9	Erythromycin	240	20
10	Acetaminophen/Codeine	78	30
11	Ampicillin	416	20
12	Prednisone	432	50
13	Amitriptyline	135	50
14	Isosorbide	210	100
15	Hydrocortisone Cream	2.85 tubes	1 oz. tube

Approximate number of tablets computed by multiplying the average number of prescriptions by the average number of tablets per Rx.

Approximate Quantities Sold of the Top 15 Prescribed Generic Drugs

All of the fifteen products listed in the preceding charts actually out performed their brand name counterparts. This list is limited to prescriptions dispensed in retail pharmacies only.

Although the number of new prescriptions increased by about 2 per cent in 1984, this number is smaller than originally hoped for. This is due to the fact that many non traditional retailers such as hospitals, health maintenance organizations, and mail order services, are trying to get a piece of the business.

Another drag in prescription activity has been due to the surge in larger size prescriptions. The average prescription in 1984 was for 59.1 doses per prescription which was higher than the average 56.8 doses per prescription in 1983.[4] This is caused by physicians' writing habits. Also, third party cost containment pressures are encouraging the filling of larger prescriptions since they incur fewer dispensing fees. This, however, only affects the number of prescriptions and not the number of actual dosage units.

Retail and Wholesale Prices for the Top 15

Prescribed Generic Drugs

Wholesale Prices for the Top 15 Generic Drugs

		Generic Drug		Brand Name Counterpart	
	Generic Drug	Cost per 100	Cost per 1000	Cost per 100	Cost per 1000
1	Amoxicillin 250 mg	$ 8.40	$ 80.70	$ 21.07	$ 200.72
2	Ampicillin 250 mg	5.35	41.75	17.68	167.79
3	Penicillin VK 250 mg	2.80	22.25	12.07	113.92
4	Tetracycline 250 mg	2.15	15.50	5.89	33.68
5	Prednisone 5 mg	1.50	8.95	Discontinued	
6	Erythromycine stearate 250 mg	6.50	61.00	12.96	123.08
7	Hydrochlorthiazide 50 mg	1.10	4.65	10.40	98.60
8	Phenobarbital 30 mg	N/A *	2.50	1.74	8.56
9	Nitroglycerin	2.04	N/A *	2.49	N/A*
10	Erythromycin base 250 mg	8.50	72.90	20.36	202.00
11	Acetaminophen/ codeine 30 mg	5.00	35.95	10.18	93.56
12	Hydrocortisone cream	1.20 per 30 g tube		3.98 per 30 g tube	
13	Doxycycline 100 mg	19.00	170.00	163.10	1412.38
14	Thyroid 60 mg	N/A*	3.95	3.33	30.25
15	Digoxin 0.25 mg	N/A*	5.95	4.31	34.68

* not available.

Source: Henry Schein Generic Co.

Medispan Pharmaceutical Pricing Guide.

Retail Prices for the Top 15 Prescribed Generic Drugs

	Generic Drug	Usual # of Doses per Rx	Generic Price	Brand Name Counterpart Price
1	Amoxicillin 250 mg	30	$ 5.29	$ 17.99
2	Ampicillin 250 mg	30	3.99	8.49
3	Penicillin VK 250 mg	40	3.99	7.69
4	Tetracycline	20	3.99	4.49
5	Prednisone 5 mg	50	3.99	N/A
6	Erythromycin 250 mg	20	3.99	6.59
7	Hydrochlorthiazide	100	3.99	14.99
8	Phenobarbital 30 mg	90	3.99	3.99
9	Nytroglycerin	100	3.99	4.49
10	Erythromycin base	30	5.29	9.79
11	Acetaminophen/codeine 30mg	30	3.99	5.29
12	Hydrocortisone cream	30 g tube	3.99	6.59
13	Doxycycline 100 mg	10	4.49	21.88
14	Thyroid 60 mg	100	3.99	5.79
15	Digoxin 0.25 mg	100	3.99	6.59

- Data supplied by White's Pharmacy - Montauk, N.Y.

Retail and Wholesale Prices for the Top 15 Prescribed Generic Drugs

The issue of prescription pricing is as old as the pharmacy profession itself. Articles on the subject date back to the nineteenth century. The subject of prescription pricing has brought about strong differences of opinion concerning the most appropriate approach. The rationale underlying the various approaches has not always been made clear.

Prescription pricing methods which have been used to date, may be listed as follows:

(1) A percentage markup.

(2) A flat or fixed fee.

(3) A combination of percentage markup and fee.

(4) A range of fees based on the cost of a drug.

(5) A range of percentages based on the cost of a drug and/or quantity of the drug being dispensed.

(6) The cost of dispensing a prescription plus a percentage of fixed net profit.

(7) A helter skelter approach.

The average price of a prescription will vary greatly from store to store. Some additional factors that affect pricing are services offered by the individual pharmacy such as charge accounts, delivery service, and patient profiles. The location of the pharmacy will also affect the price of prescriptions.

Usually, pharmacies located in major business areas will charge slightly higher for prescriptions due to higher rent and overhead prices. Therefore, prices in an individual store may differ significantly from the prices listed in the preceding chart due to any number of these factors.

The average retail prescription price in 1984 was $10.84. The average acquisition cost for each prescription was $7.28. Meanwhile, the average price for a generic prescription was $6.68 in 1984.[5]

The major reason for brand name drugs costing more than generic drugs is the cost of research and development. The pharmaceutical industry spent $3.5 billion dollars on research and development in 1984. The cost of developing a new chemical entity runs from $80 million to $100 million dollars. A new chemical entity takes a minimum of eight years to reach the marketplace in the US, which gives the pharmaceutical companies a maximum of nine years left on their patent to recover their investment.

