

# Cutter



TO: DISTRIBUTION BELOW

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

GRO-C

C. Patrick

CP:am

104 7305

104 7305

M005577 S

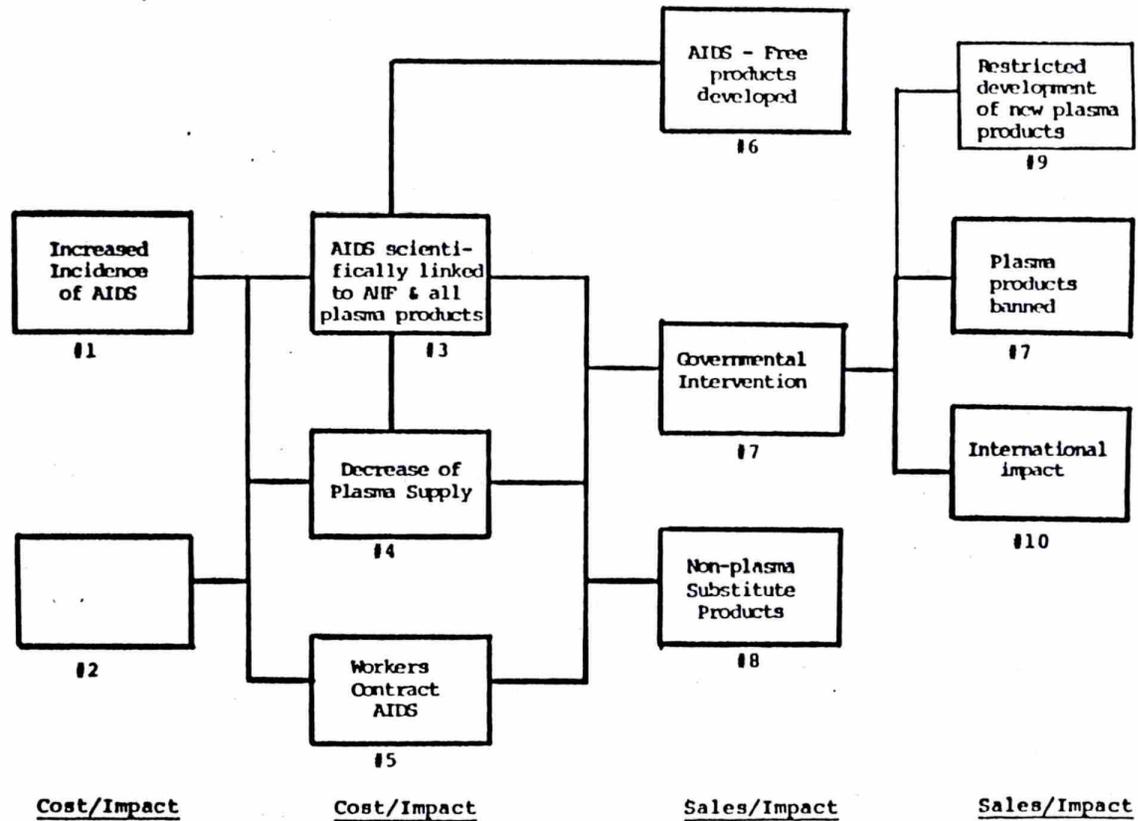
3040 881001

AIDS Scenarios

U2M00M 03 27 11

100 6159

AIDS SCENARIO - Interrelationships of Events



SELECTED PROBLEM FORMULATIONS FOR WORKSHOPS

1. HOW CAN WE BEST UPDATE OUR PLANS TO REFLECT CHANGES IN AIDS INCIDENCE?
- 2.
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

U2A000 03 7-1-77

100 6161

UZA.OOM 03 5 - - 5 -

100 6162

11

1

00

00



No.	Major Issues/Problems (short statement)	Impact on current business	Mag.
	<p>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.</p> <p>The development of AIDS indicates that one mode of transmission is through blood and blood products.</p> <p>There is no screen or blood test to determine the presence of AIDS in an asymptomatic carrier.</p> <p>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.</p>	<p>Three direct impacts have resulted:</p> <ul style="list-style-type: none"> <li>- The fear of contracting AIDS has resulted in a reduction of concentrate use by the hemophilic population.</li> <li>- Plasma Center screening requirements have been issued, including AIDS questionnaires, additional physical examining and donor, center-employee education.</li> <li>- 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.</li> </ul>	<p>3</p> <p>1</p> <p>2</p>
<p>Please show the magnitude of the impact by 3, 2, 1 (high, medium, low)</p>			

