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DATE: September 27, 1983

FROM Carolyn Patrick SUBJECT: AIDS SCENARIO

COPIES TO:

DISTRIBUTION: D. Buchner

- M. Duffy J. Hink
- T Johnson
- B. Modersbach
- s. Ojala

Attached are completed scenario forms for:

- 1. Restricted Development of New Plasma Products
- 2. Competitors Obsolete Cutter's Plasma Products

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C. Patrick

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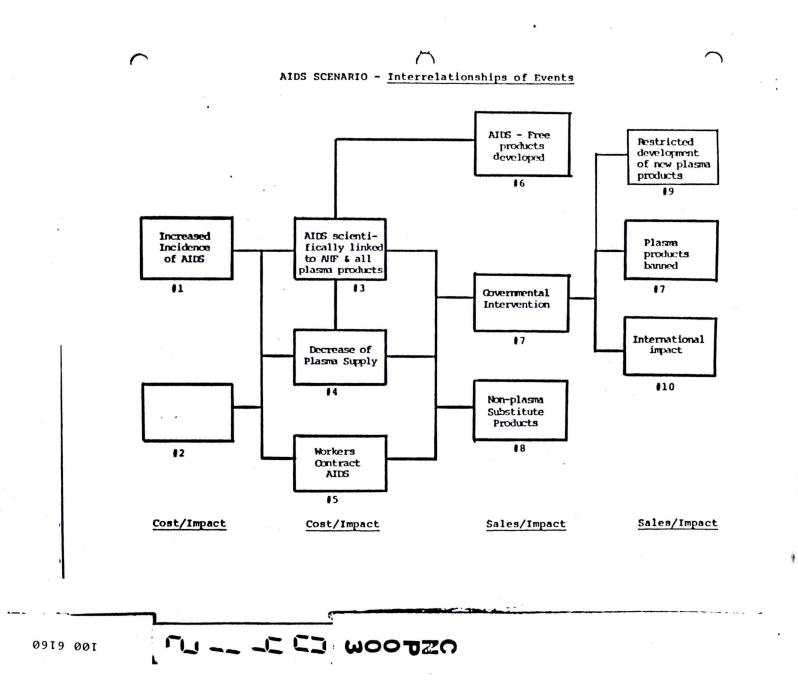
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AIDS Scenarios

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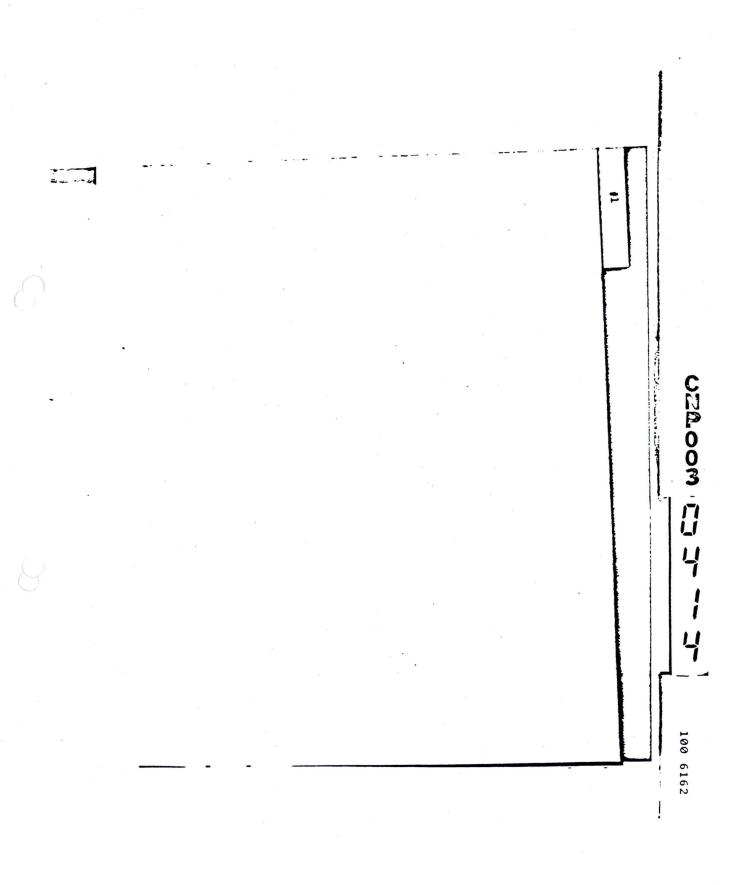
SELECTED PROBLEM FORMULATIONS FOR HORKSHOPS

- How can we best update our plans to reflect changes in AIDS incidence?
- 2.

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- 3. How can we make sure that all our finished products are not linked to AIDS?
- 4. How can we make sure and prove that Cutter plasma is free from AIDS risk?
- 5. How can we minimize AIDS RISK to WORKER?
- 6. How can we minimize perceived AIDS risk to Koate?
- 7. How can we participate to educate and inform the public, U.S. and foreign government officials, workers, and politicians to prevent emotional actions and reactions?
- 8. How can we accelerate Cutter RDNA/Biotechnology projects to a successful conclusion?
- 9. How can we prevent FDA from irrationally restricting new plasma products in response to public pressure?
- 10. How can we develop an acceptable heat treated AHF for major foreign markets?

9/30/83



TIMI

Scenario 1 Schadalo/Form Statement of Scenario Event: The Development and Incidence of AIDS.

