

BEFORE THE  
REGULAR MEETING  
OF THE

SCIENTIFIC AND MEDICAL ACCOUNTABILITY STANDARDS WORKING  
GROUP SEARCH SUBCOMMITTEE OF THE  
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE  
TO THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

LOCATION: UNIVERSITY OF CALIFORNIA, SAN FRANCISCO  
REGENTS' ROOM  
LAUREL HEIGHTS CONFERENCE CENTER  
3333 CALIFORNIA STREET  
SAN FRANCISCO, CALIFORNIA

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I N D E X

ITEM	DESCRIPTION	PAGE NO.
	CALL TO ORDER	3
	ROLL CALL	3
	PUBLIC COMMENT	4
	CONSIDERATION OF PROCESS, INCLUDING CRITERIA AND TIME LINE, USED TO SELECT MEMBERSHIP RECOMMENDATIONS OF THE SCIENTIFIC AND MEDICAL ACCOUNTABILITY STANDARDS WORKING GROUP TO THE ICOC	5
	CONSIDERATION OF SUBCOMMITTEE'S RECOMMENDATIONS ON HOW TO DEVELOP CONFLICT OF INTEREST POLICY FOR POTENTIAL MEMBERS OF THE SCIENTIFIC AND MEDICAL RESEARCH FUNDING WORKING GROUP, SCIENTIFIC AND MEDICAL ACCOUNTABILITY STANDARDS WORKING GROUP, AND SCIENTIFIC AND MEDICAL RESEARCH FACILITIES WORKING GROUP TO THE ICOC	79
	CONSIDERATION OF SUBCOMMITTEE'S RECOMMENDATIONS ON TWO MEMBERS OF THE ICOC FOR MEMBERSHIP ON THE ASSEMBLY CONCURRENT RESOLUTION 252 MANDATED COMMITTEE	87
	REPORT ON STATUS OF SENATE BILL 322 AND DISCUSSION OF THE SUBCOMMITTEE'S COOPERATION AND CONSIDERATION OF ACTIONS	91
	INVITATION OF MEMBERS OF THE PUBLIC AND THE ICOC TO SUBMIT THE NAMES AND CONTACT INFORMATION OF CANDIDATES FOR CONSIDERATION FOR MEMBERSHIP ON THE SCIENTIFIC AND MEDICAL ACCOUNTABILITY STANDARDS WORKING GROUP	96
	ADJOURNMENT	98

1 SAN FRANCISCO, CALIFORNIA; MONDAY, JANUARY 31, 2005

2

3 CHAIRMAN KESSLER: IF WE'RE ALL READY, WE'LL  
4 CALL THIS MEETING TO ORDER. CAN WE HAVE A ROLL CALL,  
5 PLEASE.

6 MR. KLEINSCHMIDT: DAVID KESSLER.

7 CHAIRMAN KESSLER: HERE.

8 MR. KLEINSCHMIDT: DAVID SERRANO SEWELL.

9 MR. SERRANO SEWELL: HERE.

10 MR. KLEINSCHMIDT: JEFF SHEEHY.

11 MR. SHEEHY: HERE.

12 MR. KLEINSCHMIDT: JOAN SAMUELSON.

13 MS. SAMUELSON: HERE.

14 MR. KLEINSCHMIDT: JONATHAN SHESTACK.

15 MR. SHESTACK: HERE.

16 MR. KLEINSCHMIDT: OSWALD STEWARD.

17 DR. STEWARD: HERE.

18 CHAIRMAN KESSLER: THANK YOU ALL FOR JOINING  
19 THE FIRST MEETING OF THE CALIFORNIA INSTITUTE FOR  
20 REGENERATIVE MEDICINE'S SCIENTIFIC AND MEDICAL  
21 STANDARDS WORKING GROUP SEARCH COMMITTEE. SO EVERYONE  
22 SHOULD KNOW, THIS IS NOT THE WORKING GROUP. THIS IS  
23 THE SEARCH COMMITTEE TO SEARCH FOR THE WORKING GROUP.  
24 SO A MATTER OF TERMINOLOGY.

25 MEMBERS OF THE PUBLIC, THANK YOU FOR BEING

1       HERE.  YOU WILL BE INVITED TO PROVIDE TESTIMONY BEFORE  
2       OR DURING CONSIDERATION OF EACH AGENDA ITEM.  SPEAKERS  
3       ARE ASKED TO KINDLY LIMIT THEIR TESTIMONY TO THREE  
4       MINUTES.

5                   BEFORE WE START WITH THE FORMAL AGENDA, ARE  
6       THERE ANY REQUESTS BY THE PUBLIC TO SPEAK TO THIS  
7       SUBCOMMITTEE?  THIS IS AT THIS TIME?  YES, IF THERE'S  
8       ANYONE WHO WOULD LIKE TO SPEAK NOW BEFORE WE EVEN  
9       BEGIN, WE WANT TO AFFORD THAT OPPORTUNITY.

10                   MR. REED:  I'M DON REED.  MY SON, ROMAN REED,  
11       IS PARALYZED.  I JUST WANTED TO SAY THANK YOU GUYS FOR  
12       DOING ALL OF THE HARD WORK THAT'S NECESSARY TO HELP  
13       THIS AMAZING UNDERTAKING GO ABOUT.  THE FRUSTRATIONS  
14       AND HASSLES THAT ARE INEVITABLE IN THIS PROCESS ARE SO  
15       MINOR COMPARED TO THE GREAT GOOD THAT YOU ARE ABOUT TO  
16       DO.  AND WHATEVER HASSLES AND HEADACHES IT BRINGS,  
17       PLEASE KNOW THAT YOUR WORK IS ENORMOUSLY APPRECIATED BY  
18       THE MILLIONS OF PEOPLE LIKE MY SON SITTING IN A  
19       WHEELCHAIR AND HOPE FOR A CURE.  THANK YOU VERY MUCH.

20                   CHAIRMAN KESSLER:  THANK YOU.  AND THANK YOU  
21       FOR REMINDING US WHY WE'RE HERE, AND WE VERY MUCH LOOK  
22       FORWARD TO WORKING WITH YOU AND ALL THE MEMBERS OF THE  
23       PUBLIC.

24                   ARE THERE ANY OTHER COMMENTS FROM THE PUBLIC  
25       BEFORE WE GET TO THE ACTUAL AGENDA?

1                   WOULD ANY SUBCOMMITTEE MEMBERS LIKE TO MAKE  
2 COMMENTS BEFORE WE BEGIN? MEMBERS OF THE SUBCOMMITTEE?

3                   THE NEXT THE ITEM ON THE AGENDA IS NO. 3.  
4 IT'S CONSIDERATION OF PROCESS, INCLUDING DISCUSSION OF  
5 CRITERIA AND TIME LINE, USED TO SELECT MEMBERSHIP  
6 RECOMMENDATIONS OF THE SCIENTIFIC AND MEDICAL  
7 ACCOUNTABILITY STANDARDS WORKING GROUP TO THE  
8 INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE.

9                   ALL THE INFORMATION THAT WE ARE ABOUT TO  
10 PRESENT IS SUBJECT TO SUBCOMMITTEE ACTION, ACTION NOT  
11 ONLY BY THE SUBCOMMITTEE, BUT ALSO BY THE INDEPENDENT  
12 CITIZENS' OVERSIGHT COMMITTEE.

13                   USING THE DOCUMENTS IN THE PACKET HANDED OUT  
14 AT THE START, AND I JUST WANT TO MAKE SURE, DOES  
15 EVERYONE -- IS THERE ANYONE WHO DOESN'T HAVE A PACKET?  
16 I ACTUALLY WILL TAKE ANOTHER ONE IF THAT'S OKAY.

17                   MR. SHESTACK: WE DON'T HAVE ANYBODY ON THE  
18 PHONE, RIGHT?

19                   CHAIRMAN KESSLER: EVERYONE IS PRESENT.  
20 THANK YOU FOR ALL BEING PRESENT TODAY.

21                   EVERYONE HAVE THE PACKET? LET ME TRY TO  
22 PRESENT OR SUGGEST A POTENTIAL PATH FOR THE STANDARDS  
23 WORKING GROUP THAT WE ARE CHARGED WITH FORMING. BEFORE  
24 WE BEGIN TO DISCUSS THIS AGENDA ITEM, I JUST WANT TO  
25 BRING TO EVERYONE'S ATTENTION THE SORT OF ROLES AND

1 RESPONSIBILITIES DOCUMENT THAT WAS POSTED WITH THE  
2 AGENDA.

3 NOW, THIS IS AN EXCERPT FROM THE ACTUAL  
4 STATUTE OF PROP 71 LAW THAT DETAILS THE MEMBERSHIP AND  
5 CHARGE TO THE SCIENTIFIC AND MEDICAL ACCOUNTABILITY  
6 STANDARDS WORKING GROUP THAT WE NEED TO FORM. IN  
7 ADDITION, I BRING YOUR ATTENTION TO THE PACKET IN FRONT  
8 OF YOU THAT INCLUDES, ONE, DRAFT CRITERIA FOR  
9 SELECTION; TWO, DRAFT FLOW CHART THAT DETAILS STEPS FOR  
10 SELECTING MEMBERS; THREE, A DRAFT TIMETABLE; FOUR, A  
11 DRAFT INFORMATION FORM; AND, FIVE, A DRAFT JOB  
12 DESCRIPTION.

13 LET ME SPEND SOME TIME ON EACH ONE OF THESE  
14 DOCUMENTS, IF I MAY. LET ME --

15 DR. SAMUELSON: THIS IS NEW, RIGHT? I  
16 SHOULDN'T HAVE FOUND THIS BEFORE?

17 CHAIRMAN KESSLER: NO. NO. THIS IS FOR  
18 DISCUSSION. THIS WAS JUST TO TRY TO GIVE US SOMETHING  
19 TO WORK WITH. WE NEED TO REVIEW THIS, AND WE NEED TO  
20 GO THROUGH THIS IN DETAIL. RATHER THAN STARTING FROM  
21 SCRATCH, WE THOUGHT WE WOULD PUT SOMETHING ON THE TABLE  
22 THAT WOULD GIVE US SOME WORKING DOCUMENTS TO TRY TO  
23 GRAPPLE WITH.

24 DR. SAMUELSON: GREAT.

25 CHAIRMAN KESSLER: SO LET ME START WITH THE

1 PROPOSED CRITERIA FOR SELECTION LISTED ON THE FIRST  
2 DOCUMENT. THE FIRST SET OF CRITERIA COMES DIRECTLY  
3 FROM THE LANGUAGE OF PROPOSITION 71. AND THERE ARE  
4 THREE BASIC ELEMENTS. MEMBERS MUST BE EITHER, ONE, A  
5 MEMBER OF THE ICOC FROM ONE OF THE TEN GROUPS THAT  
6 FOCUS ON DISEASE SPECIFIC AREAS. THAT'S FIVE SEATS.

7 NOW, WHAT I WOULD PROPOSE TO DO, AND AGAIN  
8 THIS IS ALL SUBJECT TO DISCUSSION, IS TO ASK ELIGIBLE  
9 ICOC MEMBERS TO EXPRESS THEIR LEVEL OF INTEREST IN  
10 SERVING ON THIS WORKING GROUP AT THE FEBRUARY 3D ICOC  
11 MEETING SO THAT WE HAVE NOT PREJUDGED WHO IT SHOULD BE.  
12 WE ASK FOR WHO IS WILLING TO SERVE. WE CAN'T MAKE A  
13 DECISION, I BELIEVE, ON THE FEBRUARY 3D MEETING, BUT WE  
14 CAN AT LEAST GET A SENSE OF WHO HAS INTEREST IN THESE  
15 AREAS, WHO WOULD BE WILLING TO SERVE. AND THEN IF  
16 THERE ARE MORE THAN THE FIVE, WE CAN PERHAPS ASK THE  
17 QUESTION AT THE ICOC: WHO FEELS STRONGLY ABOUT  
18 SERVING? AND SEE IF PEOPLE CAN SORT THEMSELVES INTO  
19 FIVE; AND IF NOT, WE CAN ALWAYS TAKE IT BACK AND MAKE A  
20 FURTHER RECOMMENDATION. BUT RATHER THAN US SUGGESTING  
21 WHO IT IS, WE SORT OF ASK. WE TREAT EVERYBODY WITH  
22 RESPECT, AND THEY CAN MAKE THEIR OWN RECOMMENDATIONS IF  
23 THEY WANT TO SERVE HERE. SO THAT'S NO. 1.

24 SO IT'S FIVE SEATS FROM MEMBERS OF THE ICOC  
25 FROM ONE OF THE TEN GROUPS THAT FOCUS ON DISEASE

1 SPECIFIC AREAS. OR, A, A SCIENTIST OR A CLINICIAN  
2 NATIONALLY RECOGNIZED IN THE FIELD OF PLURIPOTENT AND  
3 PROGENITOR CELL RESEARCH. THAT IS SEVEN SEATS -- NINE  
4 SEATS. SCIENTIST OR CLINICIAN NATIONALLY RECOGNIZED IN  
5 THE FIELD OF PLURIPOTENT OR PROGENITOR CELL RESEARCH.  
6 OR, A, MEDICAL ETHICIST, FOUR SEATS.

7 NOW, ACCORDING TO THE DEFINITION IN PROP 71,  
8 A MEDICAL ETHICIST IS AN INDIVIDUAL WITH ADVANCED  
9 TRAINING IN ETHICS WHO HOLDS A PH.D., M.A., OR  
10 EQUIVALENT TRAINING, AND WHO SPENDS OR HAS SPENT  
11 SUBSTANTIAL TIME, ONE, RESEARCHING AND WRITING ON  
12 ETHICAL ISSUES RELATED TO MEDICINE AND, TWO,  
13 ADMINISTERING ETHICAL SAFEGUARDS DURING THE CLINICAL  
14 TRIAL PROCESS, PARTICULARLY THROUGH SERVICE ON  
15 INSTITUTIONAL REVIEW BOARDS. AND THAT'S AN AND, SO  
16 IT'S BOTH ONE AND TWO. IT'S NOT JUST RESEARCH. IT'S  
17 NOT JUST ADMINISTERING ETHICAL SAFEGUARDS. IT'S BOTH  
18 AS PART OF THE CRITERIA.

19 MR. SERRANO SEWELL: CAN WE ASK QUESTIONS  
20 NOW?

21 CHAIRMAN KESSLER: SURE. THOSE ARE THE  
22 ACTUAL THREE FIRST CRITERIA, AND THERE IS A FOURTH IN  
23 ADDITION. IT'S ESSENTIAL THAT A POTENTIAL WORKING  
24 GROUP MEMBER HAS TIME TO DEVOTE TO MEETING SIX TO EIGHT  
25 TIMES IN THE NEXT 12 MONTHS. THAT'S THE REALITY.



1 THAT'S OUR BEST ESTIMATE OF THE AMOUNT OF TIME THAT  
2 WILL BE NECESSARY. THE FIRST YEAR OR SO WILL BE THE  
3 MOST INTENSE IN TERMS OF COMMITMENT.

4 I'D LIKE TO ALSO TALK ABOUT SOME OTHER  
5 PRACTICAL CRITERIA THAT WE WOULD LIKE TO PUT ON THE  
6 TABLE, BUT LET ME STAY WITH THE STATUTORY REQUIREMENTS  
7 FOR SELECTION AND MAKE SURE WE ALL UNDERSTAND WHAT THE  
8 LAW REQUIRES US TO DO. AND MAYBE COUNSEL, IF WE NEED  
9 HELP, YOU CAN HELP US INTERPRET THE LAW.

10 MR. SHESTACK: IS THIS WORKING GROUP, BESIDES  
11 DOING ETHICAL STANDARDS AND DEALING WITH INFORMED  
12 CONSENT ISSUES, THINGS LIKE THAT, WILL THIS GROUP ALSO  
13 BE DEALING WITH POLICY RECOMMENDATIONS ON PATENTING AND  
14 IP? IT'S NOT -- I THOUGHT IT WAS, BUT IT'S NOT CLEAR  
15 FROM THIS WHAT COMMITTEE DOES THAT.

16 CHAIRMAN KESSLER: COUNSEL CAN HELP CLARIFY.

17 MR. HARRISON: I THINK THE ANSWER TO YOUR  
18 QUESTION IS THAT IT'S UP TO THE ICOC AS TO WHAT  
19 AUTHORITY THE ICOC WANTS TO DELEGATE TO THE STANDARDS  
20 WORKING GROUP. AMONG THE PARTICULAR STANDARDS  
21 ENUMERATED IN THE ACT, THE IP STANDARDS ARE NOT  
22 INCLUDED.

23 MR. SHESTACK: BUT WE KNOW THAT SOMEONE HAS  
24 TO MAKE THOSE STANDARDS.

25 MR. HARRISON: CORRECT.

1                   MR. SHESTACK:  AND RIGHT NOW THIS MIGHT BE  
2                   THE LOGICAL COMMITTEE TO DO IT.

3                   CHAIRMAN KESSLER:  WELL, YOU KNOW, WE MAYBE  
4                   WANT TO HAVE SOME DISCUSSION.  WE HAVE TO DECIDE WHEN  
5                   TO HAVE THAT DISCUSSION.  IT'S INTERESTING WHEN I LOOK  
6                   AT THE CRITERIA THAT I JUST READ THAT'S IN THE STATUTE,  
7                   IT IS ESSENTIALLY MEDICAL ETHICISTS, ICOC MEMBERS,  
8                   SCIENTISTS AND CLINICIANS.  IT DOESN'T HAVE SPECIFIC  
9                   EXPERTISE ON IT, I JUST NOTE.  IT DOESN'T HAVE LEGAL  
10                  EXPERTISE.  NOW, ICOC MEMBERS, THERE'RE WONDERFUL  
11                  LAWYERS AROUND THIS TABLE, BUT IT DOESN'T ALLOW US TO  
12                  HAVE THAT KIND OF EXPERTISE.  SO I KNOW THAT  
13                  MR. KLEIN -- THIS MAY GET DISCUSSED AT THE ICOC AS A  
14                  BROADER ISSUE.  I KNOW BOB KLEIN HAS BEEN THINKING  
15                  ABOUT THIS.

