

# % U\Q 0DZU & ROOHJH & RPPRQ 'DWD 6HV

## Content areas covered by each section

6HFWLRQV DUH LQGLFDWHG E\ WKH FRGHV RQ WKH OHIW KDQG FROXPQ RI W\

SECTION	Section Description
\$	*HQHUDO ,QIRUPDWLRQ
%	(QUROOPHQW DQG 3HUVLVWHQFH
&	)LUVW 7LPH )LUVW <HDU )UHVKPDQ \$GPLVVLRQ
'	7UDQVIHU \$GPLVVLRQ
(	\$FDGHPLF 2IIHULQJV DQG 3ROLFLHV
)	6WXGHQW /LIH
*	\$QQXDO ([SHQVHV
+	)LQDQFLDO \$LG
,	,QWWUXFWLRQDO )DFXOW\ DQG &ODVV 6L]H
-	'HJUHHV &RQIHUUHG

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\$ \* HQHUDO ,QIRUPDWLRQ

5HVSRQGHQW , QIRUPDWLRQ	1RW IRU 3XEOLFDWLRQ
1DPH	5LFKDUG %DUU\
7LWOH	\$VVLVWDQW 'LUHFWRU RI , QVWLWXWLR
2IILFH	, QVWLWXWLRQDO 5HVHDUFK
0DLOLQJ \$GGUHVV	1RUWK OHULRQ \$YH
&LW\ 6WDWH =LS &RXQWU\	%U\Q 0DZU 3\$
3KRQH	
)D[	
(PDLO \$GGUHVV	<u>UEDUU\#EU\QPDZU HGX</u>
\$_YH\ \backslash RXU\ UHVSRSQVHV\ WR\ WKH\ & '6\ SRVWHG\ KIRU\ UHWHUHOE\ HEDV\ VR	
\$_YS\ \backslash X\ V\ _o\ CS\ _D\ Z\ H\ R\ R\ \backslash Q\ H\ AG\ H\ C\ W\ K\ H\ #€5\ Bö\ R\ Y\ K\ H\ \$B\ U\ W\ H\ A\ V\ R\ Q\ W\ G\ Q\ J	HE\ V_L\ H

For more information about the study, please contact Dr. [REDACTED] at [REDACTED].

\$ 6RXUFH RI LQVWLW X&WKHFDND RQFOR QRWQUHR O  
 \$ 3XEOLF |  
 \$ 3ULYDWH QRQSURILW ;  
 \$ 3URSULHWDU\ |

\$ &ODVVLI\ \RXU XQGHUJUDGXDWL QVWLWXWLRQ  
 \$ &RHGXFDWLRQDO FROOHJH  
 \$ 0HQ V FROOHJH |  
 \$ :RPHQ V FROOHJH ;

\$ \$FDGHPLF \HDU FDOHQGDU  
 \$ 6HPHVWHU ;  
 \$ 4XDUWHU |  
 \$ 7ULPHVWHU |  
 \$ &RQWLQXRXV |  
 \$ 'LIIHUV E\ SURJUDP GHVFULEH |  
 \$ 2WKHU GHVFULEH |

\$ 'HJUHHV RIIHUGH E\ \RXU LQVWLWXWLRQ  
 \$ &HUWLILFDWH |  
 \$ 'LSORPD |  
 \$ \$VVRFLDWH |  
 \$ 7UDQVIHU \$VVRFLDWH |  
 \$ 7HUPLQDO \$VVRFLDWH |  
 \$ %DFKHORUV ;  
 \$ 3RVWEDFKHORUV FHUWLILFDWH |  
 \$ 0DVWHU V ;  
 \$ 3RVW PDVWHU V FHUWLILFDWH |  
 \$ 'RFWRUDO GHJUHH UHVHDUFK VFKRODUVKL\\$ ;  
 \$ 'RFWRUDO GHJUHH ± SURIHVVLRQDO SUDFWLFH |  
 \$ 'RFWRUDO GHJUHH RWKHU |



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& \$ ,I \HV SODFH FKHFN PDUNV LQ WKH DSSURSULDWH ER[H V EHOFG  
DGPLVVLRQ IRU )DOO

			\$'0,66,21	
	5HTXLUH	5HF RPPHC	5HTXLUH IRU	6RNP4VLGH 6XEPLWW
6\$7 RU \$&7				
\$&7 RQO\				
6\$7 RQO\				
6\$7 DQG 6\$7 6XEMH \$&7	;			
6\$7 6XEMHFW 7HVWV RQO\				