Topic of scenario: Acquired Immune Deficiency Syndrome (AIDS)

No.	Major Issues/Problems (short statement)	Impact on current business	Mag.
	A fatal disease is striking high risk groups, including hemophiliacs, at an epidemic rate. The specific cause is not known and there is no cure. As of August 1983, over 2,000 cases were reported, including 17 hemophiliacs. The development of AIDS indicates that one mode of transmission is through blood and blood products. There is no screen or blood test to determine the presence of AIDS in an unsymptomatic carrier. With the comparative lack of specific scientific and medical knowledge, governmental, regulatory and media responses are inconsistent and unpredictable and apt to be based on emotion and sensationalism.	Three direct impacts have resulted: - The fear of contracting AIDS has resulted in a reduction of concentrate use by the hemophiliac population. - Plasma Center screening requirements have been issued, including AIDS questionnaires, additional physical examining and donor, centeremployee education. - Based on the conception that a heat-treatment concentrate product may eliminate or reduce the risk of passing AIDS, there is a "no holds" rush to complete its development, approval and manufacture; substantial additional costs and expenditures are being incurred.	2
Pleas	se show the magnitude of the impact by 3, 2, 1 (high, medium, low)		

SCENARIO 11

ran Các	te 2 Impact of major future developments and trends	Topic of scenario: AIDS
	Major Future Developments	Impact on future operations/business
	MostLikely: Scientific and medical progress is real but slow. No major breakthroughs occur in 1983. No specific blood test before 1985. The general incidence of AIDS continues at the same basic rate within the risk groups but by 1985 is not at an exponential growth level. AIDS does not spread to general population at an epidemic level, nor do any new high risk groups develop. The development of AIDS in major industrialized countries continues but at a lower rate of involvement than in the U.S.	(Note: The specific impacts based on these developments are addressed in the Scenarios prepared for the individual events.)
	Worst Case: Exponential growth continues. Lymphadenopathy and/or T-Cell Helper/Suppressor ratio are generally prodromal stages of AIDS. Limited epidemics encountered outside current high risk groups: family, prisoners, health care workers and plasma processers. No cause or cure discovered and in the meantime, a long incubation period continues to tick.	•

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7		· è		1		
	1983	1984	1985	198	36 19	198
	Most Likely:		86. P	00 to 20,000 cases*, ific blood test is form fromising research in the and preventability.		
						By 1988, 25,0 40,000 cases* to 320 hemoph iacs. Cause known, but no plete cure. dence is decl AIOS is check
	Worst Case:	hemophiliacs.	85, approximately 40,0 . Several hundred tie r major countries are ause and blood test ca	d to blood transfu- severely affected.		and slowed, b not eradicate
					2,000 hemophi largely due t susceptible p diagnosis and	IO* cases, with lacs. Decling decimation of pulations, each better treatments a major ep

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Scenario 4 Schadule/Form Formulation of problem (-How can we....-)

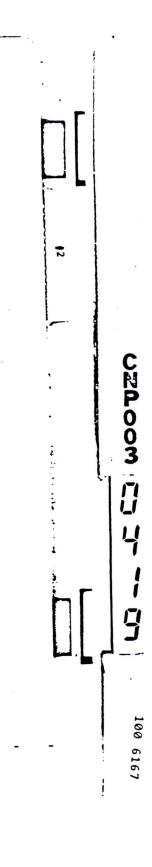
Topic of Scenario: AIDS (Incidence of AIDS)

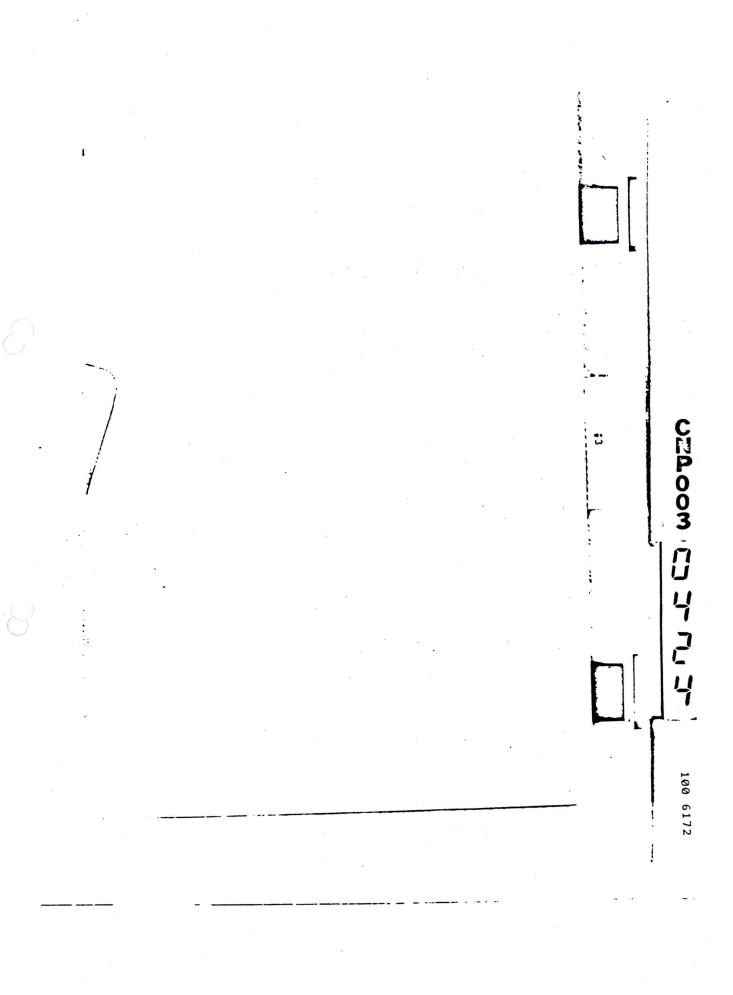
How can we track and monitor the incidence and development of AIDS?