16                  I WONDER, JUST IN MY OWN HEAD, WHETHER THIS  
17                  GROUP REALLY HAS, WHEN YOU LOOK AT THE COMPOSITION OF  
18                  SCIENTISTS, CLINICIANS, MEDICAL ETHICISTS, WHETHER  
19                  THERE'S REAL EXPERTISE ON THIS OR NOT.

20                  MR. SHESTACK:  I MEAN THERE ARE CERTAINLY  
21                  MEDICAL ETHICISTS WHO MAKE A SUBSPECIALTY IN PATENT --  
22                  IN SORT OF THE LEGAL PHILOSOPHY OF PATENTING  
23                  BIOMATERIALS.  MY QUESTION ALWAYS ABOUT THESE THINGS IS  
24                  THIS IS WHAT THE LAW SAYS.  IN ORDER, FOR INSTANCE, IF  
25                  THE ICOC IS ABLE BY A FULL VOTE TO, SAY, CHANGE A

1 COMPOSITION OF A SUBCOMMITTEE, I ASSUME, IS ABLE TO  
2 SAY, WELL, ACTUALLY YOU SHOULD ADD THREE MORE PEOPLE TO  
3 THE COMMITTEE AND FORM AN AD HOC COMMITTEE. HOW DO  
4 THOSE THINGS GET DEALT WITH?

5 MR. HARRISON: THE ANSWER TO YOUR QUESTION  
6 SPECIFICALLY IS THAT THE MAKEUP OF THE COMMITTEE IS SET  
7 BY STATUTE. SO THE ICOC CAN'T ALTER THE MAKEUP OF THE  
8 COMMITTEE. THEY COULD CREATE AN AD HOC COMMITTEE  
9 THAT'S ATTACHED TO THE STANDARDS WORKING GROUP, FOR  
10 EXAMPLE. BUT THE COMMITTEE ITSELF AND ITS MEMBERSHIP  
11 IS DETERMINED BY STATUTE, AND THE ICOC CAN'T ALTER  
12 THAT.

13 I'D ALSO POINT OUT THAT THE ISSUE OF  
14 STANDARDS FOR IP AGREEMENTS IS ON THE AGENDA FOR THE  
15 ICOC'S MEETING ON FEBRUARY 3D.

16 CHAIRMAN KESSLER: AS WE GO FORWARD WITH THE  
17 CRITERIA, MY SENSE IS WHAT SHOULD BE THE PRESUMPTION  
18 HERE. IS THERE A SENSE STAFF THOUGHT THROUGH WHAT THE  
19 PRESUMPTIONS SHOULD BE?

20 MR. KLEINSCHMIDT: AS YOU KNOW FROM THE  
21 AGENDA, ONE OF THE LATER ITEMS IS TO TALK ABOUT THE ACR  
22 252, WHICH IS THE IP GROUP. CHAIRMAN BOB KLEIN ASKED  
23 THAT THIS COMMITTEE CONSIDER IT ON SOME BASIC LEVEL  
24 THIS ISSUE, BUT IT'S REALLY UP TO YOU HOW YOU WANT TO  
25 PROCEED.

1 MR. SHESTACK: IT JUST SEEMS LIKE THEY'RE  
2 LEANING TO PUT THIS UNDER THIS COMMITTEE'S CHARGE, AND  
3 THERE'S SOME LOGIC TO IT, BUT MIGHT HAVE TO CREATE SOME  
4 AD HOC SUBCOMMITTEE TO REALLY DEAL WITH IT.

5 CHAIRMAN KESSLER: IF I'M CORRECT -- LET ME  
6 ASK COUNSEL THIS QUESTION. WHILE WE DO NOT HAVE THE  
7 DISCRETION TO ALTER THIS COMMITTEE, WE WOULD HAVE  
8 DISCRETION TO SET UP A SPECIAL WORKING GROUP ON IP, FOR  
9 EXAMPLE.

10 MR. HARRISON: CORRECT. THE ICOC COULD  
11 ESTABLISH A SEPARATE COMMITTEE, AN AD HOC COMMITTEE, TO  
12 CONSIDER IP STANDARDS THAT'S COMPRISED EITHER OF ICOC  
13 MEMBERS OR OUTSIDE EXPERTS OR SOME COMBINATION OF THE  
14 TWO.

15 CHAIRMAN KESSLER: THERE'S A COMMENT.

16 DR. CUNNINGHAM: POINT OF CLARIFICATION. YOU  
17 ENVISION NOT MAKING RECOMMENDATIONS FOR THE COMMITTEE  
18 FOR A YEAR? OR THE COMMITTEE HAS TO MEET FOR A YEAR  
19 BEFORE IT COMES UP WITH THE STANDARDS? ISN'T THE  
20 STANDARDS A CONDITION BEFORE ANY GRANTS CAN BE MADE?

21 CHAIRMAN KESSLER: THERE IS A WHOLE TIME LINE  
22 OF REGULATORY ADMINISTRATIVE PROCEDURE HERE TO GET TO  
23 THE FORMAL REGULATIONS. COUNSEL CAN MAYBE REVIEW.  
24 THERE ARE A NUMBER OF DIFFERENT ELEMENTS TO THAT.

25 MR. KLEINSCHMIDT: RIGHT. THERE WILL BE SOME

1 INTERIM STANDARDS DEVELOPED AND ENDORSED BY THE WORKING  
2 GROUP. AND THEN THAT WILL BE TAKEN TO THE ICOC FOR ITS  
3 APPROVAL, BUT THAT'S INTERIM STANDARDS. AND THEN IT  
4 STARTS THE WHOLE ADMINISTRATIVE PROCEDURES ACT PROCESS  
5 TO COME UP WITH FINAL PROCEDURES.

6 CHAIRMAN KESSLER: LET ME POINT OUT JUST FOR  
7 THE COMMITTEE, IT'S BEEN PUBLICLY DISCLOSED. ITEM 14  
8 ON OUR ICOC MEETING AGENDA FOR THURSDAY, THIS IS THE  
9 THURSDAY, THE FULL ICOC HAS CONSIDERATION OF CREATION  
10 OF AN INTELLECTUAL PROPERTY ADVISORY COUNCIL TO MAKE  
11 RECOMMENDATIONS TO THE ICOC STANDARDS FOR IP  
12 AGREEMENTS. SO I JUST NOTE THAT THAT HAS BEEN NOTICED  
13 AS AN AGENDA ITEM. WE CERTAINLY CAN HAVE A DISCUSSION  
14 HERE, IF YOU WOULD LIKE, AND ANY RECOMMENDATIONS,  
15 WHETHER YOU FEEL THIS IS AN APPROPRIATE COMMITTEE TO BE  
16 ABLE TO DO THAT, AND THEN WE CAN BRING OUR THINKING TO  
17 THE FULL ICOC ON THURSDAY, IF YOU WOULD LIKE.

18 DR. SAMUELSON: I HAVE A SIMILAR QUESTION,  
19 AND I GUESS IT'S A COUPLE OF QUESTIONS. LOOKING AT THE  
20 FIRST FUNCTION OF THIS WORKING GROUP, IT SAYS TO  
21 RECOMMEND TO THE ICOC SCIENTIFIC, MEDICAL, AND ETHICAL  
22 STANDARDS. SO THAT'S A VERY BROAD AMBIT. I'M  
23 WONDERING WHAT -- WHEN I READ THIS THE FIRST TIME, WHAT  
24 I THOUGHT, AND I THINK THIS MIGHT BE ONE  
25 INTERPRETATION, IS THAT THIS WORKING GROUP HAS THE

1 RESPONSIBILITY TO HAVE AN OVERARCHING RESPONSIBILITY  
2 FOR DEFINING THE STANDARDS THAT ARE GOING TO GOVERN HOW  
3 WE DO OUR WORK AND WHAT WE'RE DOING, AND THEN THE OTHER  
4 TWO WORKING GROUPS HAVE OTHER VERY FOCUSED  
5 RESPONSIBILITIES.

6 AND SO I WAS -- I'M WONDERING IF THERE'S  
7 ANYWHERE A DEFINITION OF WHAT THIS MEANS OR WHETHER  
8 THIS IS SOMETHING WE SHOULD BE ELABORATING ON AND  
9 CHEWING ON A BIT AS A SUBCOMMITTEE TO DECIDE WHAT WE  
10 THINK. FOR EXAMPLE, I, IN LOOKING AT THE INITIATIVE  
11 RECENTLY, WAS WONDERING WHERE THERE'S A HOME FOR  
12 STRATEGIC PLANNING, WHICH THERE ARE SEVERAL REFERENCES  
13 TO IN THE INITIATIVE AND IT'S IMPLIED IN SEVERAL  
14 OTHERS. AND THAT NEEDS ITS OWN HOME, AND THERE'S  
15 SOMETHING -- WE CAN CREATE OTHER COMMITTEES, I GUESS,  
16 BUT THERE'S SOMETHING TO THESE THREE WORKING GROUPS  
17 THAT HAVE BEEN BLESSED BY THE VOTERS. AND WE MIGHT  
18 IDEALLY TRY TO FIT EVERYTHING WITHIN THEM AS LONG AS WE  
19 HAVE ALL THE APPROPRIATE ADVICE AND WE'RE OPERATING  
20 APPROPRIATELY.

21 MR. SHESTACK: THIS IS ALWAYS THE QUESTION.  
22 AS WELL AS THE LEGISLATION WAS WRITTEN, THERE WERE  
23 GOING TO BE SITUATIONS WHERE EMPHASIS WILL CHANGE AND  
24 THINGS LIKE THAT. AND I'VE NEVER QUITE UNDERSTOOD YET  
25 HOW MUCH FREEDOM THE COMMITTEES HAD TO ADD AD HOC

1 MEMBERS TO THEIR COMMITTEE. IT SEEMS LIKE A LOT OF  
2 THINGS ARE FAIRLY RIGIDLY CIRCUMSCRIBED. WE CAN ADD A  
3 WHOLE -- IT'S EASIER TO ADD A WHOLE AD HOC COMMITTEE  
4 THAN TO JUST SAY, OH, LET'S EXPAND THIS COMMITTEE WITH  
5 A COUPLE PEOPLE TO DEAL WITH THIS PROBLEM.

6 CHAIRMAN KESSLER: THAT'S, IN FACT, THE WAY  
7 WE -- COUNSEL IS TELLING US THAT THE REALITY IS IT WILL  
8 BE EASIER, IN FACT, IT IS PERMISSIBLE TO ADD ANOTHER  
9 COMMITTEE. IT'S NOT PERMISSIBLE TO CHANGE THE  
10 COMPOSITION OF THIS COMMITTEE.

11 MR. HARRISON: THAT'S CORRECT.

12 CHAIRMAN KESSLER: THAT'S THE ADVICE OF  
13 COUNSEL.

14 MR. SHESTACK: EVEN IF THE ICOC VOTES ON IT  
15 AND SAYS YOU CAN DO IT, IT CAN'T BE DONE?

16 MR. HARRISON: WELL, YOU COULD CREATE AN AD  
17 HOC TO THE COMMITTEE, TO THE STANDARDS WORKING GROUP  
18 COMMITTEE, AND THEY COULD PRESUMABLY MAKE  
19 RECOMMENDATIONS TO THE STANDARDS WORKING GROUP, BUT THE  
20 MEMBERSHIP, THE VOTING MEMBERSHIP OF THE STANDARDS  
21 WORKING GROUP IS DEFINED BY STATUTE AND CAN'T BE  
22 ALTERED BY THE ICOC. SO YOU CAN DEAL WITH THE ISSUES.

23 MR. SHESTACK: SO WE CAN DEAL WITH THE  
24 ISSUES, BUT I WANTED TO UNDERSTAND THE LOOPS THROUGH  
25 WHICH WE HAVE TO GO.

1                   MR. SHEEHY: IT SEEMED TO ME THAT THE IP  
2                   ISSUE SHOULD BE IN HERE BECAUSE OF NO. 2 UNDER THE  
3                   DESCRIPTION, TO RECOMMEND TO THE ICOC STANDARDS FOR ALL  
4                   MEDICAL, SOCIOECONOMIC, AND FINANCIAL ASPECTS OF  
5                   CLINICAL TRIALS AND THERAPY DELIVERY TO PATIENTS. SO  
6                   THAT SEEMS -- IS IP NOT A FINANCIAL ASPECT?

7                   MR. SHESTACK: IT IS, BUT THERE ARE IP  
8                   CONSIDERATIONS WITH RESEARCH RESULTS PROBABLY  
9                   SIGNIFICANTLY BEFORE THERE WILL BE IP INTERESTS WITH  
10                  CLINICAL TRIAL APPLICATIONS.

11                  MR. SERRANO SEWELL: ON THE QUESTION OF  
12                  WHETHER IP SHOULD BE INCLUDED WITHIN THIS COMMITTEE'S  
13                  CHARGE, AND THIS IS SOMETHING YOU SAID EARLIER, DAVID,  
14                  AND THAT IS IF YOU LOOK AT THE COMPOSITION AS  
15                  PRESCRIBED BY STATUTE, YOU HAVE THE NATIONALLY  
16                  RECOGNIZED RESEARCHERS, THE PATIENT ADVOCATES, AND THE  
17                  PATIENT ADVOCATES ARE ON ALL THE WORKING GROUPS, AND  
18                  FOUR MEDICAL ETHICISTS. AND WE HAVE HERE A SUGGESTED  
19                  DEFINITION OF MEDICAL ETHICIST.

20                  IT SEEMS TO CUT -- FOR ME ARGUE MORE TOWARDS  
21                  KEEPING IT WITHIN THAT WORLD, AND THAT IP CAN SOMETIME  
22                  IN THE FUTURE BE BROUGHT INTO THE COMMITTEE'S CHARGE.  
23                  BUT IF CHAIRMAN KLEIN IS THINKING ABOUT, AND I THINK  
24                  IT'S WISE TO DO SO, HAVING A SPECIAL AD HOC COMMITTEE  
25                  TO TAKE SOME ACTION AT OUR FULL MEETING ON THURSDAY,



1 THE IDEA BEING THE MEMBERSHIPS THAT -- WORKING GROUP  
2 COMMITTEE MEMBERS THAT ARE WORKING FOR THIS WORKING  
3 GROUP MAY NOT FALL WITHIN THAT AREA OF EXPERTISE, THAT  
4 IT'S APPROPRIATE TO HAVE THIS IP TASK FORCE IN PLAY.  
5 AND WHETHER WE FOLD IT INTO -- MAYBE WE SHOULD TALK  
6 ABOUT FOLDING IT INTO THIS WORKING GROUP HAS AN AD HOC  
7 COMMITTEE.

8 MR. SHESTACK: WHEN THE MEDICAL ETHICISTS ARE  
9 NOMINATED, DON'T STRETCH TO FIND THE PEOPLE WHO HAVE  
10 EXPERTISE. CONCENTRATE ON PEOPLE WHO HAVE EXPERTISE IN  
11 WHAT THE IMMEDIATE CHARGE HERE IS YOUR SUGGESTION.

12 MR. SHEEHY: I WOULD MAKE THE POINT THAT, AT  
13 LEAST WHEN I WAS AT THE WORKSHOPS THAT WERE HELD IN  
14 IRVINE, BERNIE LO, MEDICAL ETHICIST, VERY ELOQUENT  
15 ABOUT IP ISSUES AND PUBLIC BENEFIT THAT SHOULD DRIVE.  
16 IT'S NOT LIKE THE MEDICAL ETHICISTS DON'T CONSIDER  
17 THAT. IT ALMOST FEELS AS THOUGH A MEDICAL ETHICIST  
18 MIGHT BE MORE APPROPRIATE THAN AN ATTORNEY IN SOME  
19 FASHION FOR OUR CHARGE FROM THE VOTERS.

20 MR. SHESTACK: THIS GOES TO WHAT JOAN WAS  
21 SAYING ABOUT STRATEGIC PLANNING BECAUSE SOME OF THESE  
22 BASIC ISSUES LIKE IS THIS GROUP GOING TO DECIDE TO TRY  
23 AND DO SOMETHING DIFFERENTLY THAN BAYH-DOLE STANDARDS.  
24 EVEN IN THE LITTLEST WAY, IT'S AN IMPORTANT DECISION  
25 FOR THE ICOC. IS IT A STRATEGIC PLANNING DECISION? IS

1 IT A STANDARDS DECISION? WHAT DOES IT FALL UNDER? I  
2 DON'T KNOW THE ANSWER.

3 CHAIRMAN KESSLER: WHY DON'T WE ASK AT THIS  
4 POINT, EVEN THOUGH WE HAVEN'T REACHED A CONSENSUS HERE,  
5 WHY DON'T WE ASK FOR PUBLIC COMMENT ON THIS QUESTION  
6 ABOUT WHETHER, IN FACT, INTELLECTUAL PROPERTY ISSUES  
7 SHOULD FALL UNDER THIS COMMITTEE OR WHETHER THERE  
8 SHOULD BE SOME OTHER WAY TO HANDLE THIS, A SEPARATE  
9 GROUP THAT IS PUT TOGETHER. IF YOU CAN JUST STATE YOUR  
10 NAME FOR THE REPORTER, WE WOULD VERY MUCH APPRECIATE  
11 IT.