SCENARIO #1

E919 001

U2 ROOM



<b>Scenario 2</b> <b>Impact of major future developments and trends</b> Schedule/Form		Topic of scenario: AIDS	
<b>No.</b>	<b>Major Future Developments</b>	<b>Impact on future operations/business</b>	<b>Mag.</b>
	<p><b>Most Likely:</b> Scientific and medical progress is real but slow. No major breakthroughs occur in 1983.</p> <p>No specific blood test before 1985.</p> <p>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.</p> <p>AIDS does not spread to general population at an epidemic level, nor do any new high risk groups develop.</p> <p>The development of AIDS in major industrialized countries continues but at a lower rate of involvement than in the U.S.</p>	<p>(Note: The specific impacts based on these developments are addressed in the Scenarios prepared for the individual events.)</p>	
	<p><b>Worst Case:</b> Exponential growth continues.</p> <p>Lymphadenopathy and/or T-Cell Helper/Suppressor ratio are generally prodromal stages of AIDS.</p> <p>Limited epidemics encountered outside current high risk groups: family, prisoners, health care workers and plasma processors.</p> <p>No cause or cure discovered and in the meantime, a long incubation period continues to tick.</p>		
Please give the magnitude of the impact by 3, 2, 1 (high, medium, low)			

3C4038100

100 6164

CZROOM 11-10



Scenario 3 Schedule/Form		Probability of occurrence of major developments and trends (from Schedule 2)				Topic of scenario: AIDS.	
No.	1983	1984	1985	1986	1987	1988	
	<b>Most Likely:</b>		By end of 1985, approximately 15,000 to 20,000 cases*, 120 to 160 are hemophiliacs.	A specific blood test is found in 1985-86. Promising research in terms of a vaccine and preventability.		By 1988, 25,000 to 40,000 cases*, 200 to 320 hemophiliacs. Cause is known, but no complete cure. Incidence is declining. AIDS is checked and slowed, but not eradicated.	
	<b>Worst Case:</b>		By end of 1985, approximately 40,000* cases, 1,000 are hemophiliacs. Several hundred tied to blood transfusions. Other major countries are severely affected. A specific cause and blood test cannot be determined.		By 1988, 80,000* cases, with 2,000 hemophiliacs. Decline is largely due to decimation of susceptible populations, earlier diagnosis and better treatment. But AIDS remains a major epidemic condition.		

Please show the probability against the relevant years (e. g. low till 1984, med. 1986, high 1988) \*cumulative from 1981.

5919 001

WORLDWIDE



<b>Scenario 4</b> <b>Formulation of problem (-How can we....-)</b> <b>Schedule/Form</b>	<b>Topic of Scenario: AIDS</b> <b>(Incidence of AIDS)</b>
<p>How can we track and monitor the incidence and development of AIDS? (Possible resources: R. Modersbach, R. Rouseil (or M.D. from Cutter staff), S. Ojala)</p> <p>How can we assess impact on plans or scenario that could result from changes in AIDS incidence? (Possible resources: Team or business heads)</p>	
<p>Please state the problems in as few words as possible in the form which ask for action-oriented answers.</p>	