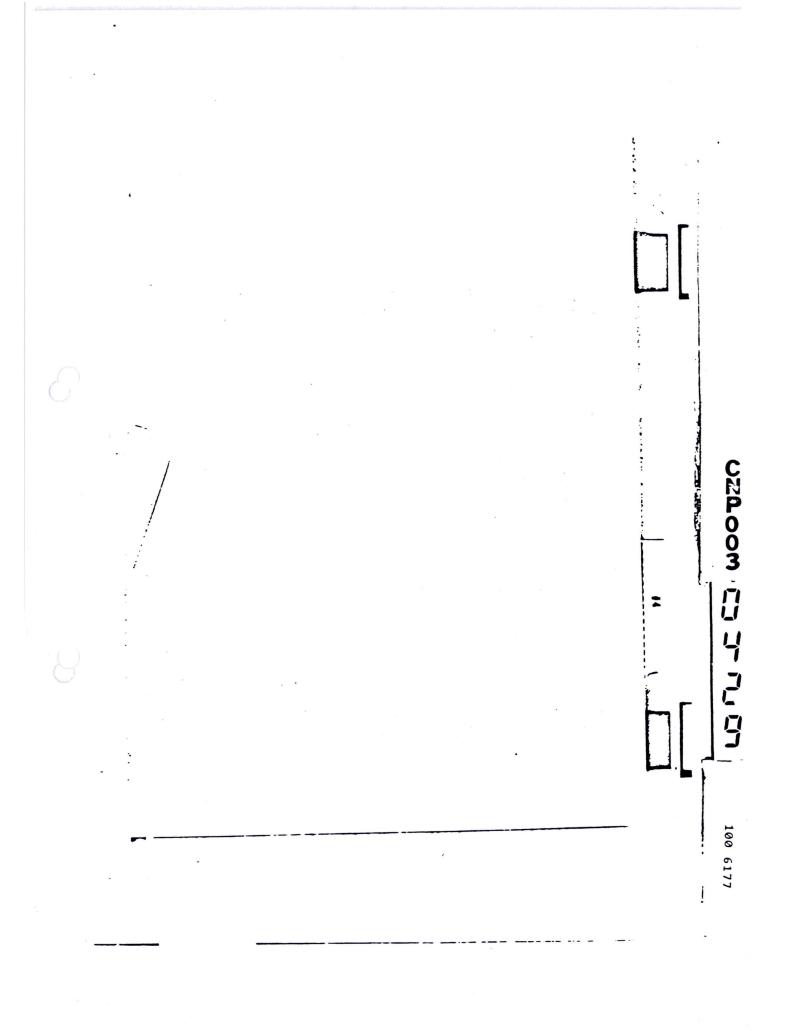
(Possible resources: R. Modersbach, R. Rousell (or M.D. from Cutter staff), S. Ojala)

How can we assess impact on plans or scenario that could result from changes in AIDS incidence? (Possible resources: Team or business heads)

Please state the problems in as few words as possible in the form which ask for action-oriented answers.







ichos	trie 1 Statement of Scenario Event: tris/Ferm Decrease of Plassa Supply	Topic of acenario:
a	Major leaves/Problems (chort statement)	Impact on current business Mag
1	Identification of AIDS in the homophilic population and in patients receiving blood donations has given rise to the postulate that AIDS is transmitted by blood and blood products. Pilot studies on surrogate testing of plasma donors has been recommended by U.S. Gov't agencies.	Additional screening requirements for plasma donors to eliminate "high risk" donors has necessitated implementation of new processing procedures and rejection of a small number from our donor panel. A study of several thousand donors for hepatitis B
	Health care workers have publicly expressed concerns regarding AIDS victims.	core antibody has provided no useful information. Concerns expressed by a small number of hospital workers have not spread to plasmapheresis workers.
	Plasma collected from prison populations has been excluded from use in the manufacture of plasma coagulation products by informal FDA guidelines.	Our competitors have discontinued significant volume placing procurement from prison sources and are replacing this volume by offering higher prices to other suppliers, thus creating a general market price increase. Cutter continues to procure prison plasma to protect its rables antibody supply. As no coagulation products are made from this plasma, cost is high.
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Sch	impact of major future developments and trends	Topic of scenario;	
-		AIDS	
No.	Major Future Developments	Impact on future operations/business	
	Most Likely:		Mag.
1 2.	Test for AIDS prodrome will be required for plasma donors.	Temporary and moderate reduction in plasma supplies causing slight shortages and minimal cost increase.	1
•.	Foreign countries (especially Europe) will become more self sufficient in production of plasma and will reduce purchases from U.S.	U.S. plasma exports will decrease creating moderate U.S. surplus and lower plasma prices.	2
-	Worst Case:		
1	All plasma donations will be required to be held for a period of 6 mos. while the donor is followed to assure no ALDS is contracted within this period.	Severe temporary shortage of plasma and considerable cost increase due to difficulties in donor follow up and loss of plasma from transient donors.	3
Please	give the magnitude of the impact by 3, 2, 1 (high, medium, low)	·	-

