Price

I.

DTP Vaccine

Current Business

Total Tetanus Market

Diphtheria, tetanus, and pertussis vaccine (DTP) is one of the four major tetanus-containing products available in the United States. Other tetanus-containing products include tetanus toxoid (both fluid and adsorbed), diphtheria-tetanus (pediatric), and tetanus-diphtheria (adult).

Total drugstore and hospital audited sales for tetanus-containing products during 1982 were MS6.7, an 8% increase over 1981 sales (Appendix I-a). Since a significant portion of sales in this market are made directly to physicians' offices and to the government sector, audited data significantly understates the market.

Audited sales of tetanus toxoid products have been decreasing during recent years (down 8% in 1982) but continue to represent 42% of the total market for tetanus-containing products. DTP and tetanus-diphtheria have 24% and 28% of the total market, respectively.

In 1982, sales of Lederle tetanus-containing products reached MS3.7, an increase of 2% over 1981 sales of MS3.6. By product, 1982 sales were as follows:

Tetanus toxoid:	k$1,019
Tetanus-diphtheria:	k$ 969
Diphtheria-tetanus:	k$ 180
DTP:	k$1,604

DTP Market

According to the Biologics Surveillance Report issued by the Center for Disease Control, the total market for DTP vaccines has been stable at approximately 18 million doses per year over the past 10 years (Appendix I-b). Lederle's share of this business has fluctuated during this period due to product availability. However, we have also steadily increased our DTP business to the point that we now represent approximately 35% to 40% of all doses sold in the United States.

Based on audited data, Wyeth Laboratories holds a lead in the drugstore and hospital segment of the DTP market (Appendix I-c). Their strength is predicated on the Tubex system of unit-dose and their intermediate pricing policies. Wyeth prices their DTP product approximately 15-18% below Lederle. In the past two years, Wyeth has followed the lead of Lederle, increasing prices approximately 60 days after we announce a price increase.

The impact of A. H. Robins' assumption of the Elkins-Sinn biological line has been very noticeable in recent years. Based on audited data, Elkins-Sinn's share of the DTP business has increased to the point that they now have approximately 10% of the private sector market. Elkins-Sinn sells primarily to wholesalers and to other larger distributors. Their price is at the lower end of the spectrum, approximately 40% below Lederle's price on DTP.

Lederle is the number two manufacturer of DTP, with an estimated market share of between 35% and 40%. In 1982, sales of TRI-IMMUNOL®, our trade name for DTP, reached MS1.61, an increase of 18% over 1981 sales of MS1.36 (Appendix I-d). Sales of DTP directly to physicians' offices (k3588) represent the largest share of total dollar sales (37%), followed closely by city, county, state (30%) and independent drugstores (25%).

In 1982, Lederle distributed approximately 480 thousand vials of DTP (Appendix I-e). This represents about 7.2 million doses. In contrast to dollar sales, over half of Lederle's unit volume (52%) is sold to the public sector (city, county, state). This discrepancy between dollar sales and unit movement results from the aggressive price bidding necessary to capture city, county and state contracts. For example, the 1982 average selling price of Lederle DTP to city, county, and state governments was $1.93 per vial, while the average price to M.D. clinics was $5.38 (Appendix I-f). The average selling price for the year was $3.34 per vial, only 2% more than the average selling price for 1981 ($3.27).

Liability Issue

Most children taking DTP will experience some side effects, the most common of which are fever, irritability and some soreness and swelling in the area where the shot was given. More serious side effects, such as high fever, convulsions or going into shock, have been associated with DTP vaccination. In some rare instances, brain damage has also occurred close in time.

In several European countries, the pertussis portion of the vaccine is no longer administered because studies there supposedly show that the risks involved outweigh the danger of contracting whooping cough. Although the medical authorities in England recommend its use, several physicians have sufficiently scared the public to reduce immunization level to about 35%. American medical authorities feel strongly that the benefits far outweigh the risks of the vaccine, and point to the current epidemic of whooping cough in England as supportive of their position.