& %,I \RXU LQVWLWXWLRQ ZLOO PDNH XVH RI WKH \$&7 LQ DGPLVVLRQ GHI  
IRU )DOO SOHDVH LQGLFDWH ZKLFK 21( RI WKH IROORZLQJ DSSOL  
LQ WKH DGPLVVLRQV SURFHVV  
& %%&7 ZLWK :ULWLQJ &RPSRQHQW UHTXLUH  
& %%&7 ZLWK :ULWLQJ FRPSRQHQW UHFRPPH  
& %%&7 ZLWK RU ZLWKRXW :ULWLQJ FRPSRQHQW DFFHSWHG

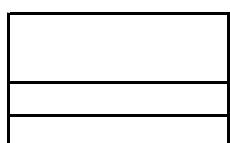
& & 3OHDVH LQGLFDWH KRZ \RXU LQVWLWXWLRQ ZLOO XVH WKH 6\$7 RU \$  
& &  
& &)RU DGPLVVLRQ  
& &)RU SODFHPHQW  
& &)RU DGYLVLQJ  
& &,Q SODFH RI DQ DSSOLFDWLRQ HVVD\<br/>& &\$V D YDOLGLW\ FKH  
DSSOLFDWLRQ HVVI  
& &1R FROOHJH SROLF\ DV RI QRZ  
& &1RW XVLQJ HVVD\ FRPSRQHQW

& , Q D G G L W L R Q G R H V \ R X U L Q V W L W X W L R Q X V H D S S O L F D Q W V W I

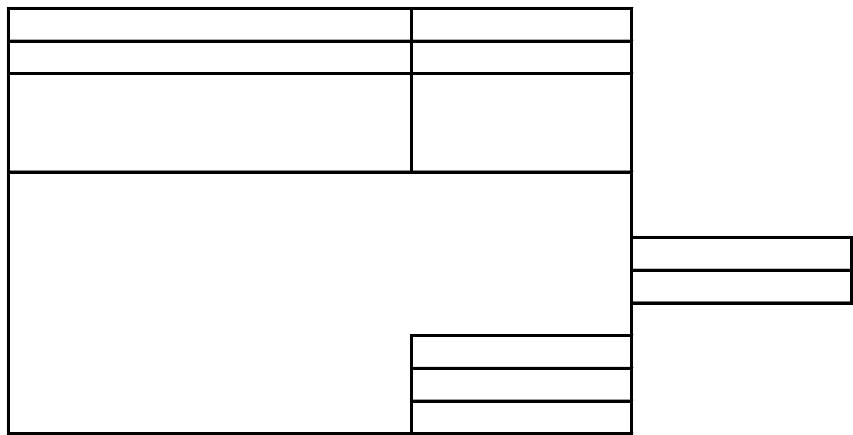
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& 'R \RX KDYH D QRQELQGLQJ HDUO\ DFWLR  
QRWLILHG RI DQ DGPLVVLRQ GHFLVLRQ Z  
QRWLILFDWLRQ GDWH EXW GR QRW KDYH ;

& & | (DUO\ DFWLRQ FORVLQJ GDWH  
& & | (DUO\ DFWLRQ QRWLILFDWLRQ GDWH )Vp&@ P 0





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( 6SHFLDO VWXG\ RSWLRQV

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\* 3OHDVH SURYLGH WKH 85/ RI \RXU LQVWLWXWLRQ V QHW SULF

SURYLGH DFDGHPLF \HDU FRVWV RI DWWHQGDQFH IRU  
DSSOLFDEOH WR \RXU LQVWLWXWLRQ

[ ] &KHFN KHUH LI \RXU LQVWLWXWLRQ V DFDGHPLF \HDU FRVWV R  
; DQG SURYLGH DQ DSSUR[LPDWH GDWH L H PRQWK GD\ ZKHQ \RXU LQ  
FRVWV RI DWWHQGDQFH ZLOO EH DYDLODEOH