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2:2:0/	Ferm (from Schedule			AIDS	
0.	1983	1984	1985	1986 198	7 1980
	Most Likely:	20%	40%	10%	
		10%	40%		
	Worst Case:	15%	30≸		
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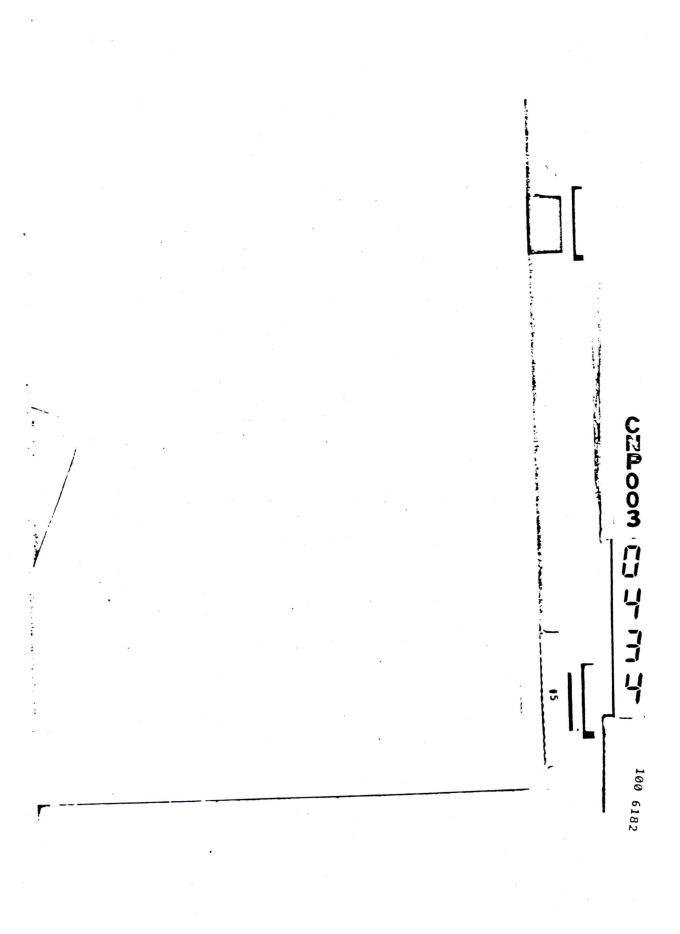
Formulation of problem (-How can we....-)

Topic of Scenario:

AIDS

How can we prove that Cutter plasma is free from AIDS risk.

Please state the problems in as few words as possible in the form which ask for action-oriented answers.



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10.	Major Issues/Problems (short statement)	Impact on current business	M
1.	Plasma fractionation workers have expressed concern for their safety regarding the perceived risks of contracting AIDS encountered while physically handling raw plasma.	Workers morale has been affected to a small degree by the fear of contracting AIDS. Worker continue to ask questions and express fears related to plasma production.	1
2.	In 1983, four hospital workers have contracted AIDS.	Incidence of AIDS among hospital workers has not significantly increased concerns of production workers.	
	*		

SCENARIO #5

Major Future Developments	Impact on future operations/business	
Most Likely: 1 or 2 non-high risk fractionation or plasma center workers contract AIDS, causing concern among all plasma workers.	Production cost increases to provide worker protection and pay premium wages.	
Worst Case: More than two workers get AIDS.	Workers refuse to work in plasma processing, leading to product shortages.	
	Most Likely: 1 or 2 non-high risk fractionation or plasma center workers contract AIDS, causing concern among all plasma workers.	Most Likely: 1 or 2 non-high risk fractionation or plasma center workers contract AIDS, causing concern among all plasma workers. Production cost increases to provide worker protection and pay premium wages. Worst Case: More than two workers get AIDS. Workers refuse to work in plasma processing, leading to product

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	One or risk or plus worked Premiser external control of the contro	Likely: or two non-high fractionation lasma center ers contract AIDS. tum wages and nsive worker pro- lon must be lded.	501	30%		101	gi	
	More	Case: than two non- risk workers	10	Ø		В	Ø	

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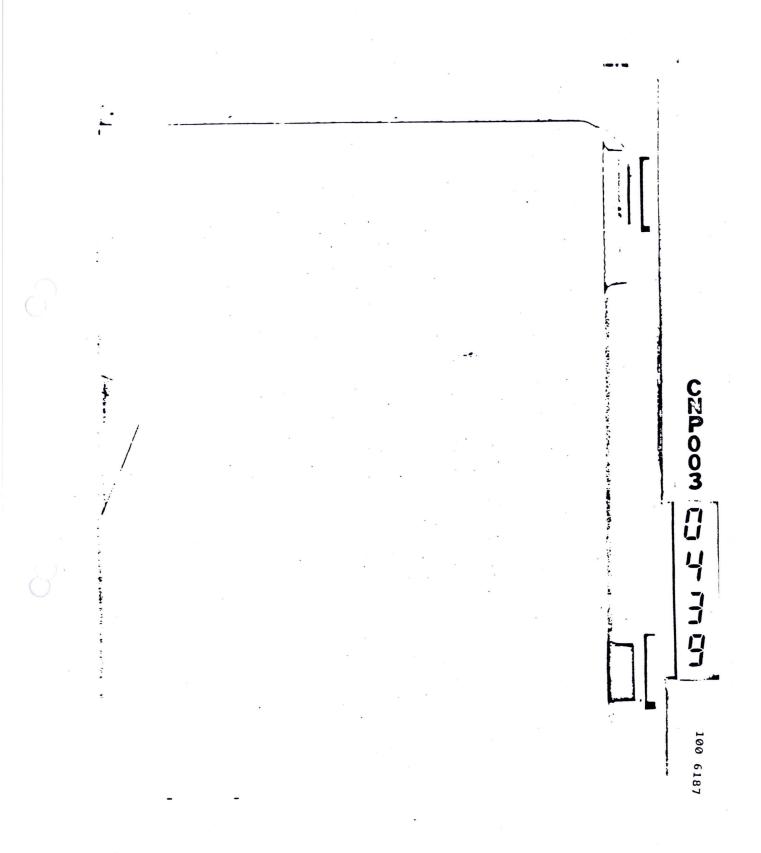


Scenario Schedule/Form Formulation of problem (-How can we...-)

Topic of Scenario: AIDS

- 1. How can we reduce the probability of non-high risk workers getting AIDS?
- 2. How can we prepare for the problems if this does occur?

Please state the problems in as few words as possible in the form which ask for action-oriented answers.