12 MR. BROWN: PATRICK BROWN. THE POINT I  
13 WANTED TO RAISE IS THAT IT SEEMS TO ME THAT  
14 INTELLECTUAL PROPERTY AS IT RELATES TO THIS ISSUE IS  
15 THERE ARE LEGAL ASPECTS TO IT, BUT I WOULDN'T CONSIDER  
16 IT TO BE PRIMARILY AN ISSUE FOR THE LAWYERS TO DEAL  
17 WITH. IT IS CRITICALLY IMPORTANT THE DECISIONS THAT  
18 ARE MADE WITH RESPECT TO INTELLECTUAL PROPERTY ARE  
19 CRITICALLY IMPORTANT TO PROMOTING THE SCIENTIFIC  
20 RESEARCH, PROMOTING THE PATIENTS' INTEREST, AND THE  
21 PUBLIC INTEREST, AND SO FORTH. AND, SURE, IT WOULD BE  
22 NICE TO HAVE LAWYERS ON THE SIDE TO CONSULT ON THE  
23 LEGAL ISSUES, BUT FROM THE STANDPOINT OF THE PUBLIC  
24 INTEREST AND THE INTERESTS OF THE SCIENTIFIC COMMUNITY  
25 AND THE PATIENTS, I THINK THAT THOSE ARE THE

1       CONSTITUENCIES THAT NEED TO BE PRIMARILY REPRESENTED IN  
2       MAKING DECISIONS ABOUT IP ISSUES.

3                   MR. VOELKER:   MY NAME IS MARK VOELKER.   IT  
4       LOOKS LIKE THIS COMMITTEE, ACCORDING TO THE STATUTE,  
5       REALLY WASN'T CHARGED WITH DEALING WITH ISSUES OF  
6       PATENTS AND INTELLECTUAL PROPERTY, MORE OUT OF  
7       STRUCTURE OF THE RULES REGARDING PATIENT RIGHTS AND HOW  
8       TO CONDUCT CLINICAL TRIALS AND THINGS LIKE THAT.   BUT I  
9       DO THINK THAT THE IP ISSUES DO NEED TO BE ADDRESSED, SO  
10      IT SEEMS TO ME THAT THERE SHOULD BE A SEPARATE  
11      COMMITTEE THAT WOULD BE CONSTITUTED SPECIFICALLY TO  
12      DEAL WITH ISSUES OF PATENTS AND INTELLECTUAL PROPERTY,  
13      HAVE SOME PATENT ATTORNEYS INVOLVED, SOME ECONOMISTS,  
14      MEDICAL ECONOMISTS, AND REALLY HAVE EXPERTS IN THAT  
15      PARTICULAR FIELD ADDRESS THOSE ISSUES SO THEY WILL GET  
16      ADDRESSED PROPERLY.

17                   MS. DARNOVSKY:   MARCY DARNOVSKY.   I WANTED TO  
18      SECOND WHAT THE FIRST SPEAKER SAID ABOUT THE IMPORTANCE  
19      TO THE PUBLIC INTEREST, AS WELL AS TO SCIENTIFIC  
20      ADVANCE REALLY, THAT THE INTELLECTUAL PROPERTY ISSUES  
21      BE DEALT WITH BY A GROUP THAT HAS ETHICAL EXPERTISE.  
22      SO HOWEVER IT WORKS STRUCTURALLY IN TERMS OF THE ENTIRE  
23      ICOC, EVEN IF THERE'S ANOTHER COMMITTEE ADDRESSING IP  
24      ISSUES, IT WOULD BE VERY IMPORTANT FOR THIS COMMITTEE  
25      TO HAVE A STRONG INTERCONNECTION AND COMMUNICATION WITH

1 THOSE CONVERSATIONS AND BRINGING THE ETHICAL ISSUES TO  
2 BEAR ON THEM.

3 CHAIRMAN KESSLER: ANY OTHER COMMENTS FROM  
4 THE PUBLIC?

5 MR. REED: DON REED. IT SEEMS TO ME THAT  
6 THIS IS SUCH A HUGE ISSUE, THAT THIS SHOULD BE  
7 SOMETHING THAT THE ICOC AS A WHOLE SHOULD DECIDE.  
8 EVERYBODY HAS GOOD POINTS TO MAKE, BUT THIS IS TOO BIG.  
9 MY SMALL READING OF THE STATUTE, I TAKE THE FINANCIAL  
10 INTEREST TO BE THE FINANCIAL INTEREST OF THE PATIENTS,  
11 BUT THAT COULD BE COMPLETELY WRONG. I THINK THIS IS AN  
12 ICOC MATTER.

13 CHAIRMAN KESSLER: I THINK THAT ANY  
14 RECOMMENDATION MADE BY ANY WORKING GROUP OR, IN FACT,  
15 IN AN AD HOC GROUP, IF THAT'S THE RIGHT TERMINOLOGY,  
16 WOULD HAVE TO IN THE END BE VALIDATED BY THE ICOC TO  
17 HAVE ANY FORCE OF STATUTE.

18 I DON'T KNOW IF THERE WAS ANY OTHER IN THE  
19 FIRST ROW. SIR.

20 MR. GANCHOFF: MY NAME IS CHRIS GANCHOFF.  
21 I'M A GRADUATE STUDENT IN SOCIOLOGY HERE AT UCSF. THE  
22 COMMENT I JUST WANTED TO ADD WAS THIS MAY BE A LITTLE  
23 BIT OUT OF PLACE HERE. I THINK THE -- I WOULD URGE THE  
24 SUBCOMMITTEE TO EXPAND THE DEFINITION OR REQUIREMENTS  
25 OF THE CATEGORY OF MEDICAL ETHICIST BECAUSE THERE ARE

1 MANY PEOPLE WHO ARE NOT FORMALLY TRAINED IN, SAY,  
2 BIOETHICS, WHICH TRADITIONALLY COMES OUT MORE  
3 PHILOSOPHY, SO IT TENDS TO BE PHILOSOPHERS WHO ARE  
4 TALKING ABOUT THESE ISSUES.

5 I'D LIKE TO URGE THE SUBCOMMITTEE TO TAKE  
6 SERIOUSLY THAT THERE ARE MANY SOCIAL SCIENTISTS,  
7 SOCIOLOGISTS, ANTHROPOLOGISTS, AND OTHER PEOPLE IN THE  
8 HUMANITIES, HISTORIANS, PEOPLE WHO WORK IN MEDICAL  
9 HUMANITIES WHO WILL GET HISTORICAL ASPECTS OF PATENTING  
10 AND IP AS WELL AS KIND OF CURRENT SOCIAL DEBATES THAT  
11 DON'T FALL UNDER THIS CATEGORY THAT WE BROADLY CALLED  
12 BIOETHICS.

13 SO I URGE THE COMMITTEE TO THAT TAKE UNDER  
14 CONSIDERATION. AND I THINK IF YOU DO THAT, THAT DOES  
15 BRING QUESTIONS OF INTELLECTUAL PROPERTY UNDER THE  
16 PURVIEW OF THIS WORKING GROUP, THINKING ABOUT, AGAIN,  
17 NOT JUST FINANCIAL BOTTOM LINE INSTRUMENTAL CONCERNS  
18 ABOUT INTELLECTUAL PROPERTY, BUT BROADER SOCIAL  
19 CONCERNS ABOUT THE OWNERSHIP OF HUMAN BIOLOGICAL PARTS.

20 CHAIRMAN KESSLER: THANK YOU. JUST FOR THE  
21 PURPOSE OF EDUCATING US ALL, LET ME JUST ASK COUNSEL TO  
22 HELP US. AS I UNDERSTAND THE DEFINITION, IT'S DEFINED  
23 BY STATUTE. SO WE CAN INTERPRET THE STATUTE, BUT WE  
24 CAN'T WRITE THE STATUTE. AND AT LEAST WE DON'T HAVE  
25 THAT PREROGATIVE TO DO THAT. AND SO WE HAVE TO BE TRUE

1 TO THOSE WORDS. WE CAN INTERPRET THOSE WORDS.

2 AND SO IT'S TALK ABOUT A PH.D., A MASTER'S,  
3 OTHER EQUIVALENT TRAINING WHO SPENDS OR HAS SPENT  
4 SUBSTANTIAL TIME BOTH -- BOTH IS MY ADDING, BUT IT'S AN  
5 ADD -- RESEARCHING AND WRITING ON ETHICAL ISSUES.  
6 DOESN'T SAY BIOETHICS. IT SAYS ETHICAL ISSUES RELATED  
7 TO MEDICINE. THAT'S THE ACTUAL --

8 MR. SHESTACK: IT'S PRETTY BROAD.

9 CHAIRMAN KESSLER: SO IT'S ETHICAL. AND THIS  
10 IS -- AGAIN, YOU HAVE BOTH IF I'M INTERPRETING THIS  
11 RIGHT, COUNSEL -- ADMINISTERING ETHICAL STANDARDS  
12 DURING THE CLINICAL TRIAL PROCESS, PARTICULARLY THROUGH  
13 SERVICE ON INSTITUTIONAL REVIEW BOARDS. SO YOU HAVE TO  
14 HAVE SOME, I ASSUME, REAL LIFE DEALING WITH ETHICAL  
15 ISSUES RELATING TO CLINICAL TRIALS IN ADDITION.

16 IS THAT -- DID I SPEAK CORRECTLY, COUNSEL?

17 MR. HARRISON: YOU DID. THAT'S A CORRECT  
18 READING OF THE DEFINITION.

19 CHAIRMAN KESSLER: SO JUST LET ME ASK YOU  
20 SOME HYPOTHETICALS. IF I'M A SOCIOLOGIST AND I HAVE  
21 WRITTEN IN ETHICAL AREAS, BUT I'VE HAD NO ROLE IN  
22 ADMINISTERING OR BEING PART OF ETHICAL STANDARDS  
23 REGARDING TO CLINICAL TRIALS, THE CLINICAL TRIAL  
24 PROCESS, I WOULD NOT QUALIFY UNDER THIS?

25 MR. HARRISON: YOU WOULD NOT MEET THE

1 CRITERIA AS SET FORTH IN THE DEFINITION. SO -- WELL --

2 DR. SAMUELSON: THAT'S AN IMPORTANT  
3 DISTINCTION BECAUSE THERE COULD BE ETHICISTS WHO  
4 QUALIFY UNDER THE FIRST SUBPART WHO HAVE BEEN VERY BUSY  
5 IN REVIEWING, INTERACTING WITH THE ETHICS OF BIOMEDICAL  
6 BASIC RESEARCH, WHICH IS WHERE THE ISSUES ARE RAISED  
7 PRIMARILY.

8 MR. SHESTACK: THERE ARE MANY ISSUES OTHER  
9 THAN THE ISSUES CONCERNING CLINICAL TRIALS. SORT OF  
10 THAT WILL NATURALLY COME UP SORT OF IN THE PROCESS OF  
11 EVER GETTING TO CLINICAL TRIALS.

12 DR. STEWARD: BUT IF BY STATUTE WE'RE LIMITED  
13 TO PEOPLE WHO ESSENTIALLY HAVE SERVED ON IRB'S, THEN  
14 THAT'S WHAT WE'RE LIMITED TO. BASICALLY --

15 CHAIRMAN KESSLER: IT SAYS PARTICULARLY  
16 THROUGH SERVICE. I DON'T READ THAT AS MEANING ONLY  
17 THROUGH SERVICE.

18 MR. HARRISON: NO. YOU WOULDN'T NEED TO ONLY  
19 HAVE HAD EXPERIENCE WITH IRB, BUT THE DEFINITION DOES  
20 HAVE TWO PRONGS, AS YOU POINT OUT.

21 DR. STEWARD: SO THE ADMINISTRATION PART OF  
22 THINGS REQUIRES SOME PARTICIPATION IN CLINICAL TRIAL  
23 PROCESS BY STATUTE, NOT RESEARCH, BUT CLINICAL TRIAL.  
24 THAT'S A DIFFERENT READING, I THINK.

25 CHAIRMAN KESSLER: WHEN I LOOK AT THE MAKEUP

1 OF THIS WITHIN THE CONSTRAINTS THAT WE ARE OBLIGATED TO  
2 FOLLOW, THIS SEEMED TO ME, THIS COMMITTEE, WAS IN SOME  
3 WAYS ANALOGOUS TO MY OLD LIFE AT FDA. THIS WAS A  
4 SCIENCE/CLINICAL COMMITTEE. AND IT WOULD BE SCIENTIFIC  
5 AND CLINICAL STANDARDS AND POLICIES, SAFETY ISSUES,  
6 ETHICAL ISSUES. THAT WAS REALLY WHAT THE PEOPLE HERE  
7 ARE, THE ETHICISTS, WOULD BE GUIDED TOWARD.

8 I CERTAINLY -- MY OWN VIEW, I THINK ALL THE  
9 COMMENTS FROM THE PUBLIC MAKE A LOT OF SENSE. ON THE  
10 INTELLECTUAL PROPERTY, YOU WANT PEOPLE WHO CARE ABOUT  
11 THE PUBLIC INTEREST. YOU CERTAINLY WOULD WANT  
12 ETHICISTS. YOU WOULD WANT PEOPLE WHO HAVE EXPERTISE IN  
13 BAYH-DOLE, WHO HAD PERHAPS ECONOMIC, UNDERSTAND  
14 INCENTIVES. SO YOU WOULD WANT A BROAD HOST OF PEOPLE.

15 WE DON'T HAVE TO DECIDE THE ISSUE TODAY.

16 MR. SHESTACK: DISCUSSION JUST INFORMS US AS  
17 WE START THIS NOMINATION PROCESS.

18 CHAIRMAN KESSLER: ABSOLUTELY. AND IF WE  
19 HAVE A RECOMMENDATION, IF THE SUBCOMMITTEE HAS A  
20 RECOMMENDATION AS WE GO TO THURSDAY'S MEETING, AND IF  
21 WE ARE SOME MINDS AND THE POINTS, WE THINK WE'D LIKE TO  
22 BE ABLE TO HAVE THE ICOC HEAR WITH REGARD TO POINT 14,  
23 YOU KNOW, PLEASE IF YOU ARE INTERESTED IN PUTTING THOSE  
24 FORWARD.

25 DR. STEWARD: LET ME MAKE A RECOMMENDATION.



1 AND THAT IS THAT WE DO NOT GET INTO IP ISSUES UNLESS WE  
2 ARE SPECIFICALLY CHARGED TO, AND THAT WE ASSUME THAT  
3 OUR SEARCH IS FOR PEOPLE WHO WILL BE DEALING WITH THE  
4 SORT OF TRADITIONAL MEDICAL-ETHICAL, CONFLICT OF  
5 INTEREST ISSUES THAT ARE GOING TO BE MORE THAN ENOUGH  
6 ON THEIR PLATE FOR THE NEXT YEAR.

7 CHAIRMAN KESSLER: HOW WOULD YOU RECOMMEND  
8 DEALING WITH THE IP ISSUES?

9 DR. STEWARD: WELL, IT SEEMS TO ME THAT, I  
10 THINK DON'S POINT ACTUALLY, DON REED'S POINT IS EXACTLY  
11 RIGHT. THE ICOC ITSELF IS CONSTRUCTED WITH, I THINK,  
12 THE APPROPRIATE REPRESENTATION, INCLUDING MEMBERS OF  
13 THE INTEREST GROUPS, LAWYERS. I THINK THAT, IN FACT,  
14 IT IS THE ICOC THAT IS BEST SUITED, NOT ONLY TO MAKE  
15 THE FINAL DECISION, BUT ACTUALLY TO DISCUSS THE ISSUES  
16 OF IP.

17 CHAIRMAN KESSLER: NOW, YOU DO HAVE FIVE  
18 MEMBERS OF THE ICOC WHO SERVE ON THIS WORKING GROUP.  
19 SO IF YOU WANTED -- OUR PLAN WAS TO ASK ON THURSDAY WHO  
20 WOULD BE INTERESTED. SO IF THIS IS GOING TO DO IP OR  
21 NOT IP, IT MAKES A DIFFERENCE WHO THOSE FIVE PEOPLE WHO  
22 MIGHT BE ON THERE. SO YOUR INCLINATION IS NOT TO HAVE  
23 THIS GROUP DO THAT.

24 SHOULD WE JUST GO AROUND AND ASK WHAT  
25 EVERYONE'S ELSE INCLINATION IS AND SEE IF THERE'S A

1        CONSENSUS?

2                    MR. SHESTACK:  MY INCLINATION WOULD BE THAT  
3        IT'S TOO COMPLICATED FOR THE ICOC TO ACTUALLY DO IN  
4        ICOC MEETINGS.  THEY'RE LIKE IMPOSSIBLE.  I WOULD  
5        SUGGEST THAT WE'LL HAVE TO SET UP AN AD HOC GROUP.  I  
6        THINK THAT IT MIGHT BE A NATURAL PLACE ULTIMATELY FOR  
7        THAT AD HOC GROUP MIGHT BE TO BE A SUBCOMMITTEE OF THIS  
8        COMMITTEE OR OF A STRATEGIC PLANNING COMMITTEE, IF  
9        THERE WAS ONE, BECAUSE THERE ARE ALSO A LOT OF ISSUES  
10       THAT HAVE TO DO WITH WHAT EXPECTATIONS ARE FOR THE  
11       CITIZENS OF CALIFORNIA AND FINANCIAL RETURN, IF THERE  
12       IS ANY.  I THINK THAT HAVING IT BE SIMPLY A STANDALONE  
13       SUBCOMMITTEE MIGHT NOT BE AS GOOD AS HAVING IT REPORT  
14       TO ANOTHER.  BUT THIS COMMITTEE ITSELF, I THINK, WE'LL  
15       HAVE ENOUGH -- IT WILL BE HARD ENOUGH TO FIND THE RIGHT  
16       FOUR PEOPLE WHO CAN COVER ALL THE AREAS AND HAVE  
17       CLINICAL TRIAL EXPERIENCE WITHOUT ALSO LOOKING FOR  
18       PEOPLE WHO RIGHT NOW HAVE REAL EXPERTISE IN SOME OF THE  
19       IP ISSUES.

