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CUTTER

MARKETING
RESEARCH

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Subject: ~~KOATE-SALES TRENDS~~ (Part 1 of Marketing Research Project #623)

Project #623: Part 1 - Koate Sales Trends (Attached)

Part 2 - Physician Teleconferences on AIDS'
Impact (In Progress)

(CONFIDENTIAL)

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I. EXECUTIVE SUMMARY

Koate® sales (in AHF units) in the period January through April 1983 were down 29% when compared with the same period in 1982. To determine why sales were down so sharply, parameters of the entire customer base during these two time periods were compared to identify general trends. The top 45 accounts of early 1982 were analyzed individually to identify specific reasons for sales decline (when present).

Concern about transmission of Acquired Immune Deficiency Syndrome (AIDS) has definitely caused shrinkage of the market for factor VIII among Cutter customers. Most institutions appear to be following the National Hemophilia Foundation's recommendations and thus have switched some patients to cryoprecipitate and are delaying elective surgery when appropriate. Additionally some centers feel some of their patients may be reducing dosage or using concentrate less frequently than in the past - even though in most cases physicians have not recommended any change in treatment.

However, sales loss may not be attributable solely to AIDS. For instance, there were 13% net fewer accounts in early 1983 than in early 1982. The biggest net loss of accounts (and sales) was in the hospital customer segment. Unfortunately it is not possible to isolate the sales impact of this general decline from other factors.

Two additional factors contributing to the sales decline are probably being helped by concern about AIDS, but they were already in progress anyway. The American Red Cross appears to be taking advantage of the AIDS crisis to increase market share with its purportedly "cleaner" (volunteer) blood in certain areas, although its political savvy is also playing a part in their growth. Hyland may be finding it easier to convert accounts to their new heat treated product due to fear of AIDS, but some accounts consider the theoretical reduced risk of hepatitis to be sufficient reason to switch, especially for new patients.

Part 2, the Physician Teleconferences on AIDS' Impact (to be published late in July), reveals a great deal about physician attitudes toward donor pool importance and the relevance of heat-treated product and is a much better predictor of the future than this descriptive report.

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II. CONCLUSIONS

- o Factor VIII usage among Cutter customers has clearly decreased due to concern about transmission of AIDS and resultant changes in treatment. However, the Red Cross also appears to be increasing its market share among Cutter customers since it uses only volunteer donors (presumably "safer" with regard to AIDS) and it also puts key clinicians on their board and thus encourages switching to Red Cross concentrate. Heat-treated product is also contributing to reduced Koate® sales, although it had affected only one large account as of April 1983. (It just became available for sale March 21, 1983.)
- o The net number of Cutter Koate® accounts has declined from 403 in early 1982 to 350 in early 1983, a 13% decrease. Since five distributors have been dropped since early 1982, one would have expected the number of accounts to increase. In absolute numbers, the most accounts were lost in the hospital segment. Impact of this net account loss versus other factors cannot be estimated however.
- o Customer Service Records (CSRs) indicate that solubility (reconstitution time) is a continuing problem with Koate® and more recently the yellow color of Koate® has caused complaints. However, it is not clear whether this has resulted in any sales loss, especially when compared with the importance of pricing.
- o Orthopedic Hospital represents a unique problem in that some portion of a very large sales decline (-2.3 million AHF units) is due to disagreement over Koate® assay results. No specific product problem is evident, yet there has been significant account market share impact (per Sales).

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III. RECOMMENDATIONS

- AIDS Surveillance: Continue to monitor developments in the spread of AIDS. Further incidence among hemophiliacs could cause even more downturn in Koate® usage and Cutter could quickly develop a massive excess inventory situation.
- Competitive Surveillance: During this volatile period it is especially important to continue aggressive investigation of competitive activity with regard to pricing, product quality and product service. AIDS may be causing some accounts to re-evaluate the value of Red Cross sourced (volunteer donor) and heat-treated alternatives.
- Heat-treated: Continue development of heat-treated product since some accounts are switching, despite higher price and total lack of clinical data. Due to AIDS, this has become an emotional issue. More discussion of this issue will be presented in Part 2 - Physician Teleconferences on AIDS' Impact.
- Product Quality: Manufacturing should continue to strive toward a clear and colorless, fibril-free, fast reconstituting product so business is not lost in the future due to patient dissatisfaction with Koate®.

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IV. PURPOSE

This study was designed to determine reasons for the Koate® sales decline in early 1983. Specifically, how have the following factors affected Cutter accounts:

- AIDS - How has concern about transmission through blood products affected concentrate usage?
- Heat-treated product - Have customers switched?
- Product characteristics - Are there problems causing dissatisfaction?
- Pricing - Has Cutter lost a great deal of business due to (high) bids?

This portion of Marketing Research Project #623 is intended to be descriptive whereas Part 2 has much better predictive value since it investigates the attitudes and thought processes of physicians.