99I9 00I

00 -- J 00 WOOTZO

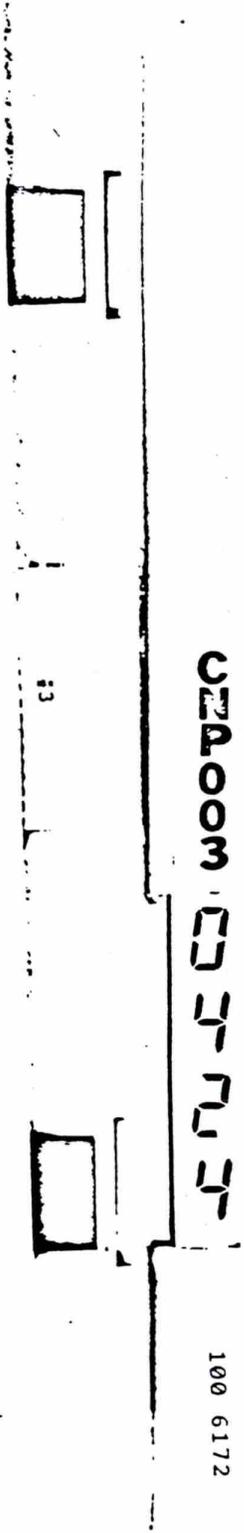
U22LOOM 03 31 07

100 6167



00

00

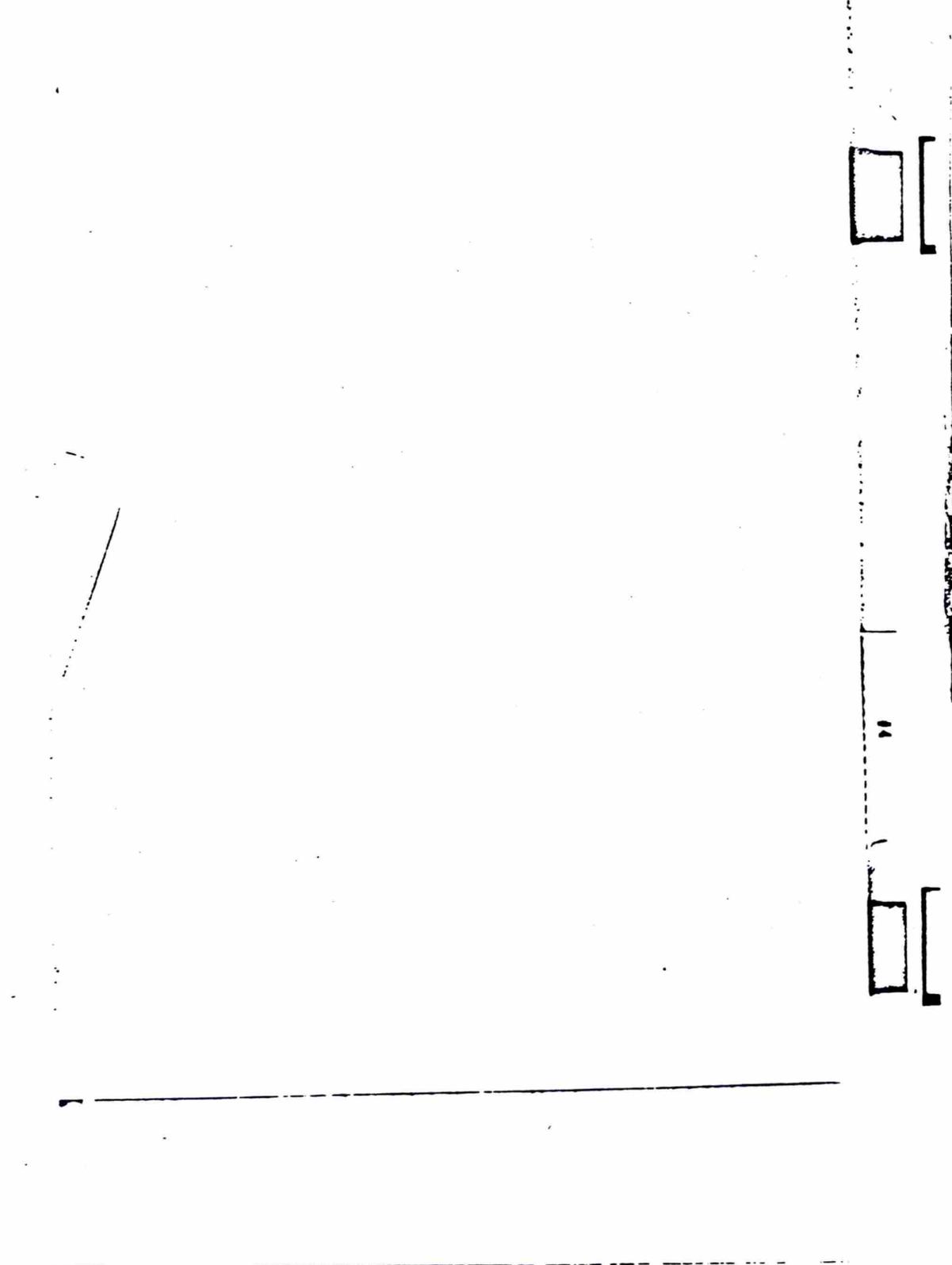


UZEALOOM . 00 00 00 00

100 6172

cc

cc



CLASSROOM

100 6177



By John H. Hint

Scenario I  
Schedule/Form

Statement of Scenario Event:

Decrease of Plasma Supply

Topic of scenario:

AIDS

No.	Major Issues/Problems (short 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.	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.	1
2	Pilot studies on surrogate testing of plasma donors has been recommended by U.S. Gov't agencies.	A study of several thousand donors for hepatitis B core antibody has provided no useful information.	1
3.	Health care workers have publicly expressed concerns regarding AIDS victims.	Concerns expressed by a small number of hospital workers have not spread to plasmapheresis workers.	1
4.	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 plasma 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 rabies antibody supply. As no coagulation products are made from this plasma, cost is high.	2

Please show the magnitude of the impact by 3, 2, 1 (high, medium, low)

SCENARIO #4

8719 001

02200 001 001 001

By John H. Hink



Scenario 2 Schedule/Form		Impact of major future developments and trends	
Topic of scenario:		AIDS	
No.	Major Future Developments	Impact on future operations/business	Mag.
<b>Most Likely:</b>			
1	Test for AIDS prodrome will be required for plasma donors.	Temporary and moderate reduction in plasma supplies causing slight shortages and minimal cost increase.  U.S. plasma exports will decrease creating moderate U.S. surplus and lower plasma prices.	1
2	Foreign countries (especially Europe) will become more self sufficient in production of plasma and will reduce purchases from U.S.		2
<b>Worst Case:</b>			