CP 9-26-83 PH

Statement of Scenario Event:
Schedule/Form
COMPETITIORS OBSOLETE CUITER HEMOPHILIA CONCENTRATES

Topic of scenario:

AIDS

No.	Major Issues/Problems (short statement)	Impact on current business	Mag.
1.	The U.S. market for hemophilia concentrates has declined drastically because of fear of AIDS transmission via these products.	Koate® sales are 30% behind budget, causing lost profits and product mix imbalance.	2
2.	All companies are seeking ways to minimize or eliminate perceived or actual AIDS risk in their products. Cutter is not at the forefront of these efforts.	Current Cutter sales are lower than they would be if a heat-treated concentrate were available. Business may be at further risk if technology gap widens.	3
,			
Please	s show the magnitude of the impact by 3, 2, 1 (high, medium, low)		

SCENARIO #6

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Scene Sched	the 2 Impact of major future developments and trends #Is/Ferm COMPETITORS OBSOLETE CUTTER HEMOPHILIA CONCENTRATES	Topic of scenario:	Managan part
No.	Major Future Developments	Impact on future operations/business	Mag.
1. 2. 3.	Most Likely: Other companies in addition to Hyland will market heat-treated concentrates prior to Cutter. Competitors and Cutter will demonstrate AIDS-free product within close time-frame. Competition will market rDNA AHF prior to Cutter.	Major short-term impact that will decrease when Cutter enters market with comparable product. Increase in total concentrate usage. No other major impact. Major negative impact on Koate® sales until Cutter rDNA product available.	2 2 3
ı.	Worst Case: Competitor introduces a patented or otherwise exclusively AIDS-free product. FDA bans all plasma-sourced AHF upon availability of rTAVA product from a competitor.	Marketplace will buy as much of this product as is available and will expect risky product to be available at low prices. Possible loss of total ANT business.	3

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7	Form (from Sched	OLETE CUTTER HEMO	OPHILIA CO	NCENTRATES		1	AIDS		
	1983	1984		198	35	198	16	1987	198
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Scenario 4
Schedule/Form

Formulation of problem (-How can we....-)

COMPETITORS OBSOLETE CUTTER HEMOPHILIA CONCENTRATES

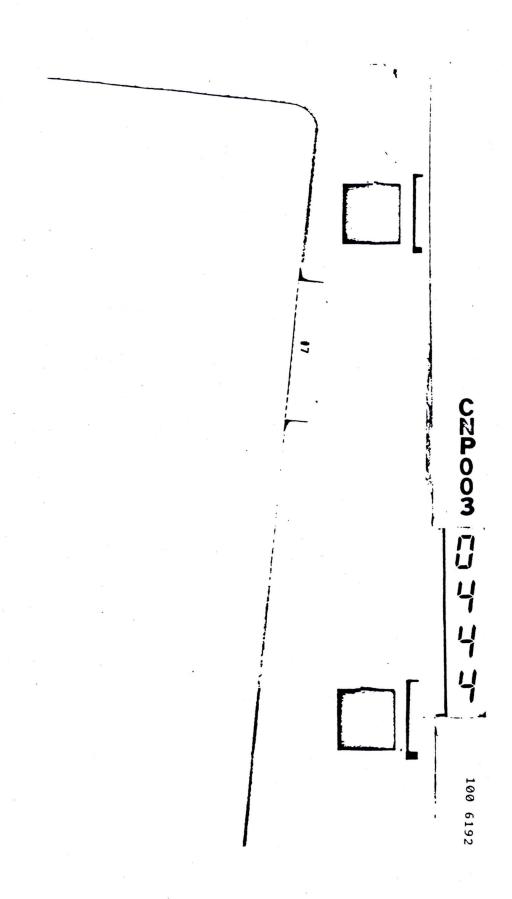
Topic of Scenario:

AIDS

- 1. How can we leapfrog to develop a hepatitis/virus-free product ahead of competition?
- 2. How can we accelerate Cutter rDNA ANF project?
- 3. How can we minimize perceived AIDS risk of Koate®?

Please state the problems in as few words as possible in the form which ask for action-oriented answers.

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		AIDS	
lo. Major Issues/Problems (short statement)	Impact on cur	rent business	_
Increased attention by the media and/or future event cause government agencies (U.S. and worldwide) to add additional restrictions to the production, sale or use of plasma derived products. The current focus is to encourage the best treatment of plasma coagulation products, and for some foreign governments to discourage the importation of U.S. plasma products. As understanding of AIDS develops, further plasma testing will be required. When alternate products from non-plasma sources are available, further restrictions will result including the possibility for eventual bans of human-derived material.	- plasma contincreased - positive products suspect 1 - additional required, - holding (could research) - once alterable, cur	identification of AIDS donors in plasma can lead to a FDA required recall of lots. al tracing of donors and users could be (quarantine) requirements for plasma	

SCENARIO #7

Sche	arie 2 Impact of major future developments and trends dule/Ferm	Topic of scenario:	
No.	Major Future Developments Most Likely:	Impact on future operations/business	Mag
1 2	- FDM/NIH predicts specific cause and possible test available in 1984 - Further miscellaneous restrictions continue on a periodic basis.	but required of all manufacturers.	2
3 4 5	 Transfusion related cases will begin to exceed hemophiliac cases by 1984. Purther recalls of individual lots of product. Genetically engineered product available by 1988 (FDA guess). 	Apply to all manufacturers Major impact on blood banking Major impact to target manufacturer. Small impact at first due to availability, rapidly growing by 1990.	1 2 2 3
1 2	Worst Case: - Major international governments restrict or ban imports of U.S. plasma derived products. - Evidence that heat-treating is not effective prompts very restrictive government action.	Loss of international sales Applys to all involved, but greater impact to U.S. manufacturer	3 2
3	 AIDS linked to other plasma products results in severe restrictions on manufacture/use. 	Major change in biological product availability -worst case fear by FDA	3