V. INTRODUCTION

Koate® sales in AHF units for the four month period January through April 1983 were 29% lower than during the same months in 1982, a decline of over 20 MM AHF units. It was clear that concern about AIDS prevention was affecting usage, but the extent of this effect was unknown. It was also possible that other factors could be contributing to a loss of market share, not just decrease in the total market size.

January 14, 1983 the National Hemophilia Foundation (NHF) gave recommendations for preventing AIDS in patients with hemophilia. Please see Appendix A for the complete text. In summary, the Medical and Scientific Advisory Council recommended that the following patients be put on (or kept on) cryoprecipitate: a) newborn infants and children under 4, b) newly identified patients and c) clinically mild hemophiliacs. Elective surgical procedures are to be evaluated carefully and possibly delayed. A synthetic antidiuretic hormone, 1-deamino-8-d-arginine vasopressin (DDAVP), should be used for some mild and moderate patients.

VI. RESEARCH METHOD

Year-to-date Koate® Sales report #BKDSL.941 showed 1982 and 1983 January through April sales of Koate® for invoiced customer accounts. (Note: Not all shipping locations were included.) Different account numbers for some institutions and multiple locations for the same account number were combined when discovered. (There is chance for some error in this manual combination process due to the way account names and numbers are assigned.)

The total number of accounts were tallied and then manually split into seven customer-type segments: Hospitals, Blood Banks, Military, Pharmacies, Distributors, Hemophilia Foundations (without specified hospital affiliation) and Other.

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The 45 accounts which purchased more than 400,000 AHF units in 1982 were analyzed individually. If sales were down, Biological Sales personnel (Headquarters, Field Sales Managers and, in some cases, Sales Representatives) were contacted to discuss the reasons. Documentation in Bids and Quotation's file was analyzed for information about "lost bid" accounts.

Due to concern about customer discomfort with direct questions on Koate® usage and duplication with Part 2 of this research project, customers were contacted as little as possible. Thus much of the information in this report comes from indirect sources. In this researcher's opinion, it is more likely that errors of omission have occurred than commission (bias, distortion).

When it was necessary to interview customers by phone, the nurse coordinator was usually surveyed since many doctors were contacted regarding participation in Part 2 of this project. Additionally it was felt that in some instances the nurse coordinators might actually have more insight on patient attitudes and current factor VIII usage. See Appendix B for the discussion guide/questionnaire.

VII. FINDINGS

There was a 13% net reduction in the number of customer accounts; unfortunately, it is not possible to quantify the relative sales impact of this net loss versus other factors for the following reasons:

- There is tremendous account turnover year to year - - approximately 50% of a sample of 147 non-distributor accounts in early 1982 had turned over by early 1983.
- Because many accounts buy from more than one supplier, a reduction in purchases does not necessarily reflect reduction in usage.
- Reduction in purchases could result from AIDS concern, product quality issues, availability, etc. There is no quantitative way to isolate these problems when they are combined in one account.

See Tables 1, 2 and 3 (pages 9 -10) for a summary of changes in Koate® accounts between early 1982 and 1983 by customer segments. Highlights follow:

- The hospital segment lost the most accounts (-4% net) and had the biggest decline in units purchased (-13.4 million AHF units net). (Tables 1 and 2).
- Aside from distributors, the military segment had the greatest percent decline in number of accounts (-42% net). (Table 1).

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- Beside distributors, blood banks had the greatest percent decrease in the number of AHF units purchased (-38% net). (Table 2).
- Blood banks represent a high percent of sales relative to the number of accounts. (Table 3).

Table 4 (pages 11-15) details the purchasing situation in the top 45 accounts (ranked by January through April 1982 sales.) Table 5 (page 16), shows new "large" (greater than 400,000 AHF units purchased in four months) accounts as of April 1983.

It is important to remember that, in the opinion of several sales managers, a 10 to 20% variance in a four month time period is normal due to different amounts of emergency surgery, inventory level changes, etc. Also keep in mind that many accounts use multiple vendors and the percent change in Cutter sales does not necessarily reflect what the account as a whole is doing. For instance, one hospital showed a 10% sales increase to Cutter but in the teleconference (Part 2) the Medical Director said his records showed a 15% decrease in factor VIII usage. Another limitation to the data is that Table 4 reflects invoiced units, not actual usage, although one should follow the other relatively closely except in times of inventory build up or reduction.