It is estimated that about 10,000 candidate drugs are synthesized for every one that actually gets to market. For every ten drugs that reach the expensive and time consuming clinical investigation stage, only one is ultimately marketed.

The wholesale prices used in this report are the average wholesale prices (AWP), which is the average price that the pharmacies' wholesalers sell the drug for. However, most generic companies do offer quantity discounts to pharmacies if they purchase a certain amount of drugs. These discounts can be in the form of decreased prices, free goods, or extended dating. Extended dating is when drugs are purchased, but don't have to be paid for until a later date. Different pharmacies look for different types of deals. Some would rather pay a little more and receive extended dating, while others are looking for the best possible prices. The price differential between buying a bottle of 100 tablets vs a bottle of 1000 tablets is shown on the previous tables.

To further understand quantity discounts, we can examine, for an example, deals which Lederle Laboratories offer. Lederle Laboratories is a major pharmaceutical manufacturer which has recently expanded into the generic drug market. By purchasing $1,200 dollars worth of generic drugs from their company, a pharmacy can receive special prices. For example, Amoxicilin 250 mg capsules' average wholesale price is $21.27 for a bottle of 100. If a pharmacy buys directly from Lederle, the price goes down to $17.91 for a bottle of 100. Lederle's price for the same merchandise after a quantity discount is agreed upon would be $10.07. In addition, the pharmacy gets a guarantee that the prices will remain at this level for at least a year.

Lederle will also include $72.45 in free merchandise, a 4% discount off of the invoice, and extended dating for six months.[6]

Another form of quantity discount is utilized by buying the merchandise in cases as opposed to single bottles. These discounts usually range from 5 to 25 per cent, depending on the company selling and the drug purchased. A well run pharmacy can save quite a bit of money by buying the right product at the right time from the right company.

The Packaging of Pharmaceuticals

Pharmaceuticals come packaged in two basic ways. The first is called bulk packaging, which is packaging in bottles of 100, 500, or 1000 dosage units. The second method is unit dose packaging (blister packs), where each dose is individually packaged. Each method has its own advantages.

The advantage of bulk packaging is that it is much cheaper than unit dose packaging and bottles can be purchased in sizes large enough to fit the individual p cy's needs.

Unit dose packaging only comes in boxes of 100 dosage units and would cost about 40 per cent more than bulk packaging. For example, Prednisone 5 mg would cost $1.50 per 100 tablets, while unit dose packaging would cost $2.95 per 100 and Hydrochlorthiazide 50 mg would cost $1.10 per 100 tablets with

bulk packaging as opposed to $2.35 per 100 tablets using unit dose packaging.[7]

Unit dose packaging does have the advantages of better inventory control, less chance of contamination, and less chance of error in dispensing medications. Unit dose packaging is found usually in hospitals, where medication is often dispensed one tablet at a time.

It is this consultants opinion that due to the expense, unit dose packaging should be avoided. If a pharmacy or hospital really has a demand for unit dose packaging, they can buy a machine which would put the medication in unit dose packs at a rate of 60 to 70 dosage units per minute for a cost of $3,000 to $5,000 dollars. This would prove to be much more economical in the long run. However, the fact that there are government regulations in the US which limit the amount of dosage units that a pharmacy or hospital is allowed to pack for themselves, should be taken into consideration.

Conclusion

Generic drugs save money and they are part of the world wide health care cost containment push. Third party plans are one of the largest supporters of the health care cost containment push. They are now starting to offer incentives to both the patient and the pharmacy for substituting a generic drug for the

brand name drug prescribed. Third party prescriptions now account for 27.8 per cent of all prescriptions filled. They are also growing at a rate that is twice as fast as the growth rate of total prescriptions (3.8% vs 1.9%).

The state of Connecticut estimates that it will save over one million dollars this fiscal year by promoting the use of generic drugs. Under this program, it is estimated that the rate of generic substitution will be increased by approximately 3 per cent, yielding an average savings of $6.56 per prescription.[8]

With the increasing world demand for pharmaceuticals growing at an annual rate of 10 to 12 per cent during the 1980s, total sales are expected to double by the early 1990s. With the market expanding in this fashion, more and more generic manufacturers are beginning to pop up. Many of the large pharmaceutical companies have now gone into the generic business. Because of all these new generic companies plus the recently passed ANDA/Patent Term Restoration Bill, competition among generic manufacturers has risen sharply. The average retail price of a generic prescription has actually decreased by 22 cents in the past year.

Generic drugs are no passing fad. There is little doubt that generic prescribing and dispensing are here to stay and pressure to use generic drugs will surely grow. Lawrence

Hutt, President of the Upjohn Company has predicted that if no new drugs were to appear, 87 per cent of the pharmaceutical business would be in non-patented products by the year 1990.

Based on these observations, one can conclude that generic drugs are an increasingly growing market with almost unlimited possibilities for future growth and development.

FOOT NOTES

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TERMS OF REFERENCE

SALES OF GENERIC DRUGS IN THE USA

The consultant will contact representatives of generic drug importers and/or wholesalers in the New York tri-state area by personal visits and by telephone contact to investigate the following questions:

1. Approximately what fraction of drugs marketed in the US are "generic" (by value)?
   To what extent are the generic drugs being imported, and what are the main sources?
2. What are the ten to fifteen generic drugs sold in greatest volume in the USA?
3. What are the approximate quantities sold of these drugs?
4. Retail and wholesale prices for these drugs, including usual quantity discounts.
5. What are the usual packaging types? Would it be advisable to use European package style (blister packs, etc.) and if so, how much higher prices (if any) would then be acceptable?

The findings are to be presented in a report and supported by tables, carefully identifying sources, with analytical discussion.