1	All plasma donations will be required to be held for a period of 6 mos. while the donor is followed to assure no AIDS 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)

3040361005

By John H. Hink



Scenario 3 Schedule/Form		Probability of occurrence of major developments and trends (from Schedule 2)			Topic of scenario: AIDS		
No.	1983	1984	1985	1986	1987	1988	
1	Most Likely: _____	20% _____	40% _____	10% _____	_____	_____	
		10% _____	40% _____	50% _____	_____	_____	
1	Worst Case: _____	15% _____	30% _____	_____	_____	_____	
Please show the probability against the relevant years (e. g. low 1984, med. 1983, high 1985)							

0819 001

U L L I C I W O O T Z O



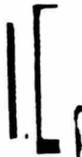
<b>Scenario 4</b> <b>Schedule/Form</b>	<b>Formulation of problem (-How can we....-)</b>  <b>Topic of Scenario:</b>  AIDS
<p>How can we prove that Cutter plasma is free from AIDS risk.</p>	
<p>Please state the problems in as few words as possible in the form which ask for action-oriented answers.</p>	

TOTQ 00T

11111 5 57 WOOTZO

U2M00M 00 3-77 3-

100 6182



15

00

00





Scenario 1 Schedule/Form		Statement of Scenario Event: Workers Contract AIDS	Topic of scenario: AIDS	
No.	Major Issues/Problems (short statement)	Impact on current business		Mag.
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.		1

Please show the magnitude of the impact by 3, 2, 1 (high, medium, low)

SCENARIO #5

189 001

WOODSON



Scenario 2      Impact of major future developments and trends Schedule/Form		Topic of scenario:    AIDS	
No.	Major Future Developments	Impact on future operations/business	Magn
	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.	1
	Worst Case: More than two workers get AIDS.	Workers refuse to work in plasma processing, leading to product shortages.	3

Please give the magnitude of the impact by 3, 2, 1 (high, medium, low)