20                   CHAIRMAN KESSLER:  LISTENING TO JON, IN YOUR  
21        RECOMMENDATION, THAT IT NOT BE THIS COMMITTEE, THAT  
22        THERE BE A SEPARATE -- NOT SEPARATE, THERE WOULD BE A  
23        GROUP THAT WOULD BE ABLE TO HANDLE THE IP ISSUES, BUT  
24        THERE'D BE SOME KIND OF LINKAGE TO EITHER THIS  
25        COMMITTEE OR TO ANOTHER APPROPRIATE BODY.  ARE YOU

1 WILLING TO INCORPORATE THAT INTO YOUR --

2 DR. STEWARD: ABSOLUTELY. I THINK I WOULD  
3 SAY WHAT WE NEED TO THINK ABOUT IS HOW WE SEARCH. DO  
4 WE SEARCH FOR PEOPLE WITH EXPERTISE IN IP, OR DO WE  
5 SEARCH FOR PEOPLE WITH EXPERTISE IN MEDICAL ETHICS,  
6 CONFLICT OF INTEREST.

7 MR. SHESTACK: I WOULD AGREE WITH OS ON THAT.  
8 FOR THIS, THAT WE HAVE -- THAT THE CHARGE FOR THESE  
9 FOUR ETHICISTS IS, FOR ME, I WOULD SAY WOULD BE THE  
10 MORE NARROW SCOPE. IF THEY HAVE THE OTHER, THAT'S  
11 GOOD, BUT I WANT TO MAKE SURE THAT WE GET THAT, AND WE  
12 ALL KNOW THAT WE HAVE TO DO SOMETHING ABOUT IP AND WE  
13 HAVE TO DO IT WELL.

14 CHAIRMAN KESSLER: OTHER MEMBERS, YOUR VIEWS.

15 DR. SAMUELSON: I'M COMING AT IT A LITTLE  
16 DIFFERENTLY. I START WITH THE TITLE OF THE GROUP.  
17 IT'S THE SCIENTIFIC AND MEDICAL ACCOUNTABILITY  
18 STANDARDS WORKING GROUP. AND I GUESS I WOULD LIKE  
19 THERE TO BE A HOME AMONG ONE OF THE THREE WORKING  
20 GROUPS, SINCE THEY WERE BLESSED BY THE STATUTE, FOR ALL  
21 OF THE WEIGHTY ISSUES, ESSENTIALLY, THE BIG ISSUES THAT  
22 WE HAVE IN FRONT OF US AND START THERE AND SEE IF  
23 THERE'S SOME WAY WE CAN DEVELOP THE EXPERTISE AROUND  
24 US.

25 SO I THINK MY INCLINATION IS THAT, IF WE CAN,

1 WE TRY TO FIND A HOME IN ONE OF THEM, AND I THINK THIS  
2 IS THE STANDARDS WORKING GROUP, SO THIS IS THE PLACE  
3 THAT THE STANDARDS THAT WE'RE GOING TO OPERATE UNDER  
4 AND THAT INFORM ALL OF OUR DECISION-MAKING SHOULD BE  
5 DEVELOPED WITH WHATEVER EXPERTISE WE NEED BEYOND.

6 CHAIRMAN KESSLER: SO YOU WOULD LIKE TO SEE  
7 THE INTELLECTUAL PROPERTY ISSUES GRAPPLED WITH BY THIS  
8 WORKING GROUP?

9 DR. SAMUELSON: YEAH. AND TO START WITH WHAT  
10 ARE ALL THE STANDARDS THAT WE HAVE IN FRONT OF US UNDER  
11 THIS DEFINITION. I GUESS I'M WONDERING WHAT SCIENTIFIC  
12 AND MEDICAL ACCOUNTABILITY STANDARDS MEAN. DO WE KNOW?  
13 IT'S NOT SO SPECIFIC AS TO JUST SOME OF THE ETHICS THAT  
14 ARE CLINICAL.

15 CHAIRMAN KESSLER: THERE ARE FIVE ELEMENTS  
16 THAT ARE SPECIFICALLY SPELLED OUT FOR THE FUNCTION. IT  
17 SHALL HAVE THE FOLLOWING FUNCTIONS. I WON'T READ THEM  
18 ALL, BUT THE FIRST ONE IS SCIENTIFIC, MEDICAL, AND  
19 ETHICAL STANDARDS.

20 DR. SAMUELSON: RIGHT.

21 MR. SHESTACK: THAT'S PRETTY BROAD AND NOT  
22 NECESSARILY FOR CLINICAL TRIALS.

23 DR. SAMUELSON: RIGHT.

24 CHAIRMAN KESSLER: ONLY THE DEFINITION OF  
25 MEDICAL ETHICIST USES THE WORD "CLINICAL TRIAL

1       PROCESS."  SO WE'RE NOT OF ONE MIND HERE AT THIS POINT.

2                   MR. SHESTACK:  WHAT'S YOUR THOUGHT?  WHAT DO  
3       YOU THINK WOULD BE APPROPRIATE?

4                   CHAIRMAN KESSLER:  YOU KNOW, IT'S  
5       INTERESTING.  I ACTUALLY THINK, YOU KNOW, I WOULD HAVE  
6       EXPERTISE IN SCIENTIFIC AND MEDICAL ACCOUNTABILITY  
7       ISSUES.  I SEE THOSE AS SORT OF THE REGULATORY ETHICAL,  
8       HOW ONE DOES SCIENCE, WHAT KIND OF PRECLINICAL  
9       REQUIREMENTS DO YOU INTRODUCE CERTAIN CELLS INTO  
10      HUMANS?  WHAT ARE THE ETHICAL REQUIREMENTS?  THAT'S THE  
11      WORLD THAT I THINK IS A VERY IMPORTANT WORLD.  AND I  
12      COME FROM A LITTLE PURIST WORLD WHERE I'D LIKE TO KEEP  
13      SOME OF THE ECONOMIC ISSUES, LEGAL ISSUES EVEN SEPARATE  
14      FROM SOME OF THE -- LET THE SCIENCE RULE.  AND LET'S  
15      FIND THE PEOPLE WHO REALLY UNDERSTAND THE CLINICAL AND  
16      ETHICAL GUIDELINES.

17                   AND THERE'S A BROADER PUBLIC POLICY QUESTION  
18      IN INTELLECTUAL PROPERTY.  I AGREE WITH EVERYONE THAT  
19      IT NEEDS -- I CERTAINLY WOULDN'T -- I THINK I WOULD  
20      HAVE EXPERTISE ON THE SCIENTIFIC AND CLINICAL ASPECTS,  
21      BUT I WOULDN'T HAVE EXPERTISE NECESSARILY ON THE  
22      INTELLECTUAL PROPERTY.

23                   I DON'T HAVE THE EXPERTISE, NOT THAT EVERYONE  
24      HAS TO HAVE IT, ON BAYH-DOLE AND UNDERSTANDING THE  
25      ECONOMICS AND UNDERSTANDING HISTORY.  I MEAN THERE ARE

1 REAL EXPERTS THAT I WOULD WANT TO BENEFIT FROM, BUT MY  
2 VIEW IS, AGAIN, I DON'T WANT TO LEAD IN ANY ONE  
3 DIRECTION.

4 JEFF, DO YOU HAVE ANY THOUGHTS ON THIS?

5 MR. SHEEHY: YOU KNOW, FIRST OF ALL, I THINK  
6 THAT ETHICAL ISSUES ARE RELATED TO THE IP ISSUES IN THE  
7 SAME WAY THAT THE ECONOMIC ISSUES OF ORGAN DONATION ARE  
8 RELATED TO THE ETHICAL ISSUES OF ORGAN DONATION. I SEE  
9 DONATIONS FOR THIS BEING SIMILAR TO ORGAN DONATION.

10 I THINK WHAT I WOULD THINK WOULD BE A GOOD  
11 IDEA WOULD BE A SET UP AN AD HOC COMMITTEE THAT FOLLOWS  
12 BAGLEY-KEENE. I THINK ETHICISTS SHOULD BE INVOLVED, BY  
13 THE WAY. I THINK THE ETHICISTS ON THIS COMMITTEE THAT  
14 WE SELECT SHOULD BE PART OF THE PROCESS BECAUSE THESE  
15 ARE ETHICAL ISSUES THAT WE'RE TALKING ABOUT. THE  
16 PUBLIC BENEFIT, BECAUSE THIS IS ALL PUBLICLY FINANCED,  
17 THIS IS \$3 BILLION OF PUBLIC MONEY, THAT WE OUGHT TO  
18 LOOK AT IT FROM THE BROADEST ETHICAL POINT OF VIEW. WE  
19 SHOULD BE INNOVATIVE.

20 I'M SCARED IF WE GO TO THE ECONOMISTS AND THE  
21 LAWYERS, WE'RE GOING TO GET THE SAME OLD. THERE'S OPEN  
22 SOURCE ISSUES. THERE'S VERY INTERESTING IDEAS GOING  
23 AROUND ABOUT COMPULSORY LICENSING THAT I THINK ARE  
24 GOING TO BE ELEMENTS THAT WE NEED TO INVOLVE IN THIS.  
25 AND, YOU KNOW, THE LAWYERS AND THE ECONOMISTS WILL SAY

1 THIS IS HOW WE DO IT. BAYH-DOLE IS THAT OLD MODEL. IF  
2 WE COULD HAVE A COMMITTEE OF LAWYERS, ECONOMISTS,  
3 ETHICISTS, REALLY A BROADBASED COMMITTEE THAT REPORTS  
4 TO THIS -- I DO THINK IT BELONGS UNDER THE SCIENTIFIC  
5 AND MEDICAL ACCOUNTABILITY STANDARD WORKING GROUP THAT  
6 REPORTS BACK TO THIS WORKING GROUP AND THAT OPERATES  
7 UNDER BAGLEY-KEENE, SO THAT WE GET -- THIS IS A BIG  
8 ISSUE TO THE PEOPLE OF CALIFORNIA. THAT WOULD BE MY  
9 RECOMMENDATION THAT WE MAKE TO THE ICOC. IT WILL COME  
10 BACK TO THE STANDARDS GROUP, AND THEN, YOU KNOW, THAT  
11 WAY IT COULD BE LOOKED AT BY PEOPLE IN THE FIELD,  
12 ACTUAL SCIENTISTS IN THE RESEARCH FIELD, WHO ARE PART  
13 OF THIS COMMITTEE, AND BE LOOKED AT BY THE FIVE  
14 ADVOCATES AND LOOKED AT BY THE FOUR ETHICISTS, AND THEN  
15 BACK TO THE ICOC FOR FINAL ADOPTION.

16 BUT I DO THINK WE NEED A SEPARATE COMMITTEE,  
17 BUT SHOULDN'T BE THAT COMMITTEE TO THE ICOC. I THINK  
18 ONE MORE COOKING MIGHT NOT BE BAD. I THINK HAVING IT  
19 BE UNDER BAGLEY-KEENE IS AN IMPORTANT ELEMENT.

20 MR. SERRANO SEWELL: MY FINAL THOUGHTS ARE,  
21 I'VE GIVEN IT SOME THOUGHT AND CONSIDERATION, AND I'D  
22 HAVE TO SAY THAT WHILE THE LANGUAGE FOR THIS WORKING  
23 GROUP IS, I DON'T THINK IT'S THAT VAGUE, BUT YOU COULD  
24 ARGUE ANYTHING. I THINK ANYONE CAN MAKE A REASONABLE  
25 ARGUMENT. BUT IT DOES PROVIDE SOME GUIDANCE AS TO WHAT

1 THIS WORKING GROUP SHOULD DO THROUGH THE DEFINITION OF  
2 MEDICAL ETHICIST, THROUGH SOME OTHER DEFINITIONS HERE  
3 ABOUT WHAT THIS WORKING GROUP SHOULD DO BA BOOM, BA  
4 BOOM.

5 AND THAT BEING SAID, BECAUSE WE'RE GOING TO  
6 HAVE TO GO THROUGH A LOT OF RESUMES, A LOT OF QUALIFIED  
7 INDIVIDUALS WILL SERVE WELL ON THIS WORKING GROUP,  
8 BOTH, AND THE RESEARCHERS AND THE ETHICISTS. AND  
9 WHATEVER WE CAN DO TO HONE THAT SEARCH PROCESS DOWN, I  
10 THINK WOULD MAKE ALL OF OUR LIVES A LITTLE BIT EASIER.

11 JEFF'S POINT IS VERY IMPORTANT. FOR  
12 THURSDAY'S DISCUSSION, SOMETHING SHOULD BE EMPHASIZED  
13 WHEN THIS IP AD HOC COMMITTEE IS SET UP FOR THURSDAY.  
14 WE SHOULD HAVE --

15 CHAIRMAN KESSLER: DISCUSSED.

16 MR. SERRANO SEWELL: DISCUSSED. IN THAT  
17 DISCUSSION, WE SHOULD RAISE SOME OF THE ISSUES THAT  
18 WE'VE DISCUSSED TODAY; NAMELY, THE ETHICAL COMPONENT,  
19 WHETHER IT SHOULD BE ULTIMATELY FOLDED IN OR NOT. BUT  
20 AS FAR AS PROCEEDING HENCEFORTH, WE SHOULD RELY ON THE  
21 DEFINITIONS WITHIN THE STATUTE AND LET THAT GUIDE --  
22 LET THAT GUIDE US BECAUSE I DO THINK WHEN IT WAS  
23 DRAFTED, THAT WAS THE INTENTION OF THE PARTIES.

24 CHAIRMAN KESSLER: LET'S SEE IF WE CAN  
25 SEPARATE SOME OF THIS. LET'S SEE IF WE CAN SEE WHAT WE



1 AGREE ON AND MAKE THE DISCUSSION ON THURSDAY A LITTLE  
2 EASIER. MY SENSE IS, WHAT I'M HEARING, IS WHICHEVER  
3 GROUP HANDLES INTELLECTUAL PROPERTY, IT IS ESSENTIAL  
4 THAT THAT GROUP BE BROADLY BASED AND COMPOSED OF PEOPLE  
5 WHO HAVE SOME ETHICAL TRAINING, HAVE PUBLIC INTEREST,  
6 ADVOCACY.

7 MR. SHESTACK: AS WELL AS LEGAL EXPERTISE AND  
8 SOME HEALTH ECONOMIC EXPERTISE.

9 CHAIRMAN KESSLER: ARE THERE OTHER AREAS?  
10 LEGAL, ECONOMIC, PUBLIC ADVOCACY, ETHICAL, AS WELL AS  
11 ANY DIRECT INTELLECTUAL PROPERTY EXPERTISE?

12 MR. SHESTACK: OBVIOUSLY. OBVIOUSLY THAT  
13 WOULD BE THE LEGAL EXPERTISE.

14 CHAIRMAN KESSLER: I JUST WANT TO SEE WHETHER  
15 WE CAN AGREE TO MAKE SURE, FIRST OF ALL, WHATEVER  
16 GROUP, THAT WE WANT IT BROADLY BASED.

17 DR. SAMUELSON: CERTAINLY IN TERMS OF THE  
18 INPUT WE'RE GETTING, I THINK I'M BACK A STEP. BECAUSE  
19 IT SEEMS TO ME THAT THERE ARE POINTS AT WHICH WE'RE  
20 GOING TO BE MAKING DECISIONS OR MAKING RECOMMENDATIONS,  
21 AND WE'RE NOT GOING TO NECESSARILY HAVE WITHIN US AS A  
22 GROUP ALL OF THE EXPERTISE THAT WE'RE BRINGING TO BEAR  
23 ON IT. BUT WE'RE CHARGED WITH USING OUR JUDGMENT AND  
24 OUR EXPERIENCE AND THE REASONS THAT WE WERE APPOINTED  
25 TO THIS BODY TO MAKE SURE THAT WE HAVE THAT ADVICE.

1 RIGHT.

2 AND WE DON'T NECESSARILY NEED A PATENT LAWYER  
3 WITH ALL OF THE EXPERTISE ON IP THAT PERTAINS TO THIS  
4 IN WHATEVER GROUP IS IN THE WORKING GROUP, FOR EXAMPLE,  
5 IF WE WERE TO DO IT. BUT WE WOULD WANT TO MAKE SURE  
6 THAT WE HAD ALL OF THAT ADVICE AVAILABLE TO US.

7 CHAIRMAN KESSLER: I GUESS THE QUESTION IS DO  
8 WE HAVE AN AGREEMENT ON JUST THE BREADTH OF WHAT WE  
9 WANT, TYPES OF INDIVIDUALS THAT SHOULD BE DEALING WITH  
10 INTELLECTUAL PROPERTY, LEAVE ASIDE WHERE THEY SIT? DO  
11 WE NEED A VOTE ON THAT? THAT COULD JUST BE A COMMENT  
12 THAT WE MAKE ON THURSDAY.

13 MR. SHESTACK: SENSE OF THE COMMITTEE.

14 CHAIRMAN KESSLER: AND THEN ALSO, MY SENSE IS  
15 THERE IS A DESIRE TO HAVE SOME LINKAGE WITH THIS.  
16 PERHAPS A WORKING GROUP OF THIS SUBCOMMITTEE IS  
17 CERTAINLY A POSSIBILITY WE COULD RAISE ON THURSDAY.

18 MR. SHESTACK: THERE ISN'T ANY OTHER  
19 SUBCOMMITTEE THAT WOULD BE MORE APPROPRIATE, AND IT  
20 SEEMS LIKE THERE ARE ENOUGH PEOPLE ON THIS SUBCOMMITTEE  
21 WHO HAVE AN INTEREST IN IT. I WOULD ALSO -- MAYBE WE  
22 SHOULD ASK AT THE MEETING, THE NEXT MEETING, TO EXPAND  
23 THE MEMBERSHIP, IF SOMEBODY ELSE WANTS TO GET ON THE  
24 SUBCOMMITTEE, THE WORKING GROUP. ACTUALLY WE DON'T  
25 NEED TO BECAUSE IT WILL BECOME THE WORKING GROUP.

1 THAT'S FINE.

2 CHAIRMAN KESSLER: SO MY SENSE IS WE PROBABLY  
3 ARE ALLOWED TO HAVE AN AD HOC COMMITTEE OF THE WORKING  
4 GROUP. I WOULD ASK COUNSEL.