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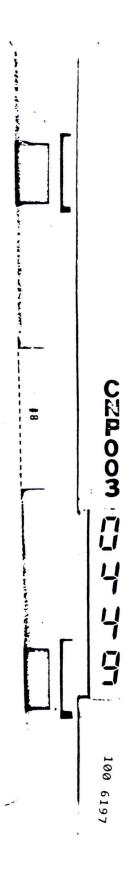
Scenar		Probability of the form Sched	f occurence of major develo ule 2)	pments and trends To	plc of scenario: AIDS		
Vo.	19	983	1984	1985	1986	1987	1988
1 2 3 4 5		Most Likely:	50\$	75\$ 75\$ 50\$ 10\$	80\$	90\$	
1 2 3		Worst Case:	201	30 1	30%30%	401 401 301	5

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Scenarie 4 Schedule/Form	Formulation of problem (-How can we)	Topic of Scenario:
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By John H, Hink

Schedule/Form

Statement of Scenario Event:

Mon-Plasma Products Introduced by Competitor

Topic of scenario:

AIDS

No.	Mictor Incues/Problems (chort statement)	Impact on current business	Mag.
1.	Crystalloids and several synthetic plasma expanders are available and acceptable by many clinicians as substitutes for plasma Fraction V products. These substitutes have been available for years and although less expensive than plasma derived products, make up a relatively small share of the total plasma expander market.	Non-plasma derived expanders have a minor but signif- icant share of the expander market and have no new impact on our business.	1
2.	Synthetic drugs (demino-d-arginine vaso pressin DDAVP and a synthetic androgen, Danizol) showing promise for the treatment of certain hemophiliacs are in the final stages of evaluation by Cutter competitors.	No impact on current business until products approved for treatment of hemophiliacs.	1
3.	Large expenditures of time and money are being directed towards producing genetic engineered proteins to replace current and future plasma derived products.	Progress has been made but no impact on our business should be noted before end of 1984.	1
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SCENARIO 48

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Most LECTY: 1 Crystalloids and synthetic expanders will continue to be used by certain hardcore clinicians rather than Fraction V plasma products. 2 Synthetic drug(s) for treatment of hemophilia will be approved and marketed. 3 Genetic engineered substitutes for plasma products will not be approved for general marketing until 1990. Worst Case: 1 Due to exponential increase in AIDS cases, spread of disease to general population (especially all plasma product recipients), increased Gov't financing, and extreme pressures on FDA; Approval for use of tDMA and MOMB plasma proteins will be markedly Use rate will not increase. Impact neglible. Drugs will be partially effective in mild hemophilia. Impact on coagulation product sales minor. Marginal impact during next 5 years. Severe reduction in the use of plasma derived products in the late 1980's.	School School	the 2 Impact of major future developments and trends sta/Ferm	Topic of scenario:	,
Crystalloids and synthetic expanders will continue to be used by certain hardcore clinicians rather than Fraction V plasma products. Synthetic drug(s) for treatment of hemophilia will be approved and marketed. Genetic engineered substitutes for plasma products will not be approved for general marketing until 1990. Worst Case: Due to exponential increase in AIDS cases, spread of disease to general population (especially all plasma product recipients), increased Gov't financing, and extreme pressures on FPA; Approval for use of 17NA and HOAB plasma proteins will be markedly Use rate will not increase. Impact neglible. Drugs will be partially effective in mild hemophilia. Impact on coagulation product sales minor. Marginal impact during next 5 years. Severe reduction in the use of plasma derived products in the late 1980's.	No.	Major Future Developments	Impact on future operations/business	Mag.
Due to exponential increase in AIDS cases, spread of disease to general population (especially all plasma product recipients), increased Gov't financing, and extreme pressures on FDA; Approval for use of rDNA and MOAB plasma proteins will be markedly	2	Crystalloids and synthetic expanders will continue to be used by certain hardcore clinicians rather than Fraction V plasma products. Synthetic drug(s) for treatment of hemophilia will be approved and marketed. Genetic engineered substitutes for plasma products will not	Drugs will be partially effective in mild hemophilia. Impact on coagulation product sales minor.	1 1 1
expedited.	1	Due to exponential increase in AIDS cases, spread of disease to general population (especially all plasma product recipients), increased Gov't financing, and extreme pressures on FDA; Approval		3

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By: John Hink STRAT Probability of occurence of major developments and trends Topic of acenerio: Schräch/form (from Schedule 2) AIDS 1983 1964 1005 1888 1987 1938 Most Likely: 100% 1 100% 100% 100% 100% 2 50% 80% 3 100% 100% 80% Worst Case: DNA VIII DNA XI DNA alb 30% MOAB CC 30% Please show the probability against the relevent years (e. g. low till 1984, med. 1986, high 1988)