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\* 8QGHUJUDGXDW<sup>H</sup> IXOO WLPH WXLWLRQ UHTXLUHG IHHV URRP  
DQG URRP DQG ERDUG IRU D IXOO WLPH XQGHUJUDGXDW<sup>H</sup> VW  
VHPHVWHU RU TXDUWHU KRXUV IRU LQVWLWXWLRQV WKDW (QXPEHU RI FUHGLWV \$ IXOO DFDGHPLF \HDU UHIHUV WR WKH  
WR -XQH XVXDOO\ HTXDWHG WR WZR VHPHVWHUV WZR WULPF  
RQH IRXU SODQ 5RRP DQG ERDUG LV GHILQHG DV GRXEON RFI  
PHDO SODQ 5HTXLUHG IHHV LQFOXGH RQO\ FKDUJHV WKDW DC  
WXLWLRQ H J UHJLVWUDWLRQ KHDOWK RU DFWLYLW\ IHHV  
XVH

	)LUVW <HDU 8QGHUJUDGXDW <sup>H</sup>	
*	35,9\$7( ,167,787,216 7XLWLRQ	
*	38%/,&,167,787,216 7XLWLRQ ,Q GLVWULFW	
*	38%/,&,167,787,216 ,Q VWWDWH RXW RI	
*	38%/,&,167,787,216 2XW RI VWWDWH	
*	1215(6,'(17 \$/,,(16 7XLWLRQ	
*	5(48,5(')((6	
*	5220 \$1' %2\$5' RQ FDPSXV	
*	5220 21/< RQ FDPSXV	
*	%2\$5' 21/< RQ FDPSXV PHDO SO	
*	&RPSUHKHQVLYH WXLWLRQ DQG UR FROOHJH FDQQRW SURYLGH VHSDU ERDUG IHHV	
*	2WKHU	

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*	1 XPEHU RI FUHGLWV SHU WHUP D V VWDWHG IXOO WLPH WXLWLRQ	0 L Q L P X P	0 D [ L P X P
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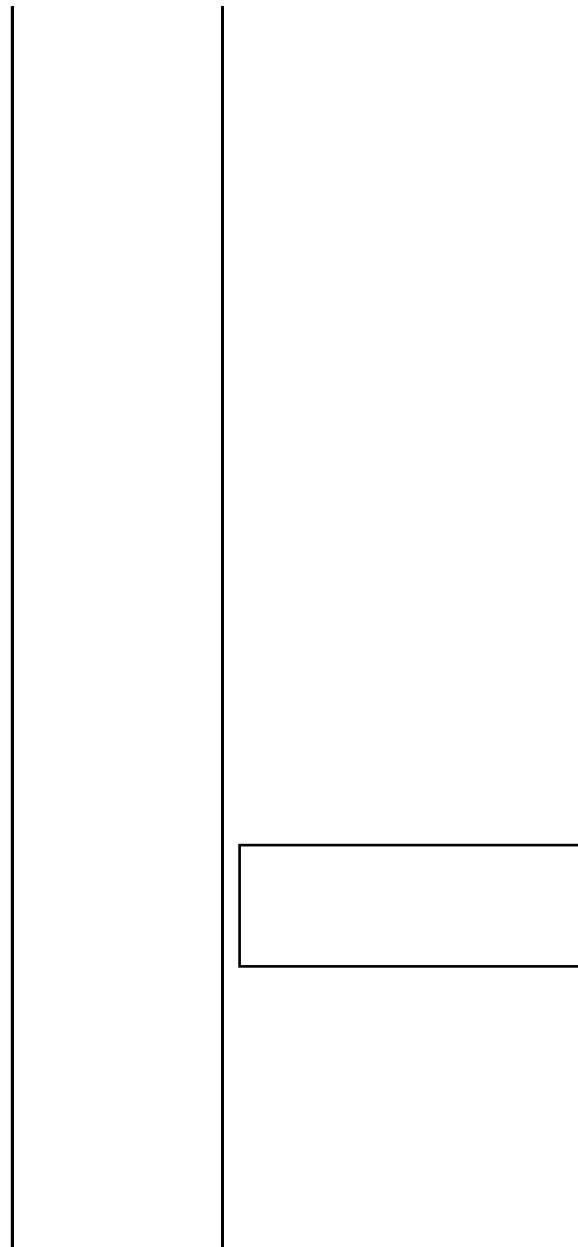
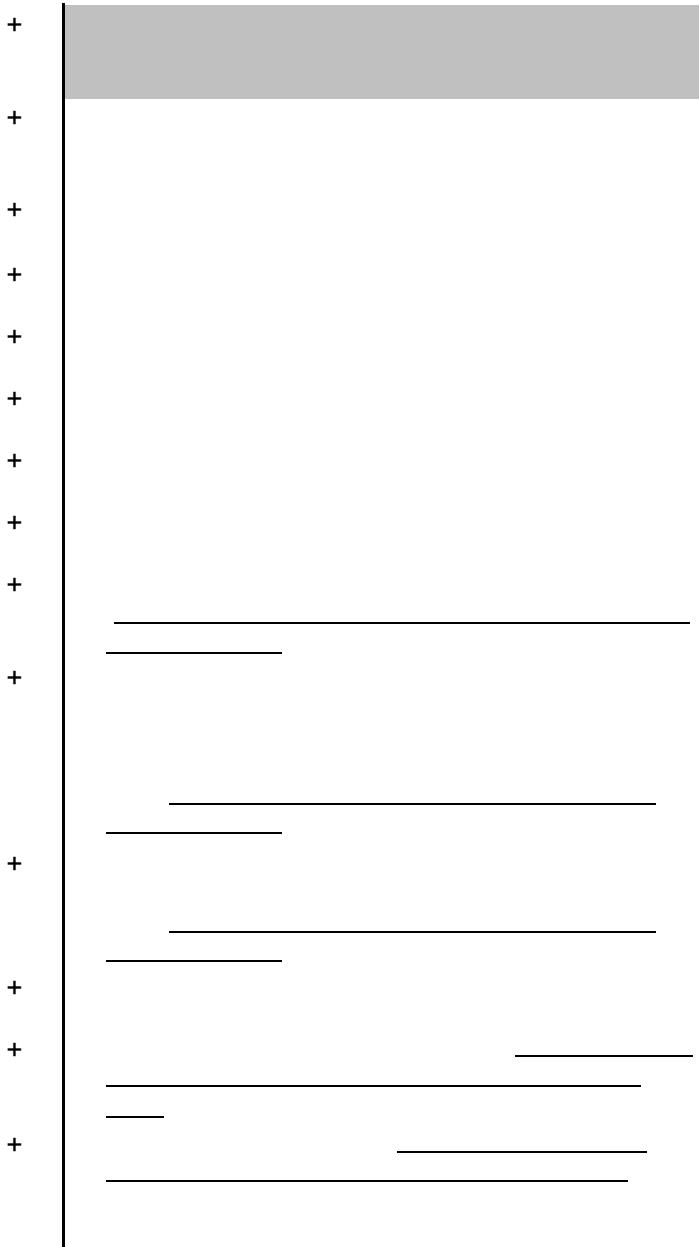
+ ) , 1 \$ 1 & , \$ / \$ , '