5 MR. HARRISON: RIGHT. THE ICOC COULD CREATE  
6 AN AD HOC COMMITTEE THAT REPORTS TO THE WORKING GROUP.  
7 THE WORKING GROUP COULD THEN TAKE ITS RECOMMENDATIONS,  
8 REVIEW THEM, AND REPORT TO THE ICOC, WHICH, AS YOU  
9 POINTED OUT, ULTIMATELY HAS TO ADOPT ANY STANDARDS.

10 CHAIRMAN KESSLER: IT'S ANOTHER LAYER, BUT IT  
11 SOUNDS LIKE THE REAL THOUGHT HERE IS TO MAKE SURE THAT  
12 THE IP ISSUES ARE BROADLY CONSIDERED BY --

13 MR. SHESTACK: UNDER THE RUBRIC OF AN  
14 ETHICIST AND PUBLIC POLICY FRAMEWORK AS WELL AS  
15 SCIENTIFIC.

16 CHAIRMAN KESSLER: SO IT'S NOT JUST A GROUP  
17 OF ECONOMISTS AND LAWYERS.

18 MR. SHEEHY: IT SHOULD FALL UNDER  
19 BAGLEY-KEENE. WE SHOULD RECOMMEND THAT. I PERSONALLY  
20 BELIEVE IT SHOULD FALL UNDER BAGLEY-KEENE.

21 MR. SHESTACK: I DON'T THINK WE HAVE A CHOICE  
22 ABOUT THAT.

23 DR. STEWARD: WE DO.

24 MR. SHESTACK: AD HOC COMMITTEES?

25 DR. STEWARD: FOR THE WORKING GROUPS.

1                   MR. SHEEHY: I MEAN FOR THE COMMITTEE THAT  
2 ADVISES THE WORKING GROUP. I MEAN IF IT'S NOT COMPOSED  
3 OF MEMBERSHIP OF THE ICOC, DOES IT HAVE TO FALL UNDER  
4 BAGLEY-KEENE?

5                   MR. HARRISON: WE NEED TO SEPARATE OUT TWO  
6 DIFFERENT THINGS. THE WORKING GROUPS THEMSELVES,  
7 INCLUDING THE STANDARDS WORKING GROUP, ARE NOT SUBJECT  
8 TO THE BAGLEY-KEENE ACT. OTHER ADVISORY COMMITTEES  
9 CREATED BY THE ICOC, SUCH AS YOURSELVES, WILL BE  
10 SUBJECT TO THE BAGLEY-KEENE ACT.

11                  CHAIRMAN KESSLER: SO LET ME ASK COUNSEL THE  
12 QUESTION THEN. IF IT IS A COMMITTEE OF THE WORKING  
13 GROUP. YOU DON'T HAVE TO GIVE AN OPINION NOW. YOU CAN  
14 THINK ABOUT THAT FOR THURSDAY.

15                  MR. SHESTACK: I UNDERSTAND. ANY AD HOC  
16 COMMITTEE DOESN'T HAVE TO BE SUBJECT TO BAGLEY-KEENE,  
17 BUT YOU WOULD RECOMMEND --

18                  CHAIRMAN KESSLER: NO. NO. NO. AN AD HOC  
19 COMMITTEE HAS TO BE SUBJECT TO BAGLEY-KEENE. THE  
20 WORKING GROUP IS NOT SUBJECT TO BAGLEY-KEENE. THE  
21 QUESTION THEN BECOMES IS AN AD HOC COMMITTEE OF A  
22 WORKING GROUP SUBJECT TO BAGLEY-KEENE? AND IF WE RAISE  
23 THIS ISSUE, COUNSEL WILL HAVE A RECOMMENDATION OF AN  
24 ANSWER ON THURSDAY.

25                  MR. HARRISON: RIGHT.

1 MR. SHESTACK: THE SENSE OF THIS ROOM WOULD  
2 PROBABLY BE THAT IT BE SUBJECT TO BAGLEY-KEENE, WHETHER  
3 IT HAS TO BE OR NOT, ON THESE ISSUES.

4 DR. SAMUELSON: WE COULD JUST DECIDE, IS THAT  
5 WHAT YOU'RE SAYING?

6 MR. SHESTACK: IT'S WHAT JEFF WAS SAYING.

7 CHAIRMAN KESSLER: THERE'S NO PROHIBITION  
8 ABOUT IF THERE IS AN AD HOC COMMITTEE OF A WORKING  
9 GROUP, IT COULD BE SUBJECT TO BAGLEY-KEENE, IF THAT'S  
10 WHAT THE ADVISORY COMMITTEE SO STIPULATES.

11 MR. HARRISON: CORRECT.

12 CHAIRMAN KESSLER: THERE WOULD CERTAINLY BE  
13 NO LEGAL OPINION AGAINST ALLOWING THAT TO BE COMPLIANT  
14 WITH BAGLEY-KEENE?

15 DR. SAMUELSON: JUST SO I UNDERSTAND, SO THAT  
16 ANY COMMITTEE THAT'S CREATED THAT WASN'T IN THE  
17 INITIATIVE, IS BY DEFINITION --

18 CHAIRMAN KESSLER: NOT A WORKING GROUP.

19 DR. SAMUELSON: -- SUBJECT TO BAGLEY-KEENE.

20 MR. HARRISON: AN ADVISORY COMMITTEE CREATED  
21 BY THE ICOC OF THREE OR MORE MEMBERS IS SUBJECT TO THE  
22 BAGLEY-KEENE ACT.

23 MR. SERRANO SEWELL: I DON'T MEAN TO ENGAGE  
24 IN A TANGENT CONVERSATION WITH COUNSEL ON THIS POINT,  
25 BUT AT OUR LAST MEETING, ICOC MEETING, WE HAD

1 REPRESENTATIVES FROM THE ATTORNEY GENERAL'S OFFICE,  
2 ALSO OUR COUNSEL ON SOME MATTERS, BUT WE WERE GIVEN  
3 SORT OF A THUMBNAIL SKETCH OF THE BAGLEY-KEENE ACT, ITS  
4 APPLICATIONS, THE DOS, THE DON'TS. AND AS I RECALL,  
5 ONE OF THE ISSUES THAT WAS DISCUSSED WAS THE WORKING  
6 GROUPS, NOT SUBJECT.

7 MR. HARRISON: CORRECT.

8 MR. SERRANO SEWELL: THAT'S THE WAY THE  
9 STATUTE WAS WRITTEN.

10 MR. HARRISON: CORRECT.

11 MR. SERRANO SEWELL: EITHER YOU'RE A WORKING  
12 GROUP OR YOU'RE NOT A WORKING GROUP. IF YOU'RE NOT A  
13 WORKING GROUP, YOU'RE AN AD HOC COMMITTEE. YOU CAN  
14 CALL IT WHATEVER NAME YOU WANT, BUT IT'S AN AD HOC  
15 COMMITTEE, AND IT'S RECOGNIZED AS SUCH. AND,  
16 THEREFORE, IT IS SUBJECT TO THE BAGLEY-KEENE ACT IF IT  
17 MEETS ALL THESE OTHER REQUIREMENTS: THREE OR MORE  
18 MEMBERS, NOTICE, BOOM-BA-BOOM-BA-BOOM. THAT WAS MY  
19 UNDERSTANDING OF THE ATTORNEY GENERAL'S PRESENTATION.

20 MR. HARRISON: THAT'S CORRECT. IF THE ICOC  
21 CREATES A COMMITTEE, AN ADVISORY COMMITTEE, TO HANDLE  
22 INTELLECTUAL PROPERTY ISSUES, AND THAT ADVISORY  
23 COMMITTEE REPORTS TO THE WORKING GROUP, IT WOULD STILL  
24 BE SUBJECT TO THE BAGLEY-KEENE ACT.

25 IF THE WORKING GROUP ITSELF WERE TO SET UP AN

1 AD HOC COMMITTEE ON ITS OWN TO REPORT TO THE WORKING  
2 GROUP, THEN I THINK WE HAVE A DIFFERENT QUESTION.

3 CHAIRMAN KESSLER: SO LET ME SEE -- AGAIN, IN  
4 A GENERAL SENSE, THE INTELLECTUAL PROPERTY ISSUES  
5 SHOULD BE HANDLED BY A GROUP THAT IS NOT JUST  
6 ECONOMISTS AND LAWYERS, BUT PUBLIC INTEREST, BUT IT CAN  
7 INCLUDE ECONOMISTS AND LAWYERS, BUT IT SHOULD NOT  
8 SOLELY BE.

9 DO WE BELIEVE THAT THIS GROUP THAT DEALS WITH  
10 INTELLECTUAL PROPERTY BE SUBJECT TO BAGLEY-KEENE?

11 MR. SERRANO SEWELL: I FEEL STRONGLY THAT IT  
12 SHOULD.

13 DR. SAMUELSON: I WOULD WANT TO CONSIDER THAT  
14 CAREFULLY BECAUSE I WOULD WANT TO FULLY UNDERSTAND WHY  
15 THE WORKING GROUPS WERE EXEMPTED. AND THERE WAS AN  
16 INSTANCE OF IT THAT PREVENTED ME FROM PARTICIPATING IN  
17 AN IMPORTANT MEETING LAST WEEK WHEN I COULDN'T JOIN A  
18 TELECONFERENCE FROM MY OFFICE, BEING UNABLE TO TAKE A  
19 WHOLE DAY TO GET THERE. SO IT'S A KIND OF -- THE STING  
20 OF THAT IS STILL PRESENT, SO I WOULD JUST WANT TO FULLY  
21 UNDERSTAND.

22 DR. STEWARD: I AGREE. I WOULD LIKE TO  
23 SUGGEST THAT WE -- THERE'S A SENSE THAT WE'VE DEVELOPED  
24 AS FAR AS THE IP ISSUES, AND I THINK THAT THE  
25 BAGLEY-KEENE IS A MUCH BROADER ISSUE. I'D RATHER NOT

1 MAKE A RECOMMENDATION ON IT EVEN UNTIL WE REALLY --

2 CHAIRMAN KESSLER: IS THERE A CONSENSUS, JUST  
3 TO REACH CLARITY, THAT THE GROUP THAT DOES INTELLECTUAL  
4 PROPERTY SHOULD BE LINKED TO THE SUBCOMMITTEE? IS  
5 THERE A FEELING OF THAT?

6 MR. SHESTACK: YEAH. THE GROUP THAT DOES  
7 INTELLECTUAL PROPERTY --

8 CHAIRMAN KESSLER: IP SHOULD BE LINKED TO  
9 THIS WORKING GROUP.

10 DR. SAMUELSON: I THINK THIS IS THE STANDARDS  
11 WORKING GROUP. THAT IS ONE OF THE STANDARDS WE SHOULD  
12 OPERATE UNDER.

13 CHAIRMAN KESSLER: LET'S JUST GO AROUND AND  
14 SEE WHAT THE SENSE OF THE GROUP WOULD BE.

15 MR. SHESTACK: I WOULD AGREE THAT IT SHOULD  
16 BE LINKED TO THIS COMMITTEE.

17 DR. STEWARD: I HAVE TO SAY SOMETHING THAT  
18 JEFF SAID REALLY TURNED ME AROUND BECAUSE IF FOR THE  
19 SCIENTIFIC ACCOUNTABILITY, WE'RE ALSO GOING TO BE  
20 THINKING ABOUT COMPULSORY LICENSING, THEN IT  
21 AUTOMATICALLY BECOMES AN IP ISSUE, AND I THINK IT HAS  
22 TO BE PART OF THIS COMMITTEE'S CHARGE.

23 MR. SHEEHY: I WOULD SAY, BUT I WORRY ABOUT  
24 THE BAGLEY-KEENE. I MEAN THAT'S AN IMPORTANT POINT.

25 CHAIRMAN KESSLER: IT CUTS BOTH WAYS.



1                   MR. SHEEHY: I UNDERSTAND JOAN'S FRUSTRATION.  
2 I THINK ON THIS PARTICULAR ISSUE, SIMPLY BECAUSE THE  
3 IDEAS, I MEAN I GET CALLS FROM PEOPLE WITH GREAT IDEAS.  
4 PEOPLE ARE SENDING ME DOCUMENTS. WE NEED THAT FEEDBACK  
5 TO COME UP WITH INNOVATIVE POLICY. IT'S OPEN SOURCE  
6 MENTALITY WE NEED TO IMPOSE ON THIS PROCESS.

7                   DR. SAMUELSON: AND I'VE ALREADY EXPERIENCED  
8 THAT MYSELF. AND I GUESS I'M IN THE OPEN CAMP, BUT I  
9 DON'T KNOW IF THAT EQUALS BAGLEY-KEENE.

10                  MR. SHESTACK: OR IF THERE'S ANOTHER WAY.

11                  DR. SAMUELSON: BAGLEY-KEENE SORT OF  
12 PREVENTED ME FROM ATTENDING LAST WEEK.

13                  CHAIRMAN KESSLER: SO SINCE WE'RE ONLY  
14 PARTIALLY THROUGH NO. 3 ON THE AGENDA, WE HAVE TO GO TO  
15 EIGHT. WE CAN KEEP ON -- I THINK WE HAVE A SENSE OF  
16 WHAT PEOPLE'S THOUGHTS ARE ON THIS.

17                  SAYING THAT, ANY OTHER COMMENTS FROM THE  
18 PUBLIC ON ANY OTHER COMMENTS YOU'VE JUST HEARD NOW? I  
19 NEED TO KEEP ON PUSHING AHEAD A LITTLE.

20                  MR. GANCHOFF: CHRIS GANCHOFF, UCSF. I WOULD  
21 JUST RECOMMEND ONE WAY TO THINK ABOUT THIS AD HOC GROUP  
22 AS THE HUMAN GENOME PROJECT FORMALLY WAS CALLED AN ELSI  
23 COMMITTEE, ETHICAL, LEGAL, AND SOCIAL IMPLICATIONS OF  
24 HUMAN GENETICS. SO THAT'S BEEN IN EXISTENCE FOR A LONG  
25 TIME, SO THAT'S ONE FORM YOU CAN LOOK TO WHEN YOU'RE

1 THINKING ABOUT WHAT AN AD HOC COMMITTEE WOULD LOOK  
2 LIKE. AGAIN, THAT'S A VERY HETEROGENEOUS GROUP OF  
3 PEOPLE WITH EXPERTISE.

4 AGAIN, I WOULD CAUTION AGAINST HAVING  
5 EXPERTISE ABOUT IP MEANS YOU MUST AUTOMATICALLY GO TO  
6 LAW OR ECONOMICS, BUT MANY DISCIPLINES TAKE ON THESE  
7 QUESTIONS FROM MANY DIFFERENT PERSPECTIVES. AND HAVING  
8 MULTIPLE PERSPECTIVES ONLY MAKES THE FINAL  
9 RECOMMENDATIONS MORE ROBUST.

10 CHAIRMAN KESSLER: THANK YOU. SO FAR ALL  
11 I'VE READ ARE THE CRITERIA THAT WE HAVE NO DISCRETION  
12 ON. THIS IS A DISCUSSION OF EXACTLY WHAT THIS STATUTE  
13 HAS, AND WE HAVE NO -- WE CAN'T REWRITE THAT.

14 LET ME SUGGEST SOME PRACTICAL CRITERIA FOR  
15 CONSIDERATION, AND THIS IS FOR INDIVIDUAL MEMBERS.

16 EXPERIENCE WITH THE BIOMEDICAL ETHICS OF STEM  
17 CELL RESEARCH, EXPERIENCE WITH NIH GUIDELINES FOR  
18 RESEARCH, EXPERIENCE WITH NATIONAL ACADEMY OF SCIENCE  
19 GUIDELINES FOR RESEARCH, STEM CELL IN PARTICULAR,  
20 EXPERIENCE WITH INFORMED CONSENT ISSUES, EXPERIENCE  
21 WITH CONTROLS ON RESEARCH INVOLVING HUMAN SUBJECTS,  
22 EXPERIENCE WITH PATIENT PRIVACY LAWS AND REGULATIONS,  
23 EXPERIENCE WITH MEDICAL STANDARDS COMPLIANCE,  
24 EXPERIENCE WITH MEDICAL REGULATORY AGENCIES, SUCH AS  
25 THE FDA.

1                   THOSE WERE MORE THE PRACTICAL CONSIDERATIONS  
2           THAT WE THOUGHT WE WOULD HAVE SOME WORKING DRAFT FOR  
3           YOUR CONSIDERATION ON THAT.   LET ME JUST LAY, IN  
4           ADDITION TO THOSE PRACTICAL CONSIDERATIONS, PRACTICAL  
5           CRITERIA, LET ME GIVE SOME QUALITIES TO LOOK FOR IN  
6           ORGANIZING A GROUP.   OUT OF THE INDIVIDUAL QUALIFYING  
7           CRITERIA, I WOULD ADD DIVERSITY OF EXPERIENCE IN THE  
8           SUBJECT AREAS LISTED ABOVE AND SOME BALANCE BETWEEN  
9           SCIENTISTS AND CLINICIANS.

10                   MR. SHESTACK:   I WOULD JUST ADD ONE THING.  
11           WE WENT THROUGH TOTALLY DIFFERENT ETHICAL ISSUES ON THE  
12           GRANTS WORKING GROUP, A QUESTION WHETHER OR NOT PEOPLE  
13           FROM CALIFORNIA WOULD BE ELIGIBLE.

14                   CHAIRMAN KESSLER:   I WILL GET TO THAT IN A  
15           SECOND, IF I MAY.   LET'S JUST STAY WITH THE DESIRABLE  
16           TRAITS AND QUALITIES TO LOOK FOR.   I LIST TEN ON THAT  
17           SHEET.   ARE THERE ANY HERE THAT YOU ARE UNCOMFORTABLE  
18           WITH?

19                   LET ME JUST OPEN DISCUSSION AMONG MEMBERS OF  
20           THE SUBCOMMITTEE ABOUT THESE PROPOSED CRITERIA.