• AIDS impact:

- Elective surgery is being postponed in some institutions (See Part 2 for physicians's attitudes about this).
- Some patients are asking to be switched to cryoprecipitate and some physicians are using cryoprecipitate for surgery now when previously they used concentrate.
- Physicians are following NHF recommendations on use of cryoprecipitate with young and mild patients.
- Some patients are cutting back on dosage and number of uses -- especially if they were treating heavily (possibly "over-treating") before. Only a few centers had recommended this reduction however.
- Two centers recommended against using concentrate prophylactically or recommended cutting back on prophylactic usage.
- Orthopedic Hospital in L.A., the single largest account, reduced purchases by 2.5 million AHF units (-45%) reportedly due to some extent on Koate® not passing their assay test (in addition to complete halt of their extremely heavy elective surgery schedule for several months). (Table 4)

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- Pricing on contracts caused a net loss of 2.1 million AHF units among large accounts. Seven accounts were lost (exclusive of distributors) and four new ones were added in early 1983. Three more accounts increased purchases to the "large" account status in 1983 (Tables 4 and 5).
- Three accounts have partially switched to Red Cross concentrate due to: (Table 4)

- Feeling that the risk of AIDS is less with volunteer donor fractionated plasma.
- Political considerations (Luminary physicians are put on the Red Cross Board and thus are encouraged to buy Red Cross products.)
- Significantly lower price of 8.5¢/AHF unit (in one account).

Note: These accounts would switch entirely to Red Cross product if the supply becomes/stays adequate (per Sales). One district sales manager felt the Red Cross was pursuing new business very aggressively and could be expected to expand production capacity long term.

- One account has partially switched to heat-treated factor VIII. Two more feel they will be switching (Table 4).
- Sales representatives for two accounts mentioned that they sent in Customer Service Reports (CSRs) on Koate® not re-constituting properly (Table 4).
- General observations: (Table 4)
 - 5 of the 45 top accounts were distributors
 - Blood banks are a high proportion of the large accounts (22%) versus just 7% of the total number of accounts.

The comments about large accounts on Table 4 help to explain about two-thirds of the total unit sales decrease. (See Table 6, page 17 for the calculation.) Please keep in mind that even among the top 45 customers there could be additional factors causing the sales downturn which were not discovered due to the way information was collected, i.e., primarily indirectly.

Table 7, page 18, shows the major non-human product problems with Koate® from January 1982 through March 1983 as reflected on CSRs. Although the number of CSRs is small relative to the number of Koate® customers, it does appear that solubility and perhaps the yellow color are continuing problems. Appendix C, a portion of a letter from a customer also succinctly

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It is completely unknown at this point how a center would weigh product cost against patient satisfaction with the product from a convenience/aesthetic standpoint (as opposed to medical effectiveness).

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Table 1

KOATE CUSTOMERS INVOICED* - BY CUSTOMER SEGMENT

Customer Segment	1982	1983	Δ	%Δ
	Jan-Apr	Jan-Apr		
Hospitals/Medical Centers	305	258	(47)	(15%)
Blood Banks/Centers	27	30	3	+11%
Military	19	11	(8)	(42%)
Pharmacies	16	17	1	6%
Distributors	6	1	(5)	(83%)
Hemophilia Centers/Foundations	4	4	0	0
Other (State Bd of Health, prisons, etc.)	26	29	3	12%
Total	403	350	(53)	(13%)

* Adjusted for obvious multiple account numbers and multiple invoice locations for the same institution.

Table 2

KOATE AHF UNITS INVOICED, BY CUSTOMER SEGMENT

Customer Segment	1982	1983	Δ	%Δ
	Jan-Apr (AHF units, 000)	Jan-Apr (AHF units, 000)		
Hospitals/Medical Centers	46.5	33.1	(13.4)	(29%)
Blood Banks/Centers	14.4	8.9	(5.5)	(38%)
Military	0.9	0.8	(0.1)	(11%)
Pharmacies	0.4	0.5	0.1	15%
Distributors	3.6	1.5	(2.1)	(57%)
Hemophilia Centers/Foundations	0.9	1.2	0.3	35%
Other (State Bd of Health, prisons, etc.)	3.4	3.5	0.1	1%
Total	70.1	49.5	(20.6)	(29%)

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Table 3

CUSTOMER SEGMENTS - RELATIVE SIZE

<u>Customer Segment</u>	1982		1983	
	% of Total	% of Total Sales (AHF units)	% of Total	% of Total Sales (AHF units)
Hospital/Medical Centers	76%	66%	74%	67%
Blood Banks/Centers*	7	21	9	18
Military	5	1	3	2
Pharmacies	4	1	5	1
Distributors	1	5	+	3
Hemophilia Centers/Foundations	1	1	1	2
Other (State Bd of Health, prisons, etc.)	6	5	8	7
Total	100%	100%	100%	100%

* United Blood Services has multiple locations. It was counted as one account for purposes of this report.

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Key: _# = Number of account numbers contributing to the indicated sales.
(If nothing is shown, assume only one account number was involved.)

_loc = Number of locations (invoice points) contributing to the indicated sales (If nothing is shown, assume only one location was involved.)