3C 40381006

100 6184

U2200M [C] J 7710



Scenario 3 Schedule/Form		Probability of occurrence of major developments and trends (from Schedule 2)			Topic of scenario: AIDS		
No.	1983	1984	1985	1986	1987	1988	
	<b>Most Likely:</b> One or two non-high risk fractionation or plasma center workers contract AIDS. Premium wages and extensive worker protection must be provided.	50%	30%	10%	β	β	
	<b>Worst Case:</b> More than two non-high risk workers get AIDS.	1%	β	β	β	β	

Please show the probability against the relevant years (e. g. low till 1984, med. 1986, high 1988)

5819 001

ROOM 3333



Scenario 4 Schedule/Form	Formulation of problem (-How can we....-) Topic of Scenario: AIDS
<ol style="list-style-type: none"><li>1. How can we reduce the probability of non-high risk workers getting AIDS?</li><li>2. How can we prepare for the problems if this does occur?</li></ol>	
Please state the problems in as few words as possible in the form which ask for action-oriented answers.	



CP  
9-26-83



<b>Scenario 1</b> <b>Scheisla/Form</b>		<b>Statement of Scenario Event:</b> COMPETITORS OBSOLETE CUTTER HEMOPHILIA CONCENTRATES	<b>Topic of scenario:</b> 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 show the magnitude of the impact by 3, 2, 1 (high, medium, low)			

SCENARIO #6

8819 001

WOODZOO

BAYP0004797\_0023

CP  
9-26-83



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

Please give the magnitude of the impact by 3, 2, 1 (high, medium, low)

3040351007

6819 001

WOODZOO

CP  
9-26-83



<b>Scenario</b> 3	Probability of occurrence of major developments and trends (from Schedule 2)	Topic of scenario:
<b>Schedule/Form</b>	COMPETITORS OBSOLETE CUTTER HEMOPHILIA CONCENTRATES	AIDS

No.	1983	1984	1985	1986	1987	1988
	<b>Most Likely:</b>					
1.	90%	90%	15%	10%	10%	
2.	0%	5%	20%	60%	75%	
3.	0%	5%	15%	20%	75%	
	<b>Worst Case:</b>					
1.	5%	5%	15%	25%	25%	
2.	0%	0%	5%	15%	25%	

Please show the probability against the relevant years (e. g. low till 1984, med. 1986, high 1988)

0619 001

WOODZON

CP  
9-26-83



Scenario 4  
Schedule/Term

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 AHF 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.

I619 00T

W J J C WOODZD

UZ200M 03 27 27 27

100 6192

07





No.	Major Issues/Problems (short statement)	Impact on current business	Mag.
	<p>Increased attention by the media and/or future events cause government agencies (U.S. and worldwide) to add additional restrictions to the production, sale or use of plasma derived products.</p> <p>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.</p> <p>As understanding of AIDS develops, further plasma testing will be required.</p> <p>When alternate products from non-plasma sources are available, further restrictions will result including the possibility for eventual bans of human-derived material.</p>	<p>Current and future actions include:</p> <ul style="list-style-type: none"><li>- plasma center screening requirements have been increased.</li><li>- positive identification of AIDS donors in plasma products can lead to a FDA required recall of suspect lots.</li><li>- additional tracing of donors and users could be required.</li><li>- holding (quarantine) requirements for plasma could result.</li><li>- once alternate products or therapies are available, current products could be banned or simply restricted into economic impossibility.</li></ul>	<p>1</p> <p>2</p> <p>2</p> <p>2</p> <p>3</p>

Please show the magnitude of the impact by 3, 2, 1 (high, medium, low)

SCENARIO #7

100 619 E6

0200W 3333

BAYP0004797\_0028



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

Please give the magnitude of the impact by 3, 2, 1 (high, medium, low)

3C40381008

100 6194

07 J J C WOOTZO



<b>Scenario 3</b> <b>Schedule/Form</b>	<b>Probability of occurrence of major developments and trends</b> (from Schedule 2)	<b>Topic of scenario:</b> <p style="text-align: center;">AIDS</p>
---	--	--

No.	1983	1984	1985	1986	1987	1988
	<b>Most Likely:</b>					
1	_____	50% _____	75% _____	80% _____	90% _____	95% _____
2	_____	75% _____	75% _____	75% _____	75% _____	75% _____
3	_____	40% _____	50% _____	60% _____	75% _____	--- _____
4	_____	50% _____	50% _____	50% _____	50% _____	50% _____
5	_____	_____	10% _____	20% _____	30% _____	50% _____
	<b>Worst Case:</b>					
1	_____	20% _____	30% _____	30% _____	40% _____	40% _____
2	_____	30% _____	30% _____	40% _____	40% _____	50% _____
3	_____	20% _____	30% _____	30% _____	30% _____	30% _____

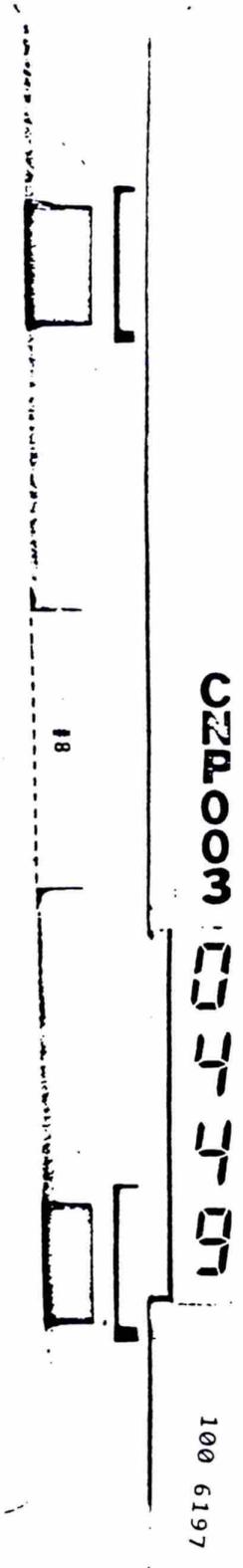
Please show the probability against the relevant years (e. g. low till 1984, med. 1986, high 1988)

ROOM 100



CC

CC



CLASSROOM 03-3-07

100 6197



By John H. Hink

Scenario I Statement of Scenario Event: Schedule/Term Non-Plasma Products Introduced by Competitor	Topic of scenario: AIDS
---	----------------------------

No.	Major Issues/Problems (short 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 significant share of the expander market and have no new impact on our business.	1
2.	Synthetic drugs (desmino-d-arginine vasopressin DDAVP and a synthetic androgen, Denizol) 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

Please show the magnitude of the impact by 3, 2, 1 (high, medium, low)

SCENARIO #8

8619 001

WOODSON

By: J. Hink



Scenario 2      Impact of major future developments and trends		Topic of scenario:	
Scenario/Form		AIDS	
No.	Major Future Developments	Impact on future operations/business	Mag.
<b>Most Likely:</b>			
1	Crystalloids and synthetic expanders will continue to be used by certain hardcore clinicians rather than Fraction V plasma products.	Use rate will not increase. Impact negligible.	1
2	Synthetic drug(s) for treatment of hemophilia will be approved and marketed.	Drugs will be partially effective in mild hemophilia. Impact on coagulation product sales minor.	1
3	Genetic engineered substitutes for plasma products will <u>not</u> be approved for general marketing until 1990.	Marginal impact during next 5 years.	1
<b>Worst Case:</b>			
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 rDNA and MOAB plasma proteins will be markedly expedited.	Severe reduction in the use of plasma derived products in the late 1980's.	3
Please give the magnitude of the impact by 3, 2, 1 (high, medium, low)			

3040381009

By: John Hink



Scenario 3 Scenario/Topic	Probability of occurrence of major developments and trends (from Schedule 2)	Topic of scenario:  AIDS
------------------------------	---	--------------------------------

No.	1983	1984	1985	1986	1987	1988
1 2 3	<b>Most Likely:</b>					
	100% _____	100% _____	100% _____	100% _____	100% _____	
	_____	50% _____	80% _____	80% _____	80% _____	
3	100% _____	100% _____	90% _____	80% _____	70% _____	
1 DNA VIII DNA XI DNA a1b NOAB CC	<b>Worst Case:</b>					
	_____	_____	_____	30% _____	60% _____	
	_____	_____	_____	30% _____	60% _____	
	_____	_____	_____	30% _____	70% _____	
	_____	_____	_____	30% _____	50% _____	