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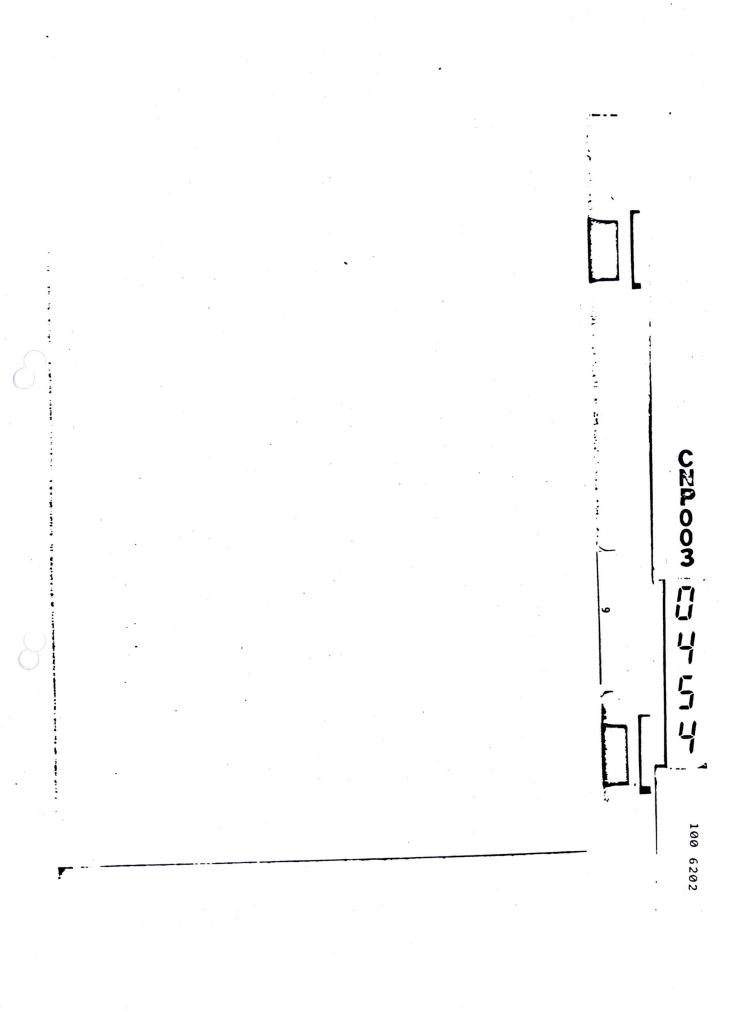
Formulation of problem (-How can we....-)

Topic of Scenario:

AIDS

How can we use new technologies to protect our plasma products.

Please state the problems in as few words as possible in the form which ask for action-oriented answers.



CP 9-26-83 PH

Scenario | Schedule/Form

Statement of Scenario Event:

RESTRICTED DEVELOPMENT OF NEW PLASMA PRODUCTS

Topic of scenario:

AIDS

No.	Major Issues/Problems (short statement)	Impact on current business	Mag.
1.	Media attention and some AIDS cases among non-high rick groups are creating increasing concern that AIDS is transmitted by blood and blood-derived products.	Koate® sales and the entire U.S. Factor VIII market have declined 20-30% because of AIDS concern among hemophiliacs. AIDS concern is beginning to surface among users of other plasma products, including Gamimune®.	2
2.	Cutter is in the process of developing new plasma products and is now attempting to set up clinical trials for these products. It is possible that concern about AIDS transmission via blood products will delay or prohibit development of new plasma products because of increased regulatory pressure or reluctance among clinical investigators and potential end-users.	New plasma products will provide major portion of Biological and Cutter Group growth for remainder of decade and will have a major favorable impact upon profitability by providing greatly increased revenues with no increase in raw material costs.	3
Pleas	e show the magnitude of the impact by 3, 2, 1 (high, medium, low)		

SCENARIO 19

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Scena Sched	rife 2 Impact of major future developments and trends rife/Ferm RESTRICTED DEVELOPMENT OF NEW PLASMA PRODUCTS	Topic of scenario:	
No.	Major Future Developments	Impact on future operations/business	Mag.
	Most Likely:		<u> </u>
1.	AIDS concern will cause some investigators to decline to perform needed clinical trials or to exclude certain population groups.	Clinicals will take more time to arrange, will perhaps be more expensive.	2
2.	FDA will view IND/NDA's with a more careful eye toward risk-benefit ratios but will not exclude new plasma products totally.	Marginally or questionably beneficial products will be difficult to license but truly beneficial products will be licensed.	1
3.	FDA will look favorably upon rDNA-sourced new products because of no AIDS risk.	Regulatory pathway for these products will be smoother than otherwise.	1
	Worst Case:		
1.	No new plasma products licensed by FDA unless conclusively proven to be AIDS-free.	No new products for Biological Division for rest of decade, with drastic negative effect on sales and profits.	3
Please	give the magnitude of the impact by 3, 2, 1 (high, medium, low)		

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(from Sched		PRODUCTS		AIDS		
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30%	60		85%	85%	85%	
808	80		80%	80%	809	
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Worst Case:						+
58	10	•	15%	150	151	
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	Most Likely: 1983 Most Likely: 1004 304 804	1983 1984 Most Likely: 1000 1000 300 600 800 800	### RESTRICTED DEVELOPMENT OF NEW PLASMA PRODUCTS 1983	1983 1984 1985 Most Likely: 1000 1000 850 850 800 800 800	1983 1984 1985 1986	1983 1984 1985 1986 1987

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Scenario 4 Schodule/Form Formulation of problem (-How can we....-)

RESTRICTED DEVELORMENT OF NEW PLASMA PRODUCTS

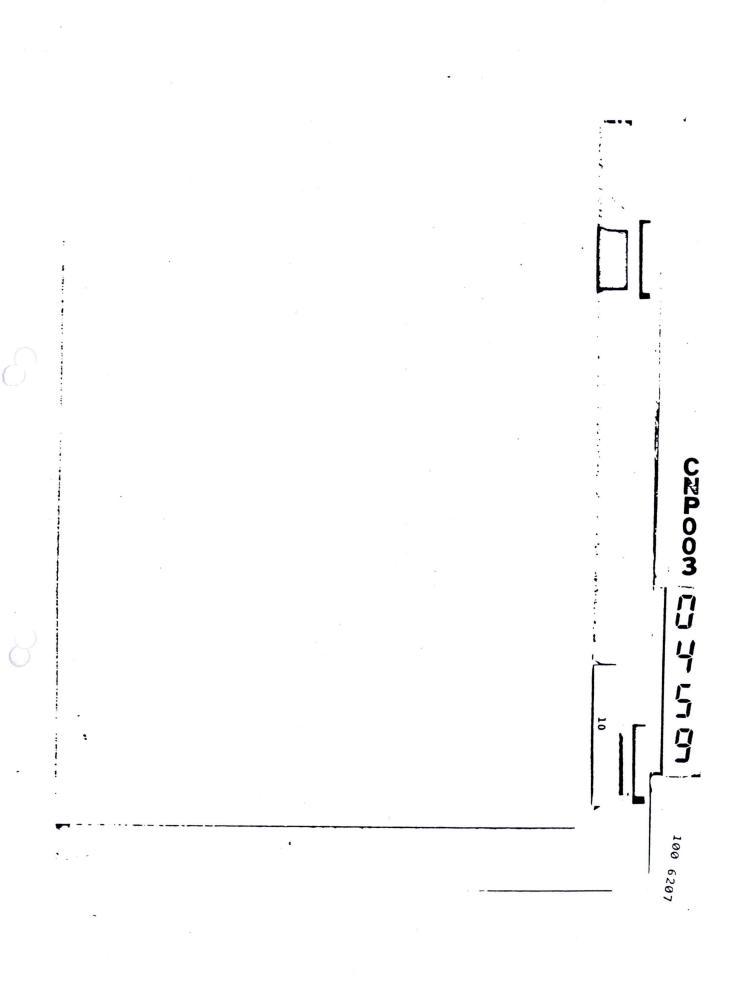
Topic of Scenario:

AIDS

- 1. How can we minimize AIDS concern regarding plasma products among clinical investigators?
- 2. How can we minimize AIDS risk in new plasma products?
- 3. How can we demonstrate minimal AIDS risk in new plasma products?
- 4. How can we prevent FDA from irrationally restricting new plasma products in response to public pressure?

Please state the problems in as few words as possible in the form which ask for action-oriented answers.

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chedule/Form D	talement of Scenario Event: ecline in International Sales through For ent Intervention	eign Covern-	Topic of scenario:	
o. Major Issues/P	roblems (short statement)	Impact on cur	rent business	Mag
Approximately United States	125 reported AIDS cases outside the	AIDS has had	small impact on International sales of	1
Heat-Treated A	WF is available from several competi-	Small impact of although a la	on total International AHF sales rger impact in West Germany.	2
Most major cou pheresis.	mtries discourage or disallow plasma-	sourced from	lasma products used in the world are the United States. Positive impact ed States fractionators.	2
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	ude of the impact by 3, 2, 1 (high, medium, low)			

SCENARIO 110

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Scena Sched	Impact of major future developments and trends Decline in International Sales through Foreign Government Intervention	Topic of scenario:	
No.	Major Future Developments	Impact on future operations/business	Mag.
1.	Most Likely: Major Foreign Governments require all Factor VIII to be heat- treated (Regular Factor VIII banned).	Positive impact if Cutter has an acceptable heat-treated Factor VIII.	2
1	Worst Case: Major Foreign Governments ban U.S. plasma sourced Factor VIII and become plasma product self-sufficient.	Significant impact on the very high pro- fit AHF sales if occurring in West Germany and Japan.	3
Please	give the magnitude of the impact by 3, 2, 1 (high, medium, low)	i i i i i i i i i i i i i i i i i i i	

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-	ment Inter	n International Sales to rvention	nrough Foreign Govern-	<u></u>	AIDS	9
lo.	1983	1984	1985	19	86 19	987 198
1	Most Likely:	25%	50%		501	50%
1	Worst Case:	51	51		51	58

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9-26-83 Statement of Scenario Event: Topic of scenario: Scenarie Schedule/Form COMPETITIORS OBSOLETE CUTTER HEMOPHILIA CONCENTRATES AIDS Mag. Impact on current business No. Major Issues/Problems (short statement) Moates sales are 30% behind budget, causing The U.S. market for hemophilia concentrates has 1. lost profits and product mix imbalance. declined drastically because of fear of AIDS transmission via these products. Current Cutter sales are lower than they would All companies are seeking ways to minimize or 2. be if a heat-treated concentrate were available. eliminate perceived or actual AIDS risk in their products. Cutter is not at the forefront of these Business may be at further risk if technology gap widens. efforts. Please show the magnitude of the impact by 3, 2, 1 (high, medium, low)

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Scenar Sched	rio 2 impact of major future developments and trends ule/Form // COMPETITORS OBSOLETE CUTTER HEMOPHILIA CONCENTRATES	Topic of scenario: AIDS 7	
, No.	Major Future Developments	/ Impact on future operations/business	Mag.
1. 2. 3.	Most Likely: Other companies in addition to Hyland will market heat-treated concentrates prior to Cutter. Competitors and Cutter will demonstrate AIDS-free product within close time-frame. Competition will market rDNA AHF prior to Cutter.	Major short-term impact that will decrease when Cutter enters market with comparable product. Increase in total concentrate usage. No other major impact. Major negative impact on Koate® sales until Cutter rDNA product available.	2
1.	Worst Case: Competitor introduces a patented or otherwise exclusively AIDS-free product. FDA bans all plasma-sourced AHF upon availability of rDNA product from a competitor.	Marketplace will buy as much of this product as is available and will expect risky product to be available at low prices. Possible loss of total AMF business.	3

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Schedule/Form

Formulation of problem (-How can we....-)

COMPETITIORS OBSOLETE CUTTER HEMOPHILLIA CONCENTRATES

Topic of Scenario:

AIDS

- 1. How can we leapfrog to develop a hepatitis/virus-free product ahead of competition?
- 2. How can we accelerate Cutter rDNA ANF project?
- 3. How can we minimize perceived AIDS risk of Koate@?

Please state the problems in as lew words as possible in the form which ask for action-oriented answers.

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מבשר שישי בר כם