21                   DR. SAMUELSON:   ONE PIECE OF INPUT.   I THINK  
22           IT'S IMPORTANT THAT SOMEWHERE IDEALLY, I THINK, IN THIS  
23           WORKING GROUP WE HAVE THE PRESENCE OF THEOLOGIANS  
24           BECAUSE I THINK THE PUBLIC LOOKS TO THEOLOGIANS FOR THE  
25           DEFINITION OF ETHICS IN MANY CASES.   AND THERE ARE

1 THEOLOGIANS WHO ARE EXPERT IN THIS FIELD. AND I'M NOT  
2 SURE IF THAT SHOULD BE A SEPARATE CRITERION OR IF IT'S  
3 EXCLUDED BY THIS OR WHAT.

4 CHAIRMAN KESSLER: THIS WAS NOT MEANT TO  
5 EXCLUDE ANYONE.

6 DR. SAMUELSON: NO, I DIDN'T THINK SO.

7 CHAIRMAN KESSLER: THIS WAS JUST AS WE GO  
8 AHEAD AND LOOK FOR DESIRABLE TRAITS OR QUALITIES, SOME  
9 GUIDING THAT. WE'RE STILL REQUIRED, YOU'VE GOT TO BE  
10 EITHER A MEMBER OF THE ICOC, YOU'VE GOT TO BE A  
11 SCIENTIST OR CLINICIAN WHO KNOWS SOMETHING ABOUT STEM  
12 CELL, OR YOU'VE GOT TO BE A MEDICAL ETHICIST. SO IF  
13 YOU ARE A THEOLOGIAN, YOU'VE GOT TO STILL FIT INTO ONE  
14 OF THOSE THREE. SO A DESIRABLE TRAIT COULD CERTAINLY  
15 BE IF THERE WAS SOMEBODY WHO HAD A THEOLOGICAL  
16 PERSPECTIVE AND ALSO MET THE OTHER CRITERIA. THERE ARE  
17 MEDICAL ETHICISTS WHO ARE THEOLOGIANS.

18 MR. SHESTACK: I WOULD ADD ONE OTHER POSSIBLE  
19 AREA OF EXPERTISE, WHICH IS RESOURCE CREATION. I HAVE  
20 SOME EXPERIENCE IN BRAIN BANKING, TISSUE BANKING, GENE  
21 BANKING. SOMEONE ON THIS GROUP WHO HAS A FAMILIARITY  
22 WITH THE NOTIONS OF CREATING PUBLIC SCIENTIFIC  
23 RESOURCES.

24 CHAIRMAN KESSLER: PUBLIC SCIENTIFIC  
25 RESOURCES.

1 MR. SHESTACK: SOMETHING TO LOOK FOR.

2 CHAIRMAN KESSLER: DO WE RAISE -- HOW DO YOU  
3 THINK -- THE STATUTE TALKS ABOUT ETHICAL, MEDICAL  
4 ETHICISTS. THERE IS A MUCH MORE COMPLICATED AREA UNDER  
5 THEOLOGY AND SCIENCE AND THE INTERSECTION. THE STATUTE  
6 DIDN'T SPECIFICALLY DISCUSS THAT. I DON'T KNOW WHETHER  
7 THERE ARE CONSTITUTIONAL ISSUES HERE THAT ARE RAISED  
8 THAT WE NEED TO BE SENSITIVE TO IN THIS BEFORE WE --

9 MR. HARRISON: WELL, THERE ARE LIMITATIONS ON  
10 THE USE OF PUBLIC FUNDS FOR SECTARIAN PURPOSES. I  
11 DON'T THINK THAT WOULD NECESSARILY PROHIBIT SOMEONE  
12 WITH A BACKGROUND IN THEOLOGY, WHO OTHERWISE MET THE  
13 CRITERIA, FROM PARTICIPATING.

14 CHAIRMAN KESSLER: COULD YOU SPECIFICALLY SAY  
15 THAT ONE OF YOUR CRITERIA INCLUDE A THEOLOGICAL  
16 BACKGROUND OR A DESIRABLE TRAIT SHOULD BE THEOLOGY, OR  
17 SHOULD WE KEEP THESE THINGS -- I SEE DIFFERENT  
18 PEOPLE --

19 DR. SAMUELSON: I DON'T KNOW THAT IT  
20 NECESSARILY SHOULD BE -- WELL, EXCEPT I DO THINK THAT  
21 IT'S IMPORTANT THAT WE ALWAYS KEEP IN MIND WHERE THIS  
22 THING CAME FROM. THIS WAS -- THE CALIFORNIA VOTERS  
23 FEEL VERY INVESTED IN THIS AND OWN IT, AND THAT WE  
24 RESPECT THAT. AND IT'S IMPORTANT THAT OUR WORK IS  
25 ALWAYS REGARDED AS APPROPRIATE AND THAT WE'VE TAKEN ALL

1 THE APPROPRIATE CONSIDERATIONS TO HEART. AND I THINK  
2 THAT'S WHERE I STARTED FROM IN THINKING ABOUT THIS.

3 AND THERE ARE THEOLOGIAN WHO HAVE THIS  
4 EXPERTISE AND WHO WORKED IN THE BIOMEDICAL RESEARCH  
5 WORLD AND COULD BRING US THAT INFORMED PERSPECTIVE.  
6 AND PERHAPS THERE'S SOME OTHER CONFIGURATION THAT WOULD  
7 GIVE IT TO US. I THINK WE'RE GOING TO PROBABLY END UP  
8 WITH ADVISORY COMMITTEES AND THAT SORT OF THING,  
9 CONSULTING RELATIONSHIPS. I DON'T KNOW WHAT. BUT I  
10 THINK IT'S IMPORTANT THAT WE'RE SEEN AS TAKING THIS  
11 SERIOUSLY AND THAT WE ALWAYS TAKE THE ETHICAL ISSUES  
12 SERIOUSLY.

13 I HEARD THE SAME CONCERNS FROM PEOPLE,  
14 WHETHER THEY VOTED FOR IT OR NOT, THAT EVERYTHING WE DO  
15 BE ETHICAL, THAT EVERYTHING WE DO BE PRUDENT, AND  
16 FISCALLY CAREFUL AND GOAL ORIENTED. THOSE WERE REALLY  
17 THE THREE BIG ONES. AND SO THAT'S WHERE MY GUT, AS  
18 WELL AS SOME OF MY THINKING, TELLS ME THAT WE SHOULD  
19 INCLUDE THAT WORLD, WHICH SPENDS A LOT OF TIME HELPING  
20 GUIDE PEOPLE IN PROPER APPROPRIATE ACTIONS IN THEIR  
21 LIVES FROM A RELIGIOUS PERSPECTIVE. AND THAT THAT'S  
22 WHERE A LOT OF OUR ETHICS COME FROM.

23 CHAIRMAN KESSLER: THE VOTERS WERE SILENT ON  
24 THAT PARTICULAR ISSUE, IF I'M CORRECT. PROP 71 SAID  
25 NOTHING. AND THERE CERTAINLY WOULD BE MANY THAT WOULD

1 BE VERY MUCH IN FAVOR AND FEEL COMFORTED BY IF THERE  
2 WAS A THEOLOGICAL PERSPECTIVE. THERE MAY BE OTHERS WHO  
3 FELT THE OTHER WAY AND SAY, NO, WE SHOULD MAINTAIN THIS  
4 IS SCIENCE, THIS IS MEDICAL ETHICS. THERE CAN BE  
5 DIFFERENT VIEWS ON THIS. I JUST WANT TO MAKE SURE THAT  
6 I'M FULLY RESPECTFUL OF ALL THOSE VIEWS AND WE STAY  
7 CONSISTENT WITH WHAT THE VOTERS ASKED US TO DO.

8 DR. STEWARD: SO WE'RE THE SEARCH COMMITTEE,  
9 AND, OF COURSE, I THINK THAT OTHER ISSUES ARE GOING TO  
10 PLAY IN AS WE GO ALONG OTHER THAN THE TEN THAT YOU'VE  
11 LISTED HERE. I'M A LITTLE UNCOMFORTABLE, FRANKLY,  
12 PUTTING THIS AS ONE OF NOW ELEVEN, AND I'M NOT SURE  
13 WHY. BUT I'M A LITTLE UNCOMFORTABLE. IT CERTAINLY  
14 DOESN'T MEAN THAT I WOULD WANT TO EXCLUDE SOMEBODY WHO  
15 HAPPENED TO BE A THEOLOGIAN WHO ALSO MET THE OTHER  
16 CRITERIA, BUT I'M JUST A LITTLE UNCOMFORTABLE ABOUT IT.

17 I WONDER IF WE NEED TO LIST IT EVEN IF WE CAN  
18 OPERATE UNDER THE CONSIDERATION THAT IF SOMEONE CAME  
19 ALONG WHO WAS A THEOLOGIAN AND MET THE OTHER CRITERIA,  
20 THAT WOULD BE FINE. I DON'T KNOW. THESE ARE NOT  
21 NECESSARILY ANYTHING MORE THAN OUR OPERATING GUIDELINES  
22 ANYWAY. THEY'RE NOT GOING TO BE PUBLISHED, I DON'T  
23 THINK, SO MAYBE IT DOESN'T MATTER.

24 MS. HALME: THEY WILL BE PUBLIC.

25 CHAIRMAN KESSLER: EVERYTHING WE DO IS

1 PUBLIC.

2 DR. STEWARD: THEN I THINK WE REALLY NEED TO  
3 THINK ABOUT IT. DO WE WANT TO HAVE A SORT OF  
4 NONDENOMINATIONAL THEOLOGIAN ON THERE? WE'RE GETTING  
5 INTO AREAS THAT ARE A LITTLE BIT MORE DIFFICULT.

6 I'M SORRY, DAVID. I'M GOING TO ASK THIS  
7 BEFORE THE HAND COMES UP. I DON'T MEAN TO BE RUDE,  
8 MA'AM. I SEE YOUR HAND UP. WHAT I WOULD LIKE TO ASK  
9 ACTUALLY OR SUGGEST IS THAT WE RESERVE THE PUBLIC  
10 COMMENT FOR THE END JUST BECAUSE WE HAVE A LOT TO  
11 COVER.

12 CHAIRMAN KESSLER: UNFORTUNATELY WE ARE  
13 COMMITTED POINT BY POINT, NOT EVERY POINT, TO TAKE  
14 PUBLIC COMMENT ON THE AGENDA ITEM. WHEN WE HAVE A  
15 SERIOUS ISSUE, WE SHOULD ALLOW PEOPLE BECAUSE THEY'RE  
16 NOT GOING TO REMEMBER EVERYTHING. SO I'M COMMITTED  
17 TO -- UNDERSTANDING I GOT TO GET THROUGH THIS BY SIX,  
18 SO IF I CAN GET A LITTLE HELP.

19 DR. STEWARD: SOME OF US HAD TO FLY UP, AND  
20 WE HAVE TO CATCH A PLANE.

21 CHAIRMAN KESSLER: IS THERE A LITTLE -- LET'S  
22 JUST FINISH THE PANEL, AND THEN I WILL ASK FOR PUBLIC  
23 COMMENT, DAVID, ON THE ISSUE OF TRAITS.

24 MR. SERRANO SEWELL: TRAITS FOR THE  
25 INDIVIDUAL MEMBERS. I WOULD LEAN TOWARD WHAT JOAN WAS



1 SAYING BECAUSE I DO IN MY EXPERIENCES WITH THE PUBLIC  
2 AND TALKING ABOUT THE ROLES AND RESPONSIBILITIES OF THE  
3 ICOC AS WE GO ABOUT EXERCISING OUR DUTIES IN MANAGING  
4 THE INSTITUTE, QUESTION NO. 1 IS HOW MUCH IS \$3  
5 BILLION? IT'S A LOT. QUESTION NO. 2 IS HOW ARE YOU  
6 GOING TO DEAL WITH THE ETHICS? IT'S A CHALLENGING  
7 PIECE OF THIS. THIS WORKING GROUP IS SO IMPORTANT.  
8 THEY ALL ARE.

9 AND I THINK IT'S DESIRABLE TO HAVE A  
10 THEOLOGIAN OF SOME SORT, AND I WOULD MAYBE LOOK TOWARD  
11 STAFF AND COUNSEL TO COME WITH LANGUAGE THAT TAKES INTO  
12 CONSIDERATION WHAT OS IS SAYING. I THINK THERE ARE  
13 PROBABLY WAYS OF DANCING AROUND IT -- NOT DANCE AROUND.  
14 THAT'S THE WRONG TERM -- BUT INCORPORATING THAT PIECE  
15 OF IT AND EMBODYING IT AS A DESIRABLE TRAIT.

16 CHAIRMAN KESSLER: WOULD YOU LIST IT?

17 MR. SHESTACK: EXPERIENCE IN THEOLOGICAL  
18 TRAINING. IT'S LIKELY THAT PERSON WOULD FALL UNDER  
19 THE -- MORE LIKELY THEY WOULD FALL UNDER THE ETHICIST  
20 THAN THE SCIENTIST OR CLINICIAN MEMBER, BUT WHO KNOWS.

21 CHAIRMAN KESSLER: OTHER COMMENTS FROM THE  
22 MEMBERS OF THE SUBCOMMITTEE ON THIS POINT, AND THEN I'M  
23 GOING TO ASK FOR PUBLIC COMMENT?

24 DR. SAMUELSON: YEAH. AND I THINK IT'S THAT.  
25 AT TIMES SLOW MAY BE GOOD, AND IT'S EXCRUCIATING

1 BECAUSE WE WANT TO JUMP AHEAD. BUT, FOR EXAMPLE, MY  
2 THINKING ON IT WAS INFORMED BY ATTENDING THE WILLIE  
3 BROWN INSTITUTE, HAD AN ALL-DAY SESSION OR TWO-DAY  
4 SESSION ON STEM CELL RESEARCH. AND THEY HAD A WHOLE  
5 BUNCH OF ETHICISTS, INCLUDING SOME THEOLOGIANs. IT WAS  
6 INTERESTING TO HEAR THEIR POINT OF VIEW. IT INFORMED  
7 THE DISCUSSION USEFULLY, I THOUGHT.

8 AND I GUESS THAT'S MY OTHER POINT, WHICH IS  
9 THAT I THOUGHT THAT -- I SORT OF ENVISIONED US SOMEHOW  
10 GETTING A TUTORIAL IN THE BASICS OF BEING AN ICOC  
11 MEMBER THAT WOULD INCLUDE SOME TRAINING IN THE  
12 FOUNDATION OF SOME OF THESE INCREDIBLY COMPLICATED  
13 ISSUES. I'M ALSO REAL GLAD I WENT TO THE IRVINE  
14 MEETING, BUT NOT EVERYBODY WAS ABLE TO. NOT EVERYBODY  
15 MAYBE WAS EVEN APPOINTED AT THE TIME THAT WAS HELD.  
16 AND THAT IS HELPING ME A LOT IN ALL OF THIS  
17 DECISION-MAKING. AND SO THERE'S A CHICKEN AND EGG  
18 PROBLEM IN EVEN MAKING THESE RECOMMENDATIONS.

19 CHAIRMAN KESSLER: JON, YOU HAVE A SPECIFIC  
20 RECOMMENDATION TO --

21 MR. SHESTACK: I JUST SAID A DESIRABLE TRAIT  
22 FOR ME WOULD BE THAT SOMEBODY AMONG THIS GROUP HAD SOME  
23 EXPERIENCE WITH SCIENTIFIC RESOURCE CREATION.

24 CHAIRMAN KESSLER: WE'RE GOING TO VOTE ON ALL  
25 THESE AS A WHOLE. LET'S FIRST START WITH THESE TEN.

1 OKAY. THEN WE CAN TALK ABOUT ADDING ADDITIONAL ONES.  
2 SEE IF WE CAN GET -- LET ME ASK IS THERE A MOTION TO  
3 ADOPT THESE TEN? AND THEN WE CAN TALK ABOUT ADDITIONAL  
4 ONES.

5 DR. STEWARD: ACTUALLY WHY DON'T WE JUST GO  
6 FOR THE MOTION TO ADOPT ALL THE 12 THAT HAVE BEEN  
7 LISTED? I BET THAT WILL -- I'M NOT GOING TO GO TO THE  
8 MAT ON THIS. I'M NOT SO UNCOMFORTABLE ABOUT IT THAT I  
9 WOULDN'T VOTE FOR IT.

10 MR. SHESTACK: WHY DON'T WE VOTE ON THESE TEN  
11 PLUS THE INCLUSION OF SOMEONE WITH EXPERIENCE IN  
12 BIOLOGICAL RESEARCH RESOURCE CREATION AND WITH  
13 APPROPRIATE THEOLOGICAL TRAINING. WOULD THAT BE WITH  
14 TRAINING IN THEOLOGY. THEY DON'T HAVE TO BE A  
15 PRACTICING THEOLOGIAN. WE WANT THIS POINT OF VIEW  
16 REPRESENTED. DOES THAT SEEM RIGHT, JOAN?

17 CHAIRMAN KESSLER: MY SENSE IS BECAUSE WE'RE  
18 GOING TO A VOTE ON IT, LET'S DO A VOTE ON ELEVEN, AND  
19 THEN WE CAN ADD THE TWELFTH ONE. THEOLOGY ONE, I THINK  
20 PEOPLE ARE GOING TO NEED TO BE ABLE TO HEAR THE  
21 LANGUAGE ON THAT. IF WE CAN INCLUDE PUBLIC, WHAT WAS  
22 YOUR WORD?

23 MR. SHESTACK: SCIENTIFIC RESOURCE CREATION.

24 CHAIRMAN KESSLER: SO THOSE ELEVEN. IS THERE  
25 A MOTION TO --

1                   MR. SHESTACK: I MOVE THAT WE APPROVE THOSE  
2 ELEVEN TRAITS.

3                   CHAIRMAN KESSLER: IS THERE A SECOND?

4                   MR. SERRANO SEWELL: SECOND.

5                   CHAIRMAN KESSLER: COULD WE ASK FOR PUBLIC  
6 COMMENT ON THESE ELEVEN? IS THERE ANY COMMENT ON THESE  
7 ELEVEN?

