PHARM/
DEFENSE
FUND

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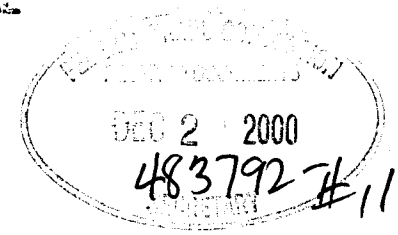
ORIGINAL



Secretary
Federal Trade Commission
Room H-159
600 Pennsylvania Avenue NW
Washington D.C. 20580

Subject: Generic Drug Study –FTC File No. V000014

The Pharmacy Defense Fund is a non-profit organization with no membership that serves as an advocacy instrument for pharmacists who strongly believe that consumers have a profound interest in drug distribution in the United States. Pharmacists are familiar with many industry practices and behaviors and it is our responsibility to contribute in those areas where our background and experience can be of value. This organization has made numerous submissions to the Federal Trade Commission over the past dozen years.

We strongly support the Agency's proposed information collection in the above subject file for it portends an opportunity for the major drug innovators, the generic industry, and consumers to better understand and explain behaviors that are now seen as murky or unfair.

We believe that the innovators of new drug entities are entitled to every single minute of patent protection that the laws allow. We also believe there is no excuse for the confusion, delay, and prolonged litigation over the last rites of a patent life.

The granting of a patent by the United States Government confirms for the patent holder a great deal of power and discretion as to how the product will be sold and the price that will be allotted to each potential purchaser. It is the posture of the Pharmacy Defense fund that patent protection also facilitates the destruction of competition by the exercise of arbitrary and capricious pricing to the advantage of one competitor over another competitor. Merck-Medco is an operational example of this astonishing discrimination.

Regardless of the ongoing destruction of competition, we strongly support the concept and laws pertaining to the rights and privileges of patents. We then plead and ask for you specific consideration in the following additional areas of this inquiry.

AVAILABILITY OF FINDINGS

In every single court action or industry examination that is undertaken, this industry requests and is usually granted a protective order so that behaviors, intrigue, agreements, kick-backs etc. are shielded from public disclosure. Would the commission make every possible effort to make available all information gathered from this effort?

SEPRACOR INC.

We believe and trust that Sepracor Inc. will also participate in your study. This company is rather unique in its operations with major patent holders and we suggest it would be helpful to understand their business model and the licensing and territory arrangements that they construct for "Improved Chemical Entities".

GENERIC COMPETITION

It is generally accepted that once a patent on prescription drug expires, the innovator will essentially abandon the drug and warn shareholders that "X" dollars in sales will be lost. Are the innovators incapable of competing in a market that they themselves have constructed? Could they not in fact defeat any competitor in the market with the experience and good will of their 17-year franchise?

There are several examples of drug items that are immune to generics by virtue of the manufacturing processes. Premarin by American Home Products, Dilantin by Pfizer, Lanoxin by Glaxo all seem to sail along on equivalency issues. In each case price escalation is the rule and price competition is the exception.

Could the Commission seek information regarding the marketing conditions that preclude competitive market pricing by the innovator company?

DIRECT TO CONSUMER DISPARAGMENT

Two major manufacturers produce the bulk of the insulin products used in the United States. In a recent mailing, the Lilly corporation sent consumers of insulin a letter headlined, "Is it safe to switch brands of Insulin"?[1] The answer is

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[1] Undated consumer mailing accompanying the January 2001 issue of "Diabetes Forecast" see attached copy.

of course it is safe if Lilly products are on the formulary. What we have with the Lilly letter is the implicit threat to shareholder interests. This threat is in the form of a reduced price in the marketplace that may result in reduced sales as a result of a contract between Wal-Mart Inc. and Novo Nordisk. The Wal-Mart insulin price is $16.94 per vial versus a price in excess of $20.00 for THE Lilly or Novo Nordisk insulin line.

This move by Wal-Mart is indeed unhealthy for Lilly shareholders.

We trust the Commission will have some room in your inquiry to examine direct to consumer disparagement.

THE HATCH-WAXMAN ACT

It seems that the good intentions of the Hatch-Waxman Act and the daily workings of the Act should be revisited. We believe that patent life should have been extended but this grant should not preclude a date certain for the validity of the patent. Why would any patent holder not file a patent-infringement action when he could guarantee himself a 30 months free of market competition? It seems that a patent should have a certain life to the last day and then move to a free for all in the market. You also have to wonder what the courts must think regarding this ritual. Is this abuse of process?

THE BURDEN

Your cited burden cost even if it is triple your estimate should be welcomed by all parties if the issues relating to patent expirations and assignments can be clarified.

Respectfully,

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Is it safe to switch brands of insulin?

Lilly's response to the recent announcement by Wal-Mart stores to switch Lilly insulin patients to Wal-Mart's store brand, ReliOn® insulin.

All insulin brands are NOT the same. We at Lilly firmly believe that a pharmacy should not switch your brand of insulin without your physician's involvement.

The type and brand of insulin you use have been carefully selected by your personal physician, based on your diabetes history and need for blood sugar control. Thus, your physician – not your pharmacist – is the medical professional who should be primarily responsible for any changes in your insulin therapy.

In fact, a statement mandated by the Food and Drug Administration (FDA) on every insulin product cautions that changing type or manufacturer of insulin should be done only under medical supervision. Your blood sugar control may need additional monitoring when switching brands, even if it is the same type of insulin.

No pharmacy can force you to switch your insulin brand. Simply insist on the same Lilly insulin you have always relied on. If you are concerned about Wal-Mart or any pharmacy switching your insulin, please call us at 1-888-88LILLY.

Lilly