BR = Blood Bank

Cryo = Cryoprecipitate

Distr = Distributor
Hem = Hemophilia treatment center/foundation
(with no hospital indicated)
Hosp = Hospital
Pt = Patient
U = Unfavorable (more than 99% reduction)

SIC 40 NF	CUSTOMER NAME (INVOICED) CITY/STATE	Sales (in Units)(000)			Summary Comment Reasons for Decline **	Detailed Comments**	Comment Source
		Jan		%			
		1982	1983				
Hosp	1. Orthopedic Hosp Phy Los Angeles, CA	5119 20	2840 10	(45%)	<ul style="list-style-type: none"> • Route often fails their assay • Temporarily discontinued extremely heavy elective surgery schedule (A1105) 	<ul style="list-style-type: none"> • Cutter account market share down from about 50% to 20%. Using Alpha, Armour, Hyland and Cutter. • Hosp gets different assay results than Cutter - Scientific difference of opinion • Hosp started doing elective surgery again. • Slight reduction due to patient concern about A1105 	Sales and Marketing
Hosp	2. U.C. Hospital & Clinics San Francisco, CA	2621	2564	(2%)	<ul style="list-style-type: none"> • No change 	<ul style="list-style-type: none"> • Lost one account (650,000 unit loss) • Four pts switched to ARC concentrate (470,000 unit loss) • Three pts switched to cryo (330,000 unit loss) • One pt moved - now at Middlesex Hosp (Cutter account) (100,000 unit shift) • Rest (379,000 unit loss) due to "A1105" BR does not have details on what every center/pt is doing. 	Sales
NR	3. Community Bld Bank of S. NJ Inc. Cherry Hill, NJ	2451	522	(79%)	<ul style="list-style-type: none"> • BR lost one account • Switch to ARC (A1105) • Switch to cryo (A1105) • Lost one patient 		Sales
NR	4. New York Blood Center New York, NY	2384 1 loc	2482 1 loc	4%	<ul style="list-style-type: none"> • No decline 		-----
Hosp	5. T. Jefferson Med Coll. & Med Ctr Philadelphia, PA	2363 2 loc	1149 1 loc	(51%)	<ul style="list-style-type: none"> • Shifted 40% to ARC (A1105) • Physical inventory in May • Reduced elective surgery (A1105) 	<ul style="list-style-type: none"> • Dr. Sherwood of ARC convinced Medical Director that ARC volunteer blood is "cleaner". ARC could not supply their entire usage however • Let inventory drop prior to May physical inventory. • Medical Director told patients not to reduce dosage/# of uses 	Sales

*Customer purchased 1,400 cc of cryo

^aCustomer purchased ~ 400,000 AVE units in 4 months

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SITE TYPE	CUSTOMER NAME (INCORPORATED) CITY/STATE	Sales (MR Units)(000)			Summary Comment Reasons for Decline*	Detailed Comments *	Comment Source
		Jan 1982	April 1983	%			
Hosp	6. Jackson Mem Hosp Miami, FL	1708 2.10	0	(0)	• Lost bid to Armour	Cutter bid 10.24, Armour won at 8.94 (7-1-82) Armour renewed contract at same price for 1983-84.	File, Sales
Hosp	7. MC Mem Hosp Chapel Hill, NC	1733	0	(0)	• Lost bid to Armour	Cutter bid 9.954, Armour won at 9.34 (7-1-82) Armour may have won again at 8.894 (7-1-83) Cutter bid 9.294	File, Sales
Hosp	8. U. of Iowa Hospitals Iowa City, IA	1725	1320	(238)	• Perioclivity	1-2 new babies on cryo, otherwise no changes due to AIFS. Still 1001 Cutter. If add in May purchases, only down 5% (per Sales). Dr. Goldsmith out until late June - no one else can answer questions	Sales
Hosp	9. William Beaumont Hosp Royal Oak, MI	1674	770	(541)	• Delaying some elective surgery (AIFS) • Less emergency surgery • Two teens switched to cryo (AIFS) • Patients reducing dosage/# of uses (AIFS)	Probably will switch to heat treated - patients have been asking about it.	Medical Director
Hosp	10. Dr. Everett Lovrien Portland, OR	1620	1370	(158)	• Stopped using prophylactically (AIFS) • Reduced # of uses (AIFS)	Doctors recommended no change due to AIFS but nurse coordinator feels some pts are cutting back Purchases in May were higher (per Sales)	Nurse Co- ordinator and Sales
Distr	11. Plasma Prod Co. Grosse Ile, MI	1477	(14)	(0)	• Dropped distributors		
Hosp	12. Children's Hosp & Stanford Palo Alto, CA	1351	817	(401)	• Took patients off prophylactic use (AIFS) • Some reduction in elective surgery (AIFS)	If patients need more concentrate with "demand therapy" they are put back on prophylactic therapy Per Sales, account ordered heavily beginning of 1982 before contract expiration to get lower prices (creating artificially high baseline usage).	Nurse Co- ordinator and Sales
BB	13. Comm Bid Bank Lincoln, NE	1308	0	(0)	• Lose bids on pricing	No contract - account get quotes for each order Will not give out competitive price quotes	Sales
BB	14. Belle Bonfills Mem Bid Bank Denver, CO	1181	344	(711)	• Using an Armour product • Reduction in elective surgery (AIFS) • Some switch to cryo (AIFS) • Patients reducing dosage/# of uses (AIFS)	Using up stock of Armour Generation II for all their surgery (from last contract) Two adults asked to be switched to cryo These care patients using less concentrate Cutter and Alpha share new contract (Started 5-1-83)	Sales
Hosp	15. Univ. of Utah Med Ctr Salt Lake City, UT	1031 20	796 10	(231)	• Patients reducing dosage/# of uses (AIFS)	Two "fender type" adult patients pushing to be switched to cryo. Medical Director is fighting this switch.	Sales