Please show the probability against the relevant years (e. g. low 1984, med. 1986, high 1988)



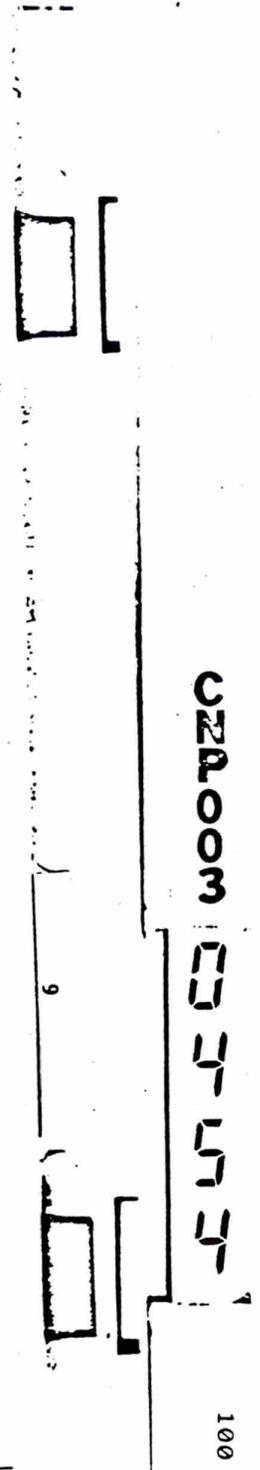
<b>Scenario 4</b> <b>Schools/Farms</b> <b>Formulation of problem (-How can we....-)</b>	<b>Topic of Scenario:</b>  AIDS
<p>How can we use new technologies to protect our plasma products.</p>	
<p>Please state the problems in as few words as possible in the form which ask for action-oriented answers.</p>	

1029 001

UJUN JCI WOOTZO

U2A ROOM 03 3-UN 3-

100 6202



00

00

CP  
9-26-83



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 risk 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
Please show the magnitude of the impact by 3, 2, 1 (high, medium, low)			

SCENARIO #9

100 6203

UNIVERSITY MICROFILMS



Scenario 2      Impact of major future developments and trends Schedule/Form      RESTRICTED DEVELOPMENT OF NEW PLASMA PRODUCTS		Topic of scenario:  AIDS	
No.	Major Future Developments	Impact on future operations/business	Mag.
<b>Most Likely:</b>			
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
<b>Worst Case:</b>			
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)

100 6204

UZZROOM : 55 J L N U D

842361 0 10

CP  
9-26-83



Scenario 3 Schedule/Form		Probability of occurrence of major developments and trends (from Schedule 2) RESTRICTED DEVELOPMENT OF NEW PLASMA PRODUCTS					Topic of scenario: AIDS	
No.	1983	1984	1985	1986	1987	1988		
	<b>Most Likely:</b>							
1.	100%	100%	100%	100%	100%	100%		
2.	30%	60%	85%	85%	85%	85%		
3.	80%	80%	80%	80%	80%	80%		
	<b>Worst Case:</b>							
1.	5%	10%	15%	15%	15%	15%		

Please show the probability against the relevant years (e. g. low till 1984, med. 1986, high 1988)

100 6205

WORLD ROOM

CP  
9-26-83



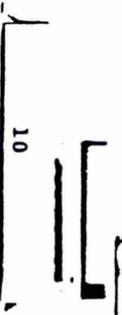
<b>Scenario 4</b> <b>Formulation of problem (-How can we....-)</b> <b>Schedule/Form</b> <b>RESTRICTED DEVELOPMENT OF NEW PLASMA PRODUCTS</b>	<b>Topic of Scenario:</b>  AIDS
<ol style="list-style-type: none"><li>1. How can we minimize AIDS concern regarding plasma products among clinical investigators?</li><li>2. How can we minimize AIDS risk in new plasma products?</li><li>3. How can we demonstrate minimal AIDS risk in new plasma products?</li><li>4. How can we prevent FDA from irrationally restricting new plasma products in response to public pressure?</li></ol>	
<p>Please state the problems in as few words as possible in the form which ask for action-oriented answers.</p>	

9029 001

00 07 13 03 W00720

U2L00M | 03 31 07

100 6207



00

00



<b>Scenario 1</b> <b>Schedule/Form</b>		<b>Statement of Scenario Event:</b> Decline in International Sales through Foreign Government Intervention	<b>Topic of scenario:</b> AIDS
No.	Major Issues/Problems (short statement)	Impact on current business	Mag.
	Approximately 125 reported AIDS cases outside the United States.	AIDS has had small impact on International sales of AHF.	1
	Heat-Treated AHF is available from several competitors.	Small impact on total International AHF sales although a larger impact in West Germany.	2
	Most major countries discourage or disallow plasma-pheresis.	Majority of plasma products used in the world are sourced from the United States. Positive impact favoring United States fractionators.	2
Please show the magnitude of the impact by 3, 2, 1 (high, medium, low)			

SCENARIO #10

8029 001

02 07 10 03 WOOTZO

TJ 9/23/83



Scenario 2 Schedule/Form		Impact of major future developments and trends Decline in International Sales through Foreign Government Intervention		Topic of scenario:  AIDS	
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 profit AHF sales if occurring in West Germany and Japan.	3		

Please give the magnitude of the impact by 3, 2, 1 (high, medium, low)

BC40384011

100 6209

U2ROOM 03 07 00

TJ 9/23/83



<b>Scenario 3</b> <b>Schedule/Form</b>		<b>Probability of occurrence of major developments and trends</b> (from Schedule 2) <b>Decline in International Sales through Foreign Government Intervention</b>				<b>Topic of scenario:</b> <p style="text-align: center;">AIDS</p>	
No.	1983	1984	1985	1986	1987	1988	
1	<b>Most Likely:</b> 0 _____	25% _____	50% _____	50% _____	50% _____	50% _____	
	<b>Worst Case:</b> 0 _____	5% _____	5% _____	5% _____	5% _____	5% _____	
Please show the probability against the relevant years (e. g. low 1984, med. 1986, high 1988)							

100 6210

U2L00M C3 J L0 N

CP  
9-26-83



Scenario 1 Schedule/Form 1/7		Statement of Scenario Event: COMPETITORS OBSOLETE CUTTER 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.	Roate® 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 show the magnitude of the impact by 3, 2, 1 (high, medium, low)					

M005578 S

104 7306

GEALON MUMM

3000 5700



CP  
9-26-83



Scenario 3 Schedule/Form 11		Probability of occurrence of major developments and trends (from Schedule 2)					Topic of scenario:	
		COMPETITORS OBSOLETE CUTTER HEMOPHILIA CONCENTRATES					AIDS	
No.	1983	1984	1985	1986	1987	1988		
<b>Most Likely:</b>								
1.	90%	90%	15%	10%	10%			
2.	0%	5%	20%	60%	75%			
3.	0%	5%	15%	20%	75%			
<b>Worst Case:</b>								
1.	5%	5%	15%	25%	25%			
2.	0%	0%	5%	15%	25%			

Please show the probability against the relevant years (e. g. low till 1984, med. 1986, high 1988)

M005580 S

104 7308

LOW WU NOSTRO

CP  
9-26-83



<b>Scenario</b> 4 <b>Schedule/Form</b> Formulation of problem (-How can we....-) COMPETITORS OBSOLETE CUTTER HEMOPHILIA CONCENTRATES	<b>Topic of Scenario:</b> AIDS
<ol style="list-style-type: none"><li>1. How can we leapfrog to develop a hepatitis/virus-free product ahead of competition?</li><li>2. How can we accelerate Cutter rDNA AIF project?</li><li>3. How can we minimize perceived AIDS risk of Koate®?</li></ol>	
Please state the problems in as few words as possible in the form which ask for action-oriented answers.	

M005581 S

104 7309

02200N 7 7 7 CD