In general, the American public was unaware of the debate surrounding DTP vaccine prior to April of 1982. On April 19, 1982, station WRC-TV in Washington, DC ran a Newscenter 4 special called "DTP Vaccine Roulette". This program was one-sided and took the position that the risk of taking DTP outweighed the benefits. Segments of the program were aired nationally on April 20 on the NBC Today Show. Lederle had only three (3) lawsuits in litigation concerning DTP

prior to April. Since the shows, Lederle has received an additional thirteen (13) lawsuits (Appendix I-g).

In December of 1982, Lederle won its first case (Malek versus Lederle Laboratories) involving DTP vaccine. The Malek case was the first brought against a manufacturer of DTP vaccine to go to trial. Malek's attorney, Mr. Allen McDowell, considers the Malek verdict a "fluke", which "...will have no affect on the other 40 cases" (Appendix I-h, Law Bulletin, Chicago, Illinois; Wednesday, December 29, 1982).

The liability problem is not unique to Lederle. We are co-defendants with Connaught on three lawsuits resulting from 2.5M doses of their material we distributed in 1980-1981. Connaught has approached Lederle to request government assistance in litigation. Verbal communication indicates that Wyeth's lawsuits number in the double digits. This information gives credence to Mr. McDowell's claim of 40 additional cases.

The liability resulting from this dramatic increase in lawsuits makes it necessary for a thorough analysis of our options relative to the DTP business. The three viable options for consideration are:

a. To stay in the DTP business with major strategy changes.

b. To withdraw from the DTP or total toxoid business.

c. To pursue a Federal liability program for the DTP vaccination program through the PMA.

Option a. - Stay in the DTP Business

Two major strategy changes are recommended which make staying in the DTP business the option of choice. They are to aggressively increase the price of the product and to decrease the liability on future lawsuits.

Significant progress has already been made on pricing strategy, as can be seen from the following action plan:

-Direction was given to the Price and Contract Administration Department to bid no lower than $5.40 on all contracts.

-We are currently attempting to get out of all existing contracts where we have a bid price below $5.40. Although 215k vials are in this category, the CDC contract for approximately 130k vials at $1.37 per vial was terminated.

-A 15% price increase on the single unit price is effective March 1, 1983. The price will be $7.85 per vial.

-Significant price increases are planned for 1983 to continue to raise the average selling price and assure a profit.

Assuming the same volume distribution in March, the average selling price (ASP) will be approximately $6.40, nearly double the ASP of $3.34 in 1982. Subsequent pricing strategy should be predicated on an analysis of a Break Even Matrix as outlined in Table 1.

Table 1: Break Even Matrix for DTP
Including Liability Costs

Sales Volume (M Doses)	Cost Per Suit (k$)	(Cost/Vial) Number of Doses for Lawsuit 2M	3M	4M
3.5	1,000	13.07	11.00	9.32
7.0	1,000	10.62	8.14	6.87
3.5	500	9.31	8.07	7.44
7.0	500	6.87	5.63	5.00

The assumptions for this analysis include:

- All lawsuits are lost or settled at corresponding cost.
- The lawsuit is added to the variable cost and the period cost is constant at MS1,142. For example, a MS1 settlement at the rate of 1 suit/2M doses would equate to $0.50 per dose.
- The variable and period costs exclude SGA and Pension and Group Insurance.

A review of the lawsuits to date indicate a level of 1 suit per 2 million doses sold.

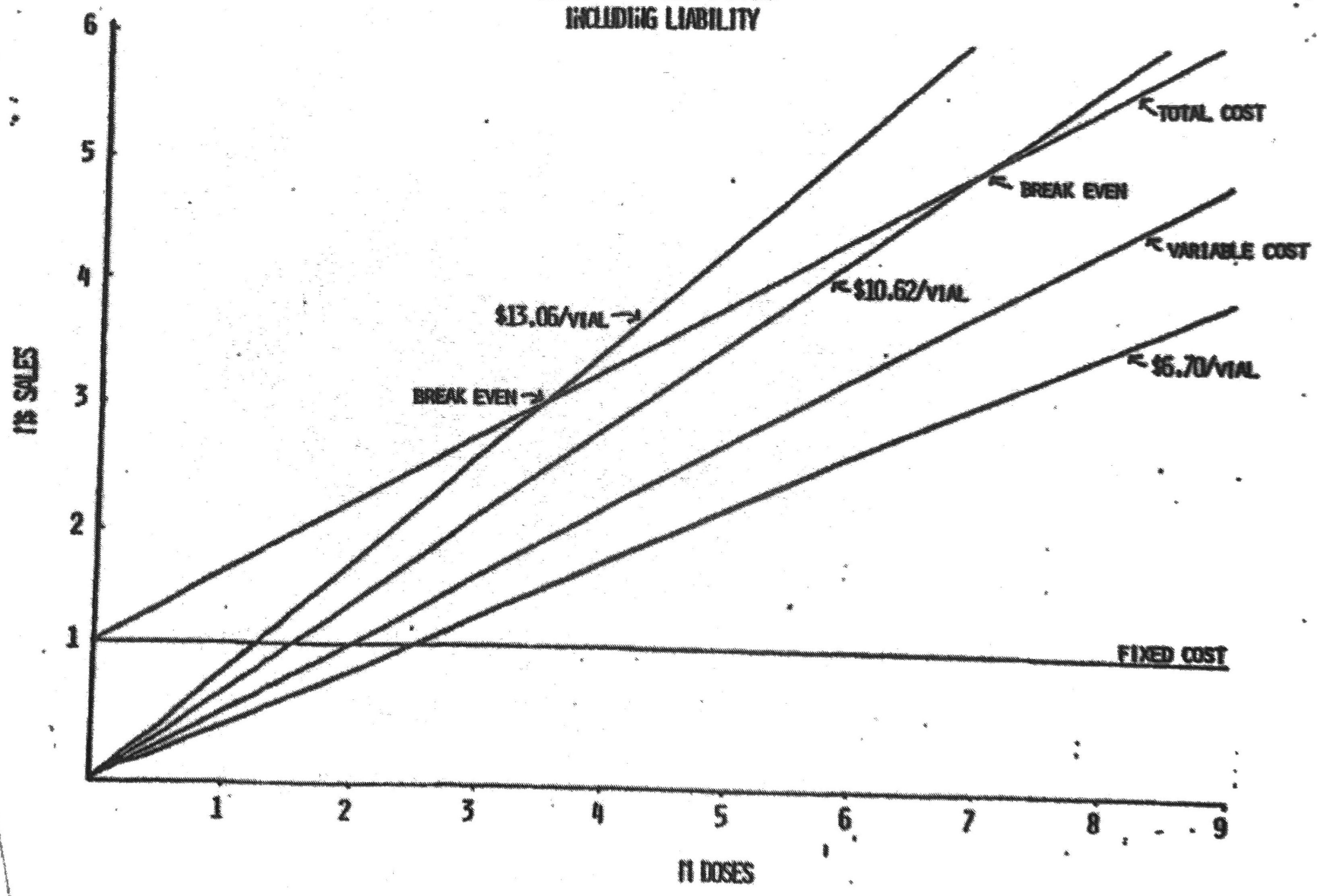
It is appreciated that these numbers must be closely monitored to assure that the peak of suits from the publicity has abated so that the projection will be accurate for pricing strategy.

A similar pricing analysis can be seen graphically keeping the suits constant at 1 per 2M doses and projecting a MS1 settlement (Graph 1).

In the short term, our strategy should cost business, but this is to our advantage because the more that is sold below the break even point, the more we lose. Given the fact that our competitors have the same problem, they can be expected to also increase their prices. If they do not, we should still be able to maintain the more desirable private business which raises our ASP. Our competitors must also be weighing their options, and it is not unreasonable

UNIT - 1.