* See text for cautions/limitations on accuracy of this data.

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S/C ID#	CARRIER NAME (INVOICE) CITY/STATE	Sales (All Units) (000)			Summary Comment Reasons for decline *	Detailed Comments *	Comment Source
		Jan 1982	April 1983	May 1983			
BB	16. North Jersey Bld Ctr East Orange, NJ	902	882	(11%)	<ul style="list-style-type: none"> Heavy switch to cryo (AHS) Stopped prophylactic use (1 center) 	<ul style="list-style-type: none"> Center serves two hemophilia centers. Medical Director of one center made patients sign a release before they could get concentrate. Patients were frightened and stopped using it. Many switched to cryo. Many of the patients had been on prophylactic therapy. Early how this center started ordering concentrate again in a lower volume. Patients may be reducing dosage and # of uses at their own initiative, but blood center is not sure since has no direct patient contact. 	Technical Coordinator
BB	17. United Blood Services Mixed	983 30 9 loc	506 28 6 loc	(49)	<ul style="list-style-type: none"> No information available 	<ul style="list-style-type: none"> UBS Management secretive about their accounts 	Sales
Hosp	18. H. Hospital San Diego, CA	970 2 loc	875 2 loc	(10%)	<ul style="list-style-type: none"> Reduced elective surgery (AHS) Patients reducing dosage/# of uses (AHS) 	<ul style="list-style-type: none"> Acting Nurse coordinator declined survey 	Sales
Other	19. FBR Reg. Finc Off. New Orleans, LA	959	720	(25%)	<ul style="list-style-type: none"> Periodicity 	<ul style="list-style-type: none"> Order sporadically Large order placed early May Product shipped to many locations 	Sales
Other	20. Ind. State Bd of Health Indianapolis, IN	953	0	(0)	<ul style="list-style-type: none"> Lost bid to Armour 	<ul style="list-style-type: none"> Outter bid 104, Armour won at 9.64 (11-1-82) 	File, Sales
BB	21. Bld Center of St. Vinc. Milwaukee, WI	890	253	(72%)	<ul style="list-style-type: none"> Using heat treated No elective surgery (AHS) Some switch to cryo (AHS) High inventory from 1982 	<ul style="list-style-type: none"> Bld clinical trial on heat treated - got free product. In May placed first order for more P 154/unit. No information on how much is used or on what kind of patients. Blood bank is producing more cryo - not clear how much more is being used though (other than new/young pts) Ordered heavily last fall to get lower price before contract expired 11-1-82. Little reduction in patient dosage - Dr. Weiss lectured and reassured the patients - explained how joint damage is worse than risk of AHS. Sales submitted 1 or 2 CSRs: Fibrils/not reconstituting properly) 	Sales
Hosp	22. Albany Medical Center Albany, NY	878	742	(15%)	<ul style="list-style-type: none"> Reduction in prophylactic use (AHS) Some reduction in dosage/# of uses (AHS) 	<ul style="list-style-type: none"> Some patients were overtreating before; Center recommends some reduction Still 100% Outter account 	Medical Director
Hosp	23. Children's Hosp Cincinnati, OH	813 2 loc	681 2 loc	(16%)	<ul style="list-style-type: none"> Postponed a few elective surgeries (AHS) Switching milds and moderates to HAVP 	<ul style="list-style-type: none"> Switch of milds and moderates to HAVP not due to AHS - is due to hepatitis concern Sales turned in 2 CSRs on solubility problem - seems to have been user related (not mixing long enough). 	Nurse Coordinator and Sales

* See text for cautions/ limitations on accuracy of this data.

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Site ID#	CSP/DBR NAME (IMMEDIATE) CITY/STATE	Sales (All Units) (000)			Summary of Unit Reasons for Decline *	Detailed Comments*	Comment Source
		Jan 1982	Apr 1983	%			
DB	24. Connecticut HBC Farmington, CT	751	749	6%	• No decline		
Hosp	25. Cincinnati Gen. Hosp Now called U. of Cin- cinnati Hosp Cincinnati, OH	728 3 loc	667 4 loc	(91)	• Switch some pts to cryo • Patient reducing # of uses	100% Cutter Two adult brothers demanded switch to cryo. They are still using (conserving) one last lot of concentrate however. Some patients may be holding back on treatment - using first aid instead. Purchasing stressing competitive bidding	Nurse Co- ordinator
Hosp	26. Bronson Methodist Hosp Evanston, MI	702	0	(0)	• Lost Hospital Purchasing Service bid to Armour	Cutter bid 10 - 10.24, Armour won at 9.6 - 9.94 (1-1-83)	File, Sales
Hosp	27. Mayo Foundation Rochester, MN	670 1 loc	668 2 loc	(0.25)	• Using cryo for surgery where possible (AIHS) • Reduced elective surgery (AIHS) • Patients reducing dosage/# of uses (AIHS)	Patients on prophylactic treatment hesitant to follow through. 100% Cutter	Sales
Hosp	28. Community Bld & Plasma Service Folcroft, PA	652	0	(0)	• Dropped distributors		
DB	29. U. of Calif. - Davis Sacramento, CA	618 2 loc	846 2 loc	37%	• No decline	More aggressive therapy	Sales
DB	30. Central Florida Blood Bk Orlando, FL	611	717	17%	• No decline	100% Cutter	Sales
Hosp	31. Children's Hospital Med San Diego, CA	607	593	(55)	• No elective surgery (AIHS) • One pt discontinued pro- phylactic use (AIHS) • Center recommends to treat PMN only (AIHS) • Maybe some patient reduction in # of uses (AIHS) • One adult pt switched to cryo (AIHS)	Will be switching to heat treated (AIHS)	Nurse Co- ordinator
Hosp	32. Okla Tchg Hosp Labs Oklahoma City, OK	570	1117	96%	• No decline		
Hosp	33. Children's Hosp E. Bay Oakland, CA	564	619	10%	• No decline	Gained account market share from Armour	Sales
Hosp	34. Indiana U. at Indianapolis (Includes Riley Children's plus University Hosp) Indianapolis, IN	560 20	286 20	(49%)	• Three pts switched to State Program • Cryo for surgery, if possible (AIHS)	State program (no longer a Cutter account) received more funding - 3 pts switched to it to get free product.	Sales

* See text for cautions/limitations on accuracy of this data.

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SIC PRIME	CUSTOMER NAME (IMPAILED) CITY/STATE	Sales (thousands)			Summary Comment Reasons for Decline *	Detailed comments *	Comment Source
		Jan 1982	April 1983	(000) 1983			
Hosp	35. U. of Minn Hosp Minneapolis, MN	545 2 to	34 1 to	(941)	• Switched to St. Paul Red Cross (A116)	1-1-83 Cutter designated secondary supplier (same as in 1982) St. Paul Red Cross is primary supplier at 8.54/100 unit. Head of Hematology announced in Jan. '83 that they would accept only factor VIII fractionated from voluntary donor's blood (A116). His "political" ties to RC. St. Paul has geared up sufficiently to supply all the university needs now (previously could not).	Sales
Hosp	36. Med College of VA Richmond, VA	539 20	168 10	(691)	• Armour won contract for both 1982 and 1983.	One doctor buys some Cutter product outside the center's contract. Is getting more difficult for him to do.	Sales
Hosp	37. Ohio State U. Columbus, OH	537	0	(0)	• lost bid to Armour	Cutter bid 10.54, Armour won at 9.84 (7-1-82)	Sales
Distr	38. Davis Enterprises Phoenix, AZ	527	0	(0)	• Dropped distributors	
Hosp	39. Fairview Hosp Minneapolis, MN	409	0	(0)	• lost Assoc. Hospital Systems bid to Armour	Cutter bid 11.14, no information on Armour	File, Sales
Hosp	40. U. of Tenn. Knoxville, TN	401 10	405 20	(161)	• No elective surgery • Lost some patients	Lost some patients to another center which is an Armour account.	Sales
Hosp	41. Mission Comm. Hosp Mission Viejo, CA	400	0	(0)	• Desirable loss of business		Sales
Hosp	42. U. Fla Shands Tch Hosp and Clinic Gainesville, FL	454 10	509 20	(321)	• Heavy year end inventory 1982 • No elective surgery	Has standing order now; did not Jan - April 1982	Sales
Hem	43. Hemophilia Center Rochester, NY	447	460	31	• No decline	Increased account market share	Sales
Distr	44. Pharms Int S. Holland, IL	441	0	(0)	• Dropped distributors	
Distr	45. Community Bld & Plasma Birmingham, AL	406	0	(0)	• Dropped distributors	
	Totals	49641	27120	(451)			
	less distributors	66158	27120	(411)			
	less distributors & lost accts	38095	27120	(301)			

* See text for cautions/limitations or accuracy of this data.

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Table 5

NEW LARGE* KOATE*ACCOUNTS: JAN. - APRIL 1983

Segment	Customer Name City/State	Sales AHF Units(000) Jan. - April		
		1982	1983	1A
Other	1. Miss State Bd of Health Jackson, MS	0	1682	•
Distr	2. Cryosan Inc. ("Z" code) Dedham, MA	0	1544	•
Hosp	3. Memorial Hosp. Worcester, MA	316	1111	2521
Hosp	4. Phcy Svcs VW Hosp & Clinic Madison, WI	0	1043	•
Hosp	5. Children's Hosp Detroit, MI	0	567	•
Hosp	6. West Virginia Univ. Morgantown, WV	91 2 loc	471 1 loc	4181
Hem	7. Natl Hem Fndn - Fl Ch Boca Raton, FL	0	444	•
Hosp	8. Maricopa County Gen Hosp Phoenix, AZ	0	432	•
BB	9. National Blood Components Minneapolis, MN	384	400	41
Total		791	7694	

* Purchased more than 400,000 AHF units in Jan. - April 1983. Purchased less than that (or none) in Jan. - April 1982.

Key: See Key at top of Table 4

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Table 6

CALCULATION OF PERCENT SALES LOSS EXPLAINABLE BY LARGE* ACCOUNTS

1982	Jan - April sales	70.1 MM	AHF units
1983	Jan - April sales	-49.5 MM	AHF units
		(20.6 MM)	AHF units

o Sales to distributors theoretically should have been converted to new small accounts, therefore, sales to distributors will be excluded.

1982	Jan - April sales to large accounts (exclusive of distributors)	46.2 MM AHF units
1983	Jan - April sales to 1982's large accounts	-27.1 MM AHF units
	Loss in 1983 of 1982's large accounts	(19.1) MM AHF units

o In 1983 new large accounts contributed a net increase of 5.4 MM AHF units

Loss in 1983 of 1982's large accounts	(19.1) MM AHF units
Gain (net) in 1983 with new large accounts (exclusive of distributors)	+5.4 MM AHF units
"Explainable" loss - large accounts	(13.7) MM AHF units

"Explainable" loss - large accounts	(13.7) MM AHF units
Total loss	(20.6) MM AHF units

= 67% Explainable

*Customer purchased 400,000 AHF units in 4 months.

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KOATE® CUSTOMER SERVICE REPORTS®

* Source: Extracted from CRS Summary Report for First Quarter 1983 and Fourth Quarter 1982 - Karen Fernandez

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THE NATIONAL
HEMOPHILIA FOUNDATION

Recommendations of
the Medical and Scientific
Advisory Council submitted
to the NHF Board of Directors

THE NATIONAL HEMOPHILIA FOUNDATION
MEDICAL AND SCIENTIFIC ADVISORY COUNCIL

January 14, 1983

RECOMMENDATIONS TO PREVENT AIDS IN PATIENTS WITH HEMOPHILIA

- I. Recommendations for physicians treating patients with hemophilia.
 - A. It is recommended that cryoprecipitate be used to treat patients in the following groups except when there is an overriding medical indication:
 - newborn infants and children under 4;
 - newly identified patients never treated with factor VIII concentrate;
 - patients with clinically mild hemophilia who require infrequent treatment.
 Similar guidelines should be applied to factor IX deficiency patients where fresh frozen plasma can be used instead of concentrate.
 - B. The potential advantages and disadvantages of cryoprecipitate versus factor VIII concentrate therapy for severe hemophilia A are not clear at the present time and are controversial. The Medical and Scientific Advisory Council does not offer a specific recommendation at this time, but will continue to review the data.
 - C. DDVP should be used whenever possible in patients with mild or moderate hemophilia A.
 - D. All elective surgical procedures should be evaluated with respect to the possible advantages or disadvantages of a delay.
- II. Recommendations to factor VIII concentrate manufacturers:
 - A. Serious efforts should be made to exclude donors that might transmit AIDS. These should include:
 1. Identification, by direct questioning, individuals who belong to groups at high risk of transmitting AIDS, specifically male homosexuals; intravenous drug users; and those who have recently resided in Haiti.
 2. Evaluation and implementation (if verified) of surrogate laboratory tests that would identify individuals at high risk of AIDS transmission.
 3. In addition, the manufacturers should cease using plasma obtained from donor centers that draw from population groups in which there is a significant AIDS incidence. It is clear from the epidemiologic data that the pool of individuals at risk for AIDS transmission is not uniform throughout the country and that a great deal could be achieved by excluding donors from the "hot spots".
 - B. Efforts should be continued to expedite the development of processing methods that will inactivate viruses potentially present in factor VIII concentrates.

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- C. There should be an evaluation of the possibility that the yield of factor VIII in pleretic donors could be increased using DDAVP or exercise to maximize yield. This would permit a reduction in the size of the donor pool and would compensate for losses in plasma that might occur due to steps noted above.
 - D. There should be an evaluation of the feasibility of fractionating and processing plasma so that ~~lyophilized~~ small pool products are available. While this will certainly be more costly, it may be the only way to break out of the present dilemma without going to an all-cryoprecipitate effort.
 - E. Concentrate manufacturers should immediately cease purchase of recovered plasma for factor VIII concentrate from blood centers that do not meet the criteria listed in II A above. These criteria should also apply to the production of cryoprecipitate.
 - F. Manufacturers should accelerate efforts towards the production of coagulation factor concentrates by recombinant DNA technology.
- III. Recommendations to regional and community blood centers:
- A. Those centers that are in regions in which there is a very low incidence of AIDS should increase capacity for cryoprecipitate production to be used locally and in other regions.
 - B. These centers should evaluate the feasibility of preparing small pool lyophilized cryoprecipitate for hemophilia treatment.

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LARGE KATIE CUSTOMERS
TELEPHONE INTERVIEW GUIDE

Respondent _____ Title _____
 _____ Nurse Coordinator
 _____ Center Coordinator
 _____ Medical Director
 _____ Other

Hemophilia Center Name _____ Phone # () _____

 City _____ State _____

1st call -83/ _____
 Date / Time

2nd call -83/ _____
 Date / Time

3rd call -83/ _____
 Date / Time

Sales Comments:
Person/Date: _____

Introduction

Good morning/afternoon. I'm Kathy Egenes from Cutter Laboratories' Marketing Research Department. I'd like to ask you a few questions about usage of factor VIII in your center, particularly in light of the current concern about AIDS. Would you be able to spend some time with me on that subject now? (IF NO) Is there another time that would be more convenient for me to call back?

1. Recently there has been a great deal of publicity about AIDS and its occurrence in some hemophilia patients has been of particular concern. Has this affected your center's usage of factor VIII?

☐ Yes (CONTINUE TO 2)
☐ No (GO TO 3)
☐ Not sure (CONTINUE TO 2)
☐ Don't know

Who could I talk to that would have this information?

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2. In what ways has concern about AIDS changed your center's factor VIII usage?
(PROBE on all not mentioned - CIRCLE THE "P")

a. P - Y N S Stopped elective surgery
Stop _____ Restart _____

b. P - Y N S Switched to cryoprecipitate
Adult _____ Peds _____
Start _____ Stop _____
Home treatment patients too? Y N

c. P - Y N S Stopped using prophylactically
Stop _____ Restart _____

d. P - Y N S Reduced number of uses
Doctor recommended _____
Patient initiated _____

e. P - Y N S Reduced dosage
Doctor recommended _____
Patient initiated _____

f. P - Y N S Other (SPECIFY)

Key: P = Probe N = No Y = Yes S = Some

3. (So far we've been talking in general about factor VIII usage changes due to AIDS.) Are there any other factors which could be causing a reduction in your usage specifically of Konate this year versus the same period last year?

(If asked for example: Oh, things like inventory level, patient population size, delivery time or product characteristics.)

a. P _____ High year-end inventory of product (PROBE)

b. P _____ Less emergency surgery (PROBE)

c. P _____ Switching to heat treated (PROBE)

d. _____ Fewer patients

e. _____ Delivery time

f. _____ Price

g. _____ Product characteristics (SPECIFY)

h. _____ (SPECIFY)

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4. Is there anything else that you feel will affect your Koite usage over the next six months either positively or negatively?

POSITIVE

NEGATIVE

NO 10-3 83 Rev. 1

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APPENDIX C

June 13, 1983

Jan Peterson
Product Marketing Manager
Cutter Biological
2200 Powell
Emeryville, CA 94608

Dear Ms. Peterson,

As the mother of a hemophiliac who has been using various brands of Factor VIII for the past 12 years, I thought you may be interested in some feedback on how Koate compares to other brands from the user's point-of-view.

My first concern is that Koate is not vacuum packed, although I hear that that process is now changing. Transferring the sterile water to the concentrate is much easier when using a transfer needle in vacuum jars. So easy, in fact, that my son does it himself with Profilate (Alpha), but cannot with Koate.

Why does it take so long for Koate to mix? The particles are so large and clumped together that it takes at least five minutes of stirring, even when both water and factor were warmed. As I'm rushing to get the injection done and get to work on time, those minutes mean a lot. Profilate takes about 1 - 1½ minutes.

Another issue is your filter needle. It is old technology that I've seen ten years ago. Check out some of the new plastic disc filters. The factor goes into the syringe with very few bubbles.

The last issue, which you're very aware of, is the color. I'm not sure of its real effect, but psychologically it looks dirty or polluted.

May I take this opportunity to sincerely thank Cutter for the money and effort expended for Northern California Hemophilia Summer Camp. My son enjoys it, I need the break, and this year it is especially appreciated as Ian will learn to infuse himself at camp. Bravo.

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