\$LG \$ZDUGHG WR (QUROOHG 8QGHL  
(QWHU WRWDO GROODU DPRXQWV DZDUGHG WR HQUROOHG IXO  
XQGHUJUDGXDWHV XVLQJ WKH VDPH FRKRUW UHSRUWHG LQ &  
XQGHUJUDGXDWHV LQ WKH IROORZLQJ FDWHJRLHV 1RWH ,I  
DFDGHPFL \HDU VHH WKH QH[W LWHP EHORZ XVH WKH  
FRKRUW ,QFOXGH DLG DZDUGHG WR LQWHUQDWLRQDO VWXGH  
QRQ QHHG EDVHG EXW WKDW ZDV XVHG WR PHHW QHHG VKRKO  
)RU D VXJJHVWHG RUGHU RI SUHFHGHQFH QV-2(DG)4(HP)-QFH QV

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For more information about the study, please contact the study team at 1-800-258-4929 or visit [www.cancer.gov](http://www.cancer.gov).

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+ \$	)LUVW W )XOO WL )UHVVKPH	)XOO WL 8QGHUJU ,QFO )U	/HVV 7KD )XOO WL 8QGHUJU
+ \$	Q 1XPEHU RI VWXGDHQVVKIDQG QQLRQHLQ DQG ZKR ZHUH DZDUGHG LQVWLW VFKRODUVKLS RU JUDQW DLG H DZDUGHG DWKOHWLF DZDUGV DQ		
+ \$	R \$YHUDJH GROODU DPRXQW RI LQ VFKRODUVKLS DQG JUDQW DLG D		
+ \$	S 1XPEHU RI VWXGDHQVVKIDQG QQLRQHLQ LQVWLWXWLRQDO QRQ QHHG EDV JUDQW		
+ \$	T \$YHUDJH GROODU DPRXQW RI LQ DWKOHWLF VFKRODUVKLSV DQG OLQH S		

+ ,QFRUSRUDWHG LQWR + DERYH

1RWTHKHVH DUH WKH JUDGXDW HV DQG ORDQ W\SHV WR LQFOX  
+ DQG + D  
,QFOXGH XQGHUJUDGXDWH FODVV ZKR  
JUDGXDWHG XEΘWZHHQ DQG -XQH  
ZKR VWDUWHG DW \RXU LQVWLWXWLRQ DV ILUVW WLPH  
VWXGHQWV DQG UHFHLYHG D EDFKHORU V GHJUHH  
EHWZHHQ -XO\ DQG -XQH  
RQO\ ORDQV PDGH WR VWXGHQWV ZKR ERUURZH  
ZKLOH HQUROOHG DW \RXU LQVWLWXWLRQ  
FR VLJQHG ORDQV

([FOXGHWKRVHP Z  
VWXGHQWV DQG UHFHL


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\$LG WR 8QGHUJUDGXDW 'HJUHH VHHNB@H 15RHQRJUHW Q  
GROODU DPRXQWV IRU WKH VDPH DFDGHPLF \HDU FKHFNHG LQ

+ , QGLFDWH \RXU LQVWLWXWLRQ¶V SROLF\ UHJDUGLQJ LQVWLWX  
VHHNLQJ QRQUHVLGHQW DOLHQV

+ , QVWLWXWLRQDO QHHG EDVHG VFKRODUV ;  
+ , QVWLWXWLRQDO QRQ QHHG EDVHG VFKRC  
+ , QVWLWXWLRQDO VFKRODUVKLS RU JUDQW

+ , I LQVWLWXWLRQDO ILQDQFLDO DLG LV DYDLODEOH  
DOLHQV SURYLGH WKH QXPEHU RI XQGHUJUDGXDW  
ZHUh DZDUGHG QHHG EDVHG RU QRQ QHHG EDVHG D

+ \$YHUDJH GROODU DPRXQW RI LQVWLWXWLRQDO ILQD  
VHHNLQJ QRQUHVLGHQW DOLHQV

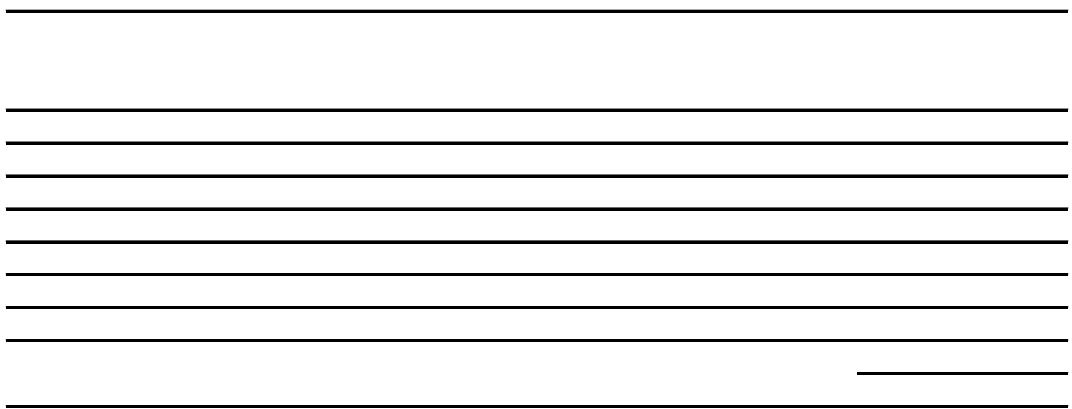
+ 7RWDO GROODU DPRXQW RI LQVWLWXWLRQDO ILQDQ  
VHHNLQJ QRQUHVLGHQW DOLHQV

+ &KHFN RII DOO ILQDQFLDO DLG IRUPV QRQUHVLGHQW DOLHQ IL  
+ , QVWLWXWLRQ¶V RZQ ILQDQFLDO DLG IRU ;  
+ &66 )LQDQFLDO \$LG 352),/(  
+ , QWHUQDWLRQDO 6WXGHQW¶V )LQDQFLDO ;  
+ , QWHUQDWLRQDO 6WXGHQW¶V &HUWLILFD  
+ 2WKHU VSHFLI\ ;

3URFHVV IRU )LUVW <HDU )UHVVPDQ 6WXGHQWV

+ &KHFN RII DOO ILQDQFLDO DLG IRUPV GRPHVWL F ILUVW \HDU I  
+ )\$)6\$ ;  
+ , QVWLWXWLRQ V RZQ ILQDQFLDO DLG IRUP ;  
+ &66 )LQDQFLDO \$LG 352),/( ;  
+ 6WDWH DLG IRUP  
+ .064 7. Q q' WRm [(, Q G)5( L)5( D3, Q 2J ET )D 95.184 74.904 384J C

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J	7RWDO QXPEHU ZKRVH KLJKHVW GHJUHH PDVWHU V			
K	7RWDO QXPEHU ZKRVH KLJKHVW GHJUHH			
L	7RWDO QXPEHU ZKRVH KLJKHVW GHJUHH WHPV I J K DQG L PXVW VXP XS WR LV			
M	7RWDO QXPEHU LQ VWDQG DORQH JUDGX ZKLFK IDFXOW\ WHDFK YLUWXDOO\ RQO\			

6WXGHQW WR )DFXOW\ 5DWLR  
5HSRUW WKH )DOO UDWLR RI IXOO WLPH HTXLYDOHQW VWXO  
LQVWUXFWLRQDO IDFXOW\ IXOO WLPH SOXV SDUW WLPH ,C

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- 'HJUHHV FRQIHUUHG EHWZHHQ -XO\ DQG -XQH  
- )RU HDFK RI`WKH IROORZLQJ GLVFLSOLQH DUHDV SURYLGH WKH SHUFHQWDJH RI`GLSORPDV FH  
GHWHUPLQH WKH SHUFHQWDJH XVH PDMRUV QRW KHDFGRXQW H J VWXGHQWV  
&DOFXODWH WKH SHUFHQWDJH IURP\RXU LQVWLWXWL RQ\`V, 3('6 &RPSOHWLRQV\`E\)  
QXPHUDWRU DQG WKH VXP RI WKH \*UDQG 7RWDO E\ VW ODMRUV DQG WKH \*UDQG  
FRPSXWH WKH SHUFHQWDJHV XVLQJ VW PDMRUV RQO\



&R P P R Q 'D W D 6 H W

&DUHHU DQG SODFH \$HUQHQ JHH QRY LVFHUVYLFHV LQFOXGLQJ RIWHQ  
HPSOR\HUV WR FDPSXV DSWLWXGH DQG YRFDWLRQDO WHVWLQJ  
UHVXPH ZULWLQJ LQWHUYLHZLQJ ODXQFKLQJ WKH MRE VHDUFK  
WKRVH VHHNLQJ SHUPDQHQW SRVLWLRQV HVWDEOLVKPHQW RI D

&DUQHJLH XQLWV

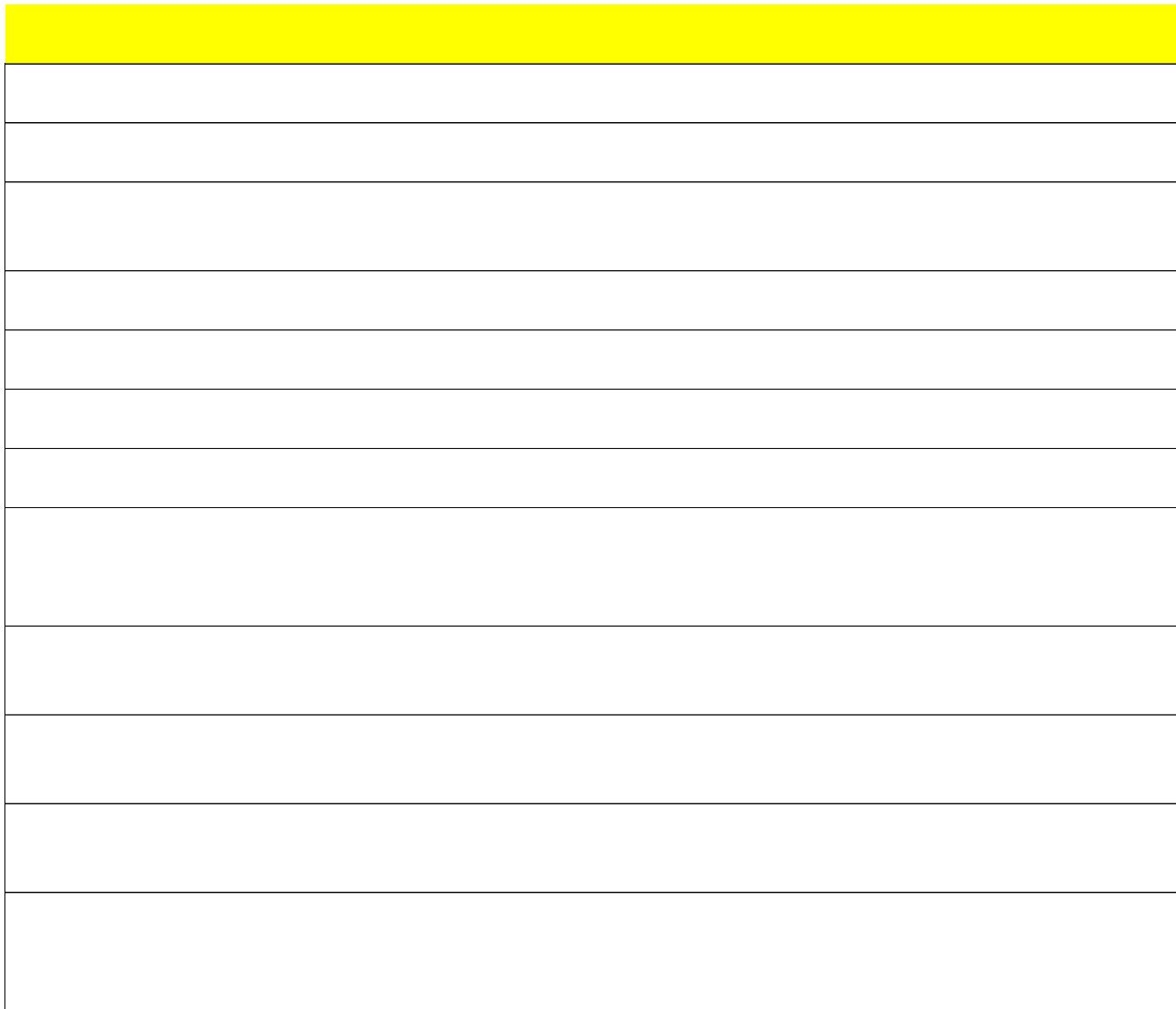


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/LEHUDO DUWV FDUH~~SHWR~~~~JR~~~~DE~~LQ~~W~~KR~~Q~~K D VWXGHQW HDUQV XQGH  
ILHOGV RQH LQ D OLEHUDO DUWV PDMRU DQG WKH RWKHU LQ D  
WKURXJKUHJR~~V~~WUDWLRQ

0DVWHU V \$QJDZHUG WKDW UHTXLUHV WKH VXFFHVVIXO FRPSOHY  
WZR IXO UB €`RQDO GPIURQDUQVX L U  
IXO UB €`RQDO GPIURQDUQVX L



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\$W /HDVW %XW /HV V 7KDQ5H\$KDGHPLFRPISDQWLRQ RI DQ RUJDQ SRVWVHFRQGDU\ OHYHO EHORZ WKH EDFFDODXUHDWH GHJUHH DFDGHPLF \HDUV RU GHVLJQHG IRU FRPSOHWLRQ LQ DW OHDVW EXW OHVV WKDQ FRQWDFW KRXUV  
3ULYDWH LQ\$QVHV\ XW\ QRQDO LQVWLWXWLRQ FRQWUROOHG E\ DJHQF\ XVXDOO\ VXSSRUWHG SULPDULO\ E\ RWKHU WKDQ SXEOL DSSRLQWHG RIILFLDOV  
3ULYDWH IRU SURSLV ULLQWWLWDQW\ RQW\ p, Q p, ZK\ BFC\ ZKQH WLQVH4 FRPSHQVDWLRQ RWKHU WKDQ ZDJHV UHQW RU RWKHU H[SHQVH  
3ULYDWH S PPP \$ BPLPY\ W\ Q\ V\ W\ L\ W\ K\ W\ L\ R\ Q\ Q\ L\ Q\ Z\ K\ L\ F\ K\ W\ K\ H\ L\ Q\ G\ L\ FRPSHQVDWLRQ RWKHU WKDQ ZDJHV UHQW RU RWKHU H[SHQVH





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; . 5XXXg j] Yriei Ygjhcb lC W` YMh YI F@'cZgWcc`gB YhDf] W7UW Ucf  
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