PRICING STRATEGY FOR DTP
INCLUDING LIABILITY



to see one get out of the business. This should make our pricing strategy easier and the market more profitable. If one or both don't follow our lead, they get the business and associated liability and Lederle is effectively out of the business.

The second major strategy change is to develop a patient package insert to inform DTP recipients of the risks versus benefits of the vaccine. Sufficient quantities of this insert would be mailed with each vial of DTP distributed.

. At this time, most physicians are aware of the risks, but have done little to inform patients. A patient package insert could get us closer to this goal. The American Academy of Pediatrics' Redbook also recommends this procedure and has developed a consent form as a guideline for physicians (Appendix I-1).

In summary, the option of major strategy changes is recommended at this time; however, it needs close monitoring to assure its effectiveness, specifically to assure that the costs cover the liability anticipated for current production. There are additional favorable conditions which can be expected to improve the economic analysis just presented. They include:

- -Significant period cost reductions which will start in the second half of 1983 (approximately k$250).
- -The capacity to bid on defense contracts.
- -The Class I recommendation for all Lederle toxoids, which can provide a marketing advantage for the other toxoid products.

Option b. - Immediate Withdrawal from DTP or Toxoid Business

This option is not favored at this time, but it becomes the desirable option if the recommended strategy changes are not effective. Though future liability is avoided, significant financial penalties will occur in terms of inventory and period cost distributions.

Marketing Considerations. Withdrawal from the DTP business would have little or no impact on the sales volume of the balance of our toxoid business. Most pediatricians view DTP vaccine as a commodity item and make their buying decision on price rather than company image or reputation.

Financial Considerations. Total period costs for DTP are k$1,143, consisting of k$381 prime period, and k$762 allocated. Withdrawal from the business in 1983 would only reduce this cost by k$87. Thus, the remaining 1983 prime and allocated period costs for TRI-IMMUNOL® (k$1,056) would have to be adsorbed by

the balance of the toxoid line in 1983. Adsorbing these costs would make the remaining toxoid products unprofitable in 1983.

The 1983 total prime and allocated cost for the total toxoid line (including DTP) is MS3.1. Withdrawal from the total toxoid business in 1983 would only reduce these costs by KS823. Thus, it can be seen that both TRI-IMMUNOL® and the balance of the toxoid line are responsible for approximately MS2.4 of overhead that would have to be distributed.

From an inventory point of view, we currently have approximately KS850 full cost inventory at various stages of development. Withdrawal from this business would probably require writing off this entire inventory. It is possible that we might be able to sell some of this material to foreign governments if we were absolved of any liability. This contingency has not been explored.

At the present time, we have firm contract commitments to supply 215,000 vials of DTP vaccine to various state governments. Almost all of these contracts have penalty clauses which, if Lederle failed to supply, would require Lederle to pay the difference between our bid price and what the state would have to pay another supplier for DTP vaccine.

Legal Considerations. Withdrawal from the DTP business could possibly be viewed by a jury as an admission of guilt on the part of Lederle. R. Crakas and M. Teicher did not believe that this would have any effect on the outcome of pending trials. The only concern which they expressed was that our withdrawal from this business might possibly alienate some of our expert witnesses so that they would be less willing to testify on our behalf.

Option c. - Pursue Government Assistance in Litigation

The objective would be for the three manufacturers, under the auspices of the PMA, to pursue a Federal program to cover liability for DTP vaccinations. Dr. Vallancourt has already been contacted by Connaught Laboratories, who suggested that we meet to discuss this option.

We do not believe that a Federal liability program would be in the best interest of Lederle. This issue, as it pertains to ORIMUNE®, was thoroughly reviewed by Mr. Bowman in July of 1982. We would recommend against pursuing a government indemnification program for DTP vaccine because it could lead to a Federal liability for all vaccines, including ORIMUNE®.