8                   MS. MCMURRY: MICHELLE MCMURRY, UCSF. I  
9 WOULD JUST ADD ONE THAT HASN'T BEEN MENTIONED ELSEWHERE  
10 IS SOMEONE WITH EXPERIENCE IN HEALTHCARE DISPARITIES,  
11 MINORITY HEALTH ISSUES GIVEN THE UNIQUE POSITIONING OF  
12 THIS INITIATIVE AMONG HEALTH OF THE VOTERS. THEN I'D  
13 ALSO JUST BEG YOU TO CONSIDER ON SOME OF THE PREVIOUS  
14 POINTS, AND I'M NOT A SOCIAL SCIENTIST BY TRAINING, BUT  
15 DEFINITION OF SCIENTIST DOES NOT HAVE TO BE A LAB OR  
16 LIFE SCIENTIST BECAUSE THAT'S NOT IN THE LANGUAGE OF  
17 THE INITIATIVE. IT COULD BE A SOCIAL SCIENTIST, AN  
18 ECONOMIST, ETC.

19                  CHAIRMAN KESSLER: SO NO. 9 IS WRITTEN IN  
20 SOME WAYS TO GET DIVERSITY OF EXPERIENCES WITH REGARD  
21 TO THOSE AREAS. ANYONE WANT TO AMEND THIS IN LIGHT OF  
22 THE PUBLIC COMMENT?

23                  MR. SHEEHY: I'D MAKE THAT AMENDMENT,  
24 ESPECIALLY ON THE HEALTH DISPARITIES, AS A DESIRABLE  
25 TRAIT. I THINK THAT THAT WOULD BE GOOD.

1 CHAIRMAN KESSLER: SO WE NOW HAVE AN  
2 AMENDMENT.

3 MR. SHEEHY: IF THAT'S OKAY WITH THE MAKER.

4 MR. SHESTACK: SOMEONE WITH EXPERIENCE IN --

5 MR. SHEEHY: AS A DESIRABLE TRAIT, NOT AS A  
6 QUALIFICATION.

7 MR. SHESTACK: DISPARITY OF, WHAT IS IT, THE  
8 ECONOMICS OF DISPARITY -- HEALTH DISPARITY.

9 CHAIRMAN KESSLER: HEALTH DISPARITIES. SO  
10 THAT WOULD BE AN ADDITIONAL ONE. IS THERE A MOTION?

11 MR. SHESTACK: I'M HAPPY TO AMEND THE INITIAL  
12 MOTION.

13 CHAIRMAN KESSLER: WHOEVER SECONDED WOULD BE  
14 WILLING -- DO THEY SECOND THAT?

15 MR. SERRANO SEWELL: I DON'T THINK IT'S  
16 REQUIRED. I'M SORRY. THE MAKER -- I THINK IT'S JUST  
17 THE MAKER OF THE MOTION HAS TO ACCEPT THE FRIENDLY  
18 AMENDMENT.

19 CHAIRMAN KESSLER: YOU ACCEPT IT AS A  
20 FRIENDLY AMENDMENT.

21 MR. SHESTACK: YES. FRIENDLY AMENDMENT.

22 CHAIRMAN KESSLER: FROM ROBERTS RULES, MY  
23 PROCEDURE HERE. COUNSEL WILL TELL ME IF I MISSPOKE.

24 WE'VE HEARD PUBLIC COMMENT ON THESE, ON THESE  
25 NOW 12 POINTS, AS I UNDERSTAND IT. CAN WE HAVE A ROLL

1 CALL ON THESE 12?

2 MR. KLEINSCHMIDT: DAVID KESSLER.

3 CHAIRMAN KESSLER: AYE.

4 MR. KLEINSCHMIDT: DAVID SERRANO SEWELL.

5 MR. SERRANO SEWELL: AYE.

6 MR. KLEINSCHMIDT: JEFF SHEEHY.

7 MR. SHEEHY: AYE.

8 MR. KLEINSCHMIDT: JOAN SAMUELSON.

9 DR. SAMUELSON: AYE.

10 MR. KLEINSCHMIDT: JONATHAN SHESTACK.

11 MR. SHESTACK: AYE.

12 MR. KLEINSCHMIDT: OSWALD STEWARD.

13 DR. STEWARD: AYE.

14 CHAIRMAN KESSLER: THAT IS UNANIMOUS.

15 JOAN, DO YOU HAVE A RECOMMENDATION THAT YOU'D

16 LIKE TO PUT FORWARD ON OR, DAVID, ON THE POINT THAT YOU

17 MADE EARLIER?

18 MR. SERRANO SEWELL: WELL, I DON'T WANT TO

19 PUNT TO OUR COLLEAGUES AT THE ICOC, BUT I THINK IT MAY

20 BE SOMETHING THAT ALL OF THE COMMITTEE MEMBERS MAY WANT

21 TO WEIGH IN ON.

22 CHAIRMAN KESSLER: SO YOU WOULD ASK US TO

23 HOLD ON THAT CRITERIA?

24 MR. SERRANO SEWELL: I WOULD. BUT IT'S

25 SOMETHING IN YOUR REPORT, CHAIRMAN KESSLER, THAT YOU

1 RAISE.

2 DR. SAMUELSON: I GUESS AT LEAST I'D LIKE, I  
3 GUESS -- I DON'T SEE IT AS CONTROVERSIAL, BUT I THINK  
4 IT'S A DESIRABLE EXPERTISE, THAT IT WOULD BE NICE TO  
5 HAVE CONSIDERED AT THE LEAST. I COULD MAKE THAT.

6 CHAIRMAN KESSLER: DO YOU WANT --

7 MR. SHESTACK: HOW DO YOU PHRASE IT? MAYBE  
8 WE CAN PHRASE IT IN A WAY THAT JUST SAILS THROUGH RIGHT  
9 HERE AND THEN YOU'RE DONE.

10 DR. SAMUELSON: UNDER DESIRABLE TRAITS OF  
11 INDIVIDUAL MEMBERS --

12 CHAIRMAN KESSLER: CAN I MAKE A SUGGESTION?  
13 SOMETHING LIKE RECOGNIZING THE SEPARATION OF RELIGIOUS  
14 ACTIVITIES AND GOVERNMENTAL ACTION, THAT INDIVIDUALS  
15 WHO CAN BRING A MORAL THEOLOGICAL PERSPECTIVE, IF THEY  
16 MET -- ASSUMING THEY MET ALL THE OTHER CRITERIA, WOULD  
17 BE SOMETHING THAT WOULD BE VIEWED FAVORABLY.

18 DR. SAMUELSON: SOUNDED GOOD.

19 CHAIRMAN KESSLER: WE'RE GOING TO TAKE PUBLIC  
20 COMMENT ON THIS. JUST THE QUESTION IS --

21 MR. SHESTACK: LEAVE IT -- LET'S LEAVE OUT  
22 MORAL BECAUSE WE ASSUME THAT. AND THERE'S THE  
23 ETHICIST. YOU'RE ASKING FOR A SPECIFIC THEOLOGICAL  
24 TRAINING OR EXPERTISE.

25 DR. SAMUELSON: YES.

1                   CHAIRMAN KESSLER:  DISCLOSURE.  I MAY HAVE  
2                   SOME PROBLEMS VOTING IN FAVOR OF JUST BECAUSE THAT'S MY  
3                   OWN PERSONAL VIEW HERE.  BUT I'D BE HAPPY -- I JUST  
4                   WANT TO BE HELPFUL IN GIVING YOUR VIEWS HERE IN TRYING  
5                   TO GIVE VOICE.  YOU WANT TO MAKE A MOTION?

6                   DR. STEWARD:  COULD I MAKE JUST A  
7                   RECOMMENDATION FOR CONSIDERATION, AND THAT IS THAT WE  
8                   SUGGEST THIS AS THE TOPIC FOR DISCUSSION AT THE ICOC?

9                   DR. SAMUELSON:  I THINK THAT SOUNDS FINE.

10                  CHAIRMAN KESSLER:  SO YOU WITHDRAW YOUR  
11                  AMENDMENT?

12                  DR. SAMUELSON:  YES, I DO.  BUT ASK THAT IT  
13                  BE SOMEHOW PRESENTED TO THE ICOC AS A WHOLE.

14                  DR. STEWARD:  AS A POSSIBLE ELEVENTH,  
15                  TWELFTH.

16                  MR. SHESTACK:  THIRTEENTH TRAIT.

17                  DR. SAMUELSON:  MAYBE WE COULD HAVE COUNSEL,  
18                  WHETHER IT'S YOU OR SOMEONE FROM THE AG'S OFFICE, COME  
19                  WITH WHATEVER BRIEF DESCRIPTION OF WHATEVER THE BRIGHT  
20                  LINE IS THAT WE HAVE TO BEAR IN MIND, IF THERE IS  
21                  SOMETHING.  OBVIOUSLY WE'RE NOT GOING TO PRACTICE  
22                  RELIGION.

23                  CHAIRMAN KESSLER:  RECOGNIZING THAT THERE IS  
24                  NO AMENDMENT THAT'S GOING TO BE VOTED ON TODAY, BUT  
25                  THIS WILL BE A CONTINUED ISSUE, IT WILL BE RAISED AT



1 THE ICOC, I DON'T KNOW IF WE'RE ON THE AGENDA, IS THERE  
2 PUBLIC COMMENT NOW ON THE ISSUE THAT DR. SAMUELSON HAS  
3 RAISED?

4 DR. REED: I WOULD OBJECT STRONGLY TO ANY  
5 MENTION OF RELIGION IN ANY WAY WITH THIS. I THINK  
6 THAT, A, IT'S UNNECESSARY. MOST BIOETHICISTS HAVE A  
7 FAITH-BASED BACKGROUND. SECONDLY, IF WE DO, THEN WE  
8 HAVE TO SAY WHICH FAITH. AND THIRDLY, I REMEMBER  
9 WALKING IN TO SEE MY SON BAPTIZED AND SEEING A  
10 FIVE-FOOT TALL DISPLAY THAT SAID PROPOSITION 71, BABY  
11 KILLERS IN THE CATHOLIC CHURCH. I THINK THAT WE OPEN  
12 UP A WHOLE CAN OF WORMS. THE BIOETHICS ISSUE ITSELF  
13 TAKES CARE -- RONALD GREEN, DARTMOUTH UNIVERSITY,  
14 OUTSTANDING BIOETHICIST, STRONG RELIGIOUS BACKGROUND,  
15 RELIGIOUS COLLEGE, HE WOULD BE TOTALLY ELIGIBLE. WE DO  
16 NOT NEED TO ACTUALLY MENTION THE WORD "RELIGION." ONCE  
17 WE DO, WE OPEN A HUGE CAN OF WORMS. I'D VOTE NO.

18 MR. VOELKER: MARK VOELKER AGAIN. FIRST,  
19 DISCLOSURE. I'M NOT A RELIGIOUS PERSON, BUT I AM A  
20 MORAL PERSON. THERE SEEMS TO BE THIS SORT OF UNWRITTEN  
21 ASSUMPTION THAT IF YOU'RE MORAL, YOU HAVE TO BE  
22 RELIGIOUS. WELL, I'M NOT PARTICULARLY RELIGIOUS AND I  
23 DO CONSIDER MYSELF TO BE MORAL.

24 THERE ARE SOME PRACTICAL PROBLEMS WITH TRYING  
25 TO PUT THEOLOGICAL CRITERIA AS ONE OF THE DESIRABLE

1 TRAITTS FOR THE MEMBERS. AS THE OTHER GENTLEMAN SAID,  
2 THERE'S SO MANY, ESPECIALLY IN CALIFORNIA, THERE'S SO  
3 MANY DIFFERENT RELIGIONS AND SECTS, AND THEY ALL  
4 POTENTIALLY HAVE CONFLICTING ETHICAL STANDARDS ON THESE  
5 VERY ISSUES. IF WE TRY TO CHOOSE PEOPLE WITH THE  
6 THEOLOGICAL BACKGROUND, WE'RE GOING TO PER FORCE  
7 EXCLUDE MANY OF THOSE OTHER VOICES. SO THAT IF THERE'S  
8 GOING TO BE A RELIGIOUS COMPONENT TO THE ETHICAL  
9 DEBATES, PERHAPS IT SHOULD BE DONE NOT IN THIS  
10 COMMITTEE, IN A SEPARATE GROUP. WE'VE ALREADY SORT OF  
11 SPUN OFF ISSUES OF INTELLECTUAL PROPERTY INTO A  
12 SUBCOMMITTEE OR SUBWORKING GROUP.

13 THE ETHICAL ISSUES FROM RELIGIOUS  
14 PERSPECTIVES TO BE CONSIDERED, PERHAPS YOU NEED TO HAVE  
15 AN OPEN FORUM FOR ALL THE DIFFERENT SECTS THAT ARE HERE  
16 IN CALIFORNIA, AND ALL THE DIFFERENT SUBSECTS, AND HAVE  
17 MEETINGS WHERE PEOPLE CAN COME AND DEBATE THE ISSUE  
18 WHERE THIS RELIGIOUS VIEWPOINT IS IN CONFLICT WITH THE  
19 OTHER RELIGIOUS VIEWPOINT. LET ALL THOSE PEOPLE SPEAK  
20 FREELY ABOUT THEIR FEELINGS AND IDEAS. AND REALLY THIS  
21 COMMITTEE, IT SEEMS TO ME, TO BE CONSTITUTED TO DEAL  
22 WITH THE ETHICAL CONSIDERATIONS OF CLINICAL MEDICINE  
23 AND PUTTING STEM CELLS INTO HUMAN BEINGS AND HOW YOU DO  
24 THAT IN A WAY THAT DOESN'T VIOLATE THE INDIVIDUAL  
25 RIGHTS OF PATIENTS OR THINGS LIKE THAT. AND TO EXPAND

1 THE PURVIEW OF THIS GROUP OF PEOPLE HERE TO INCLUDE  
2 PATENTING INTELLECTUAL PROPERTY AND NOW RELIGIOUS  
3 ISSUES, I THINK REALLY ISN'T PRACTICAL. SO IF YOU WANT  
4 TO CONSIDER THESE OTHER ISSUES, YOU REALLY HAVE TO  
5 CREATE GROUPS OF PEOPLE THAT CAN SPEAK TO THOSE  
6 DIRECTLY.

7 CHAIRMAN KESSLER: REMIND YOU OF THE THREE  
8 MINUTES. I WANT TO GIVE FULL AIRING.

9 MR. REYNOLDS: HI, I'M JESSE REYNOLDS FROM  
10 THE CENTER FOR GENETICS IN SOCIETY. AND I SUPPOSE I  
11 HAVE TWO COMMENTS. FIRST, BEFORE I NAME A COUPLE OF  
12 ADDITIONAL DESIRABLE TRAITS, JUST A POSSIBILITY.  
13 THERE'S A NUMBER OF DESIRABLE TRAITS, BOTH LISTED HERE  
14 AND NAME, AND THIS CREATES SOME PROBLEMS WITH THE  
15 LIMITED POOL OF PEOPLE FOR THE WORK -- POTENTIAL  
16 CANDIDATES FOR THE WORKING GROUP THAT IS SPELLED OUT BY  
17 THE STATUTORY LANGUAGE. A POSSIBILITY TO DEAL WITH  
18 THIS MIGHT BE AN ADDITIONAL AD HOC COMMITTEE, SOME SORT  
19 OF ELSI-TYPE COMMITTEE THAT WOULD REPORT TO THE ICOC AS  
20 A WHOLE AND/OR THE STANDARDS WORKING GROUP, THAT COULD  
21 INCORPORATE SOME OF THESE OTHER DESIRABLE TRAITS  
22 BECAUSE IT MIGHT BE DIFFICULT TO FIND CANDIDATES WHO  
23 MEET THE STATUTORY GUIDELINES AND OTHER DESIRABLE  
24 TRAITS.

25 JUST A COUPLE OTHER DESIRABLE TRAITS THAT

1 HAVE COME TO MIND DURING THIS CONVERSATION. EXPERIENCE  
2 WITH THE LAWS AND REGULATIONS SURROUNDING CONFLICTS OF  
3 INTEREST, REPRESENTATIVES OF THE PUBLIC INTEREST, THE  
4 GENERAL PUBLIC INTEREST OUTSIDE OF THE BROADER  
5 SCIENTIFIC ESTABLISHMENT. THE WOMAN OVER THERE ALREADY  
6 MENTIONED REPRESENTATIVES WHO HAVE STUDIED HEALTH  
7 DISPARITIES WITH UNDER-REPRESENTED COMMUNITIES.

8 AND FINALLY, GIVEN THE NATURE OF THE RESEARCH  
9 AT HAND, PEOPLE WITH EXPERIENCE WITH THE ETHICS AND  
10 PROBLEMS SURROUNDING PROVIDING EGGS AND, THUS, SOME  
11 REPRESENTATIVES OF THE WOMEN'S HEALTH COMMUNITY, AS  
12 WELL, GIVEN THE LIKELY NEED FOR EGGS IN STEM CELL  
13 RESEARCH.

14 CHAIRMAN KESSLER: SO YOUR SPECIFIC  
15 RECOMMENDATIONS ARE ON CONFLICTS, WOMEN'S HEALTH,  
16 HEALTH DISPARITIES, WE'VE ALREADY VOTED. THERE WAS A  
17 FOURTH ONE. I'M SORRY.

18 MR. REYNOLDS: YEAH. REPRESENTATIVES OF THE  
19 PUBLIC INTEREST AT LARGE THAT MIGHT BE OUTSIDE THE  
20 TRADITIONAL SCIENTIFIC AND BIOETHICS COMMUNITY.

21 CHAIRMAN KESSLER: SOMEONE FROM THE PUBLIC  
22 RECOMMENDED WE ALSO INCLUDE CONFLICTS, WOMEN'S HEALTH,  
23 AND PUBLIC INTERESTS, AS I HEAR THAT. DOES ANYONE --  
24 WE VOTED ON 12. WE'VE DECIDED TO HOLD THE THEOLOGY  
25 ONE.

1                   MR. SHESTACK: I WOULD CONTINUE TO HOLD. I  
2                   WOULD JUST SORT OF SAY FOR THE MOMENT THAT CLEARLY THE  
3                   ISSUE OF WOMEN'S HEALTH ISSUES IS AN IMPORTANT ONE THAT  
4                   WILL BE DEALT WITH BY THESE PEOPLE WHO ARE -- I MEAN  
5                   THIS IS SORT OF ONE OF THE CLEAR THINGS THAT THE GROUP  
6                   HAS TO DEAL WITH. AND I WOULD HOPE THAT PERHAPS  
7                   DISEASE ADVOCATES MIGHT ALSO BE ABLE TO HANDLE SOME OF  
8                   THE ISSUES OF SCIENCE IN THE PUBLIC INTEREST ISSUE.  
9                   CERTAINLY THEY DON'T HAVE FINANCIAL INTERESTS. THEY  
10                  DON'T HAVE INSTITUTIONAL ADVANCEMENT INTEREST, PERHAPS,  
11                  LIKE SOME OF THE PEOPLE FROM BIG ACADEMIC INSTITUTIONS.  
12                  ONE MIGHT THINK THAT THEY MIGHT EVEN IF THEY DON'T.

13                         CONFLICT OF INTEREST, I BELIEVE, IS ON THIS  
14                         AGENDA AND WILL BE DEALT WITH IN A PRETTY STRONG WAY.  
15                         I THINK ALL THESE THINGS ARE REALLY IMPORTANT ISSUES  
16                         THAT THIS SUBCOMMITTEE HAS TO DEAL WITH AND I THINK  
17                         PRETTY MUCH IS AWARE THAT IT HAS TO DEAL WITH. I DON'T  
18                         KNOW THAT -- I'M NOT SURE WE HAVE TO CHANGE THESE  
19                         STANDARDS TO MAKE SURE THAT WE DEAL WITH THEM. WE  
20                         HAVE -- IT'S GOOD THAT YOU LAID THEM, THAT YOU SHINE A  
21                         LIGHT ON THEM, AND IT'S SOMETHING WE HAVE TO CONSTANTLY  
22                         BE LOOKING AT.

23                         CHAIRMAN KESSLER: IS YOUR RECOMMENDATION --  
24                         IS THERE ANY PROPOSAL TO ADD ANYTHING OTHER THAN THESE  
25                         12 THAT WE'VE DONE AT THIS POINT?

1 DR. SAMUELSON: I THINK IT'S ENOUGH.

2 CHAIRMAN KESSLER: IT'S ENOUGH?

3 MR. SHESTACK: YEAH, FOR NOW.

4 CHAIRMAN KESSLER: THEN LET ME MOVE ON TO ASK  
5 THE QUESTION. DO YOU THINK THAT WE SHOULD LIMIT THE  
6 MEMBERSHIP TO CALIFORNIANS?

7 MR. SHESTACK: AS OPPOSED TO THE OTHER GROUP  
8 WHICH LIMITED IT TO PEOPLE WHO WERE NOT FROM  
9 CALIFORNIA?

10 CHAIRMAN KESSLER: NOT CALIFORNIAN. SO YOU  
11 CAN DEFINE. DO YOU WANT TO EXCLUDE? DO YOU WANT TO  
12 LIMIT? HOW DO YOU DEFINE A CALIFORNIAN? I LEAVE THAT  
13 TO OTHERS.

14 MR. SHESTACK: I SEE NO REASON -- I WOULD  
15 JUST SPEAK ON THIS. I SEE NO REASON TO LIMIT IT. I  
16 WOULD SAY THAT IT WOULD BE NICE TO MAKE IT HEAVILY  
17 CALIFORNIAN FOR NO OTHER REASON THAN IT'S HARD TO DO  
18 THESE THINGS. AND SINCE PEOPLE IN THIS ARE NOT  
19 INVOLVED IN THE SAME KIND OF CONFLICT OF INTEREST  
20 ISSUES AS THE GRANTS COMMITTEE, I THINK WE SHOULD BE  
21 OPEN TO ALL MEMBERS AND WE SHOULD LOOK TOWARDS  
22 CALIFORNIA TO HELP US.

23 CHAIRMAN KESSLER: IT'S OPEN, BUT A  
24 PREFERENCE IS YOUR VIEW FOR CALIFORNIANS?

25 DR. STEWARD: I THINK OPEN IS THE --

1                   MR. SHESTACK:  OPEN IS THE WORD.  WE SHOULD  
2 JUST SAY OPEN.

3                   MR. SHEEHY:  OPEN IS FINE.

4                   MR. SERRANO SEWELL:  OPEN.

5                   DR. SAMUELSON:  (NODS.)

6                   CHAIRMAN KESSLER:  OPEN.  CAN I ASK -- BEFORE  
7 I ASK FOR THE VOTE OF THE SUBCOMMITTEE, ARE THERE  
8 COMMENTS FROM THE PUBLIC ON THE PROPOSED CRITERIA ON  
9 WHETHER TO LIMIT -- ON THIS ISSUE OF MEMBERSHIP TO  
10 CALIFORNIANS?  THE SUBCOMMITTEE LOOKS LIKE IT'S GOING  
11 TOWARD AN OPEN REQUIREMENT.  COMMENTS FROM THE PUBLIC  
12 ON THIS, PLEASE.

13                   DR. REED:  COULD WE MAKE IT OPEN WITH A GOOD  
14 FAITH EFFORT TO REACH OUT TO THE CALIFORNIA SCIENTIFIC  
15 COMMUNITY FIRST?

16                   CHAIRMAN KESSLER:  OTHER VIEWS OF THE PUBLIC;  
17 AND THEN IF THERE'S ANY CHANGES TO THE RECOMMENDATION,  
18 WE CAN HEAR THEM.  ARE THERE ANY OTHER PUBLIC COMMENTS  
19 ON THE ISSUE OF CALIFORNIA?  LET'S GO BACK AND DO IT IN  
20 REVERSE ORDER.  THE LAST ROW.

21                   MS. DARNOVSKY:  MARCY DARNOVSKY.  I WANTED TO  
22 RESPOND TO THE POINT THE SPEAKER IN THE FRONT ROW  
23 RAISED.  SHE RAISED A QUESTION ABOUT WHETHER SCIENTIST  
24 HAS TO BE A NATURAL SCIENTIST GIVEN THE DEFINITION.  
25 AND THAT REALLY BEARS ON THE ISSUE OF HOW BIG THE POOL

1 IS GOING TO BE.

2 CHAIRMAN KESSLER: OTHER COMMENTS ON THE  
3 ISSUE OF CALIFORNIA?

4 MR. VOELKER: MARK VOELKER. I THINK OPEN  
5 WOULD BE GOOD. I THINK IT'S A PRETTY SMALL POOL. YOU  
6 ARE GOING TO BE DRAWING FROM THIS YOUNG INDUSTRY, AS IT  
7 WERE; AND ESPECIALLY WHEN YOU HAVE CONFLICT OF INTEREST  
8 TO TAKE INTO ACCOUNT, YOU MAY BE OVERRESTRICTING THE  
9 POOL OF CANDIDATES IF YOU JUST SAY ONLY CALIFORNIANS.

10 CHAIRMAN KESSLER: COMMENTS.

11 MR. GARRIN: STEVE GARRIN, ASIAN RESOURCE  
12 CENTER. I WOULD AGREE TO OPEN, BUT WITH PREFERENCE TO  
13 CALIFORNIANS.

14 CHAIRMAN KESSLER: THE RECOMMENDATION IS, AS  
15 I UNDERSTAND IT FROM THE SUBCOMMITTEE, IS JUST THE WORD  
16 "OPEN." ANYONE WANT TO AMEND THAT? RIGHT NOW IT'S  
17 OPEN, IT'S ALL COMERS, AS I DEFINE OPEN, RIGHT? DO YOU  
18 WANT TO LEAVE IT THAT WAY? CAN I HAVE A RECOMMENDATION  
19 FROM --

20 DR. STEWARD: I WOULD LEAVE IT. I THINK THAT  
21 THE PRACTICAL MATTER IS THAT IT'S GOING TO BE SKEWED  
22 FOR CALIFORNIANS ANYWAY.

23 MR. SERRANO SEWELL: LOOKING FOR A MOTION?

24 CHAIRMAN KESSLER: YES, I'M LOOKING FOR A  
25 MOTION.



1                   MR. SERRANO SEWELL: I MOVE THAT THE  
2 MEMBERSHIP OF THIS WORKING GROUP BE COMPRISED OF  
3 RESIDENTS AND NONRESIDENTS OF CALIFORNIA.  
4                   MR. SHESTACK: I SECOND.  
5                   CHAIRMAN KESSLER: THAT COULD BE INTERPRETED  
6 THAT YOU WOULD HAVE TO HAVE BOTH, THAT MOTION.  
7                   MR. SERRANO SEWELL: AND/OR. I'M SORRY. OR.  
8                   MR. HARRISON: SO MEMBERSHIP WOULD BE OPEN  
9 TO.  
10                  CHAIRMAN KESSLER: IT'S AN OR. IS THERE A  
11 SECOND ON THAT MOTION?  
12                  DR. SAMUELSON: SECOND.  
13                  CHAIRMAN KESSLER: ROLL CALL, PLEASE.  
14                  MR. KLEINSCHMIDT: DAVID KESSLER.  
15                  CHAIRMAN KESSLER: AYE.  
16                  MR. KLEINSCHMIDT: DAVID SERRANO SEWELL.  
17                  MR. SERRANO SEWELL: AYE.  
18                  MR. KLEINSCHMIDT: JEFF SHEEHY.  
19                  MR. SHEEHY: AYE.  
20                  MR. KLEINSCHMIDT: JOAN SAMUELSON.  
21                  DR. SAMUELSON: AYE.  
22                  MR. KLEINSCHMIDT: JONATHAN SHESTACK.  
23                  MR. SHESTACK: AYE.  
24                  MR. KLEINSCHMIDT: OSWALD STEWARD.  
25                  DR. STEWARD: AYE.

1 CHAIRMAN KESSLER: THAT'S UNANIMOUS.

2 THE SECOND DOCUMENT IN THE PACKET --

3 DR. SAMUELSON: EXCUSE ME. DID WE EXCLUDE  
4 THE HEALTH DISPARITIES?

5 CHAIRMAN KESSLER: NO. THAT WAS INCLUDED.  
6 WE VOTED IN FAVOR OF THAT. THAT WAS ONE OF THE 12 THAT  
7 WAS ADDED.

8 SECOND DOCUMENT IN THE PACKET, THE FLOW CHART  
9 IS BASED ON THE PROCESS THAT THE GRANT SELECTION  
10 SUBCOMMITTEE IS USING FOR THEIR SELECTION PROCESS. AS  
11 INDICATED ON THAT PAGE, WE HAVE TWO MAJOR MECHANISMS  
12 FOR SEEKING NOMINATIONS FOR MEMBERS TO SERVE ON THE  
13 WORKING GROUP. ONE, PROFESSIONAL SOCIETY NEWSLETTERS,  
14 LIST SERVES, AND WEBSITES LIKE THE AMERICAN JOURNAL OF  
15 BIOETHICS, THE AMERICAN SOCIETY FOR BIOETHICS AND THE  
16 HUMANITIES, AND THE INTERNATIONAL SOCIETY OF STEM CELL  
17 RESEARCH, AND TWO PUBLIC RECOMMENDATIONS.

18 AFTER ALL OF THE INITIAL NOMINATIONS HAVE  
19 BEEN MADE, THEY WILL BE SCREENED FOR ELIGIBILITY AND  
20 DISTRIBUTED TO THREE REVIEW TEAMS FOR FURTHER  
21 EXAMINATION. THE THREE REVIEW TEAMS WE WOULD SUGGEST  
22 WOULD BRING SUGGESTIONS FOR SELECTION TO THE NEXT  
23 MEETING OF THE SEARCH SUBCOMMITTEE, AT WHICH TIME THE  
24 POTENTIAL NOMINEES WILL BE DISCUSSED IN AN OPEN  
25 MEETING. EACH REVIEW TEAM WILL BRING AT LEAST EIGHT

1 NAMES TO THE MEETING, GIVING US A MINIMUM OF 24 FOR  
2 PUBLIC DISCUSSION. THE SUBCOMMITTEE WILL THEN SELECT  
3 13 NOMINEES TO BE RECOMMENDED TO THE ICOC FOR THEIR  
4 REVIEW AND APPROVAL.

5 I'D LIKE TO OPEN DISCUSSION AMONG MEMBERS OF  
6 THE SUBCOMMITTEE ABOUT THIS SCREENING PROCESS FOR  
7 REVIEWING NAMES. COMMENTS?

8 MR. SHEEHY: JUST AN ISSUE THAT WAS RAISED IN  
9 THE RESEARCH WORKING GROUP, AND YOU ALL KNOW MORE ABOUT  
10 THIS, AND OS WILL KNOW, THAT THERE IS GOING -- WE KIND  
11 OF IN THE RESEARCH WORKING GROUP IT WAS KIND OF DECIDED  
12 THAT GIVEN PUTTING PEOPLE OUT THERE AND HAVING TO KIND  
13 OF SAY THIS ONE VERSUS THIS ONE, THAT WE SET OUT --

14 MR. SHESTACK: IN A PUBLIC FORUM.

15 MR. SHEEHY: IN A PUBLIC FORUM WE SET UP  
16 WHERE ALL THE NAMES THAT WENT FORWARD WOULD EITHER BE  
17 MAYBE -- AND IT MAY BE DIFFERENT HERE BECAUSE THE PEER  
18 REVIEW PROCESS IS MUCH MORE COMPLEX THAN THIS, BUT IT  
19 WAS SET UP IN A WAY THAT EITHER YOU BECAME A NOMINEE OR  
20 YOU BECAME AN AD HOC MEMBER.

21 MR. SHESTACK: AD HOC ALTERNATE WHEN SPECIAL  
22 REVIEW SECTIONS WERE NEEDED TO ALLOW PEOPLE TO SAY I'D  
23 BE WILLING TO DO THIS FOR YOU, BUT DON'T SLAP ME IN  
24 FACE ABOUT IT AND SAY YOU DON'T WANT ME.

25 CHAIRMAN KESSLER: I DON'T THINK -- THIS IS

1 DIFFERENT. THIS ISN'T AS ANALOGOUS, AS I UNDERSTAND  
2 IT. IS THAT A FAIR?

3 MR. HARRISON: YEAH. THAT WAS A MODIFICATION  
4 THAT WAS MADE TO THE PROPOSAL THAT WAS BEFORE THE GRANT  
5 REVIEW WORKING GROUP, AND THEY DID ULTIMATELY DECIDE TO  
6 RECOMMEND TO THE ICOC THAT THEY WOULD NOMINATE 15  
7 CANDIDATES FOR MEMBERSHIP AND THE OTHER 15 NAMES WOULD  
8 BE FORWARDED AS ALTERNATES ESSENTIALLY.

9 MR. SHESTACK: DID THEY HAVE THE SAME PROCESS  
10 WHERE REVIEW OF ALL NOMINATIONS FOR ELIGIBILITY WAS OUT  
11 OF THE CHAIRMAN'S OFFICE?

12 MS. HALME: YES.

13 DR. STEWARD: COULD I ASK A QUESTION, I  
14 THINK, OF COUNSEL? IS THIS A PERSONNEL MATTER AND,  
15 THEREFORE, OUT OF THE PURVIEW OF BAGLEY-KEENE?

16 MR. HARRISON: THE PROBLEM WE ENCOUNTER IS  
17 THAT THE ACT DEFINES THE MEMBERS -- THE ACT STATES  
18 SPECIFICALLY THAT THE MEMBERS OF THE WORKING GROUP ARE  
19 NOT OFFICERS OR EMPLOYEES OF THE STATE FOR SPECIFIC  
20 ENUMERATED PURPOSES AND, THEREFORE, IT BECOMES  
21 DIFFICULT TO TREAT THEM AS OFFICERS OR EMPLOYEES FOR  
22 THE PURPOSES OF THE PERSONNEL EXCEPTION.

23 DR. STEWARD: THAT HAS IMPLICATIONS FOR HOW  
24 WE WILL DISCUSS THE CANDIDATES.

25 CHAIRMAN KESSLER: SO THESE ARE THE COMMITTEE

1 SELECTION PROCESS, THIS DRAFT. ANY OTHER COMMENTS FROM  
2 THE MEMBERS OF THE SUBCOMMITTEE ON THIS PROCESS?

3 MR. SERRANO SEWELL: I THINK IT'S VERY  
4 PRACTICAL.

5 CHAIRMAN KESSLER: OTHER COMMENTS? COMMENTS  
6 FROM THE PUBLIC ON THIS PROCESS, PLEASE. HEARING NONE,  
7 LET ME KEEP ON MOVING. I WILL ASK FOR A VOTE ON THE  
8 WHOLE PROCESS WHEN WE GO THROUGH ALL THESE DOCUMENTS.

9 THE NEXT DOCUMENT, THE THIRD DOCUMENT IN THE  
10 PACKET, IS SUGGEST A TIME LINE FOR THE SUBCOMMITTEE TO  
11 COMPLETE THE TASK OF IDENTIFYING POTENTIAL MEMBERS TO  
12 THE STANDARDS WORKING GROUP. ONE ITEM THAT WE NEED TO  
13 FINALIZE TODAY IS THE DUE DATE FOR SUBMITTING  
14 INFORMATION FORMS. LET ME SUGGEST --

15 MR. SHESTACK: NOMINATION FORMS?

16 CHAIRMAN KESSLER: NO. THESE ARE INFORMATION  
17 FORMS, AND YOU WILL SEE THERE IS AN INFORMATION FOR  
18 POTENTIAL MEMBERS. THAT'S THE FOURTH DOCUMENT. SO AN  
19 INFORMATION FORM HAS TO BE FILLED OUT BY WHOM, THE  
20 NOMINATOR OR THE NOMINEE?

21 MR. KLEINSCHMIDT: IT'S UP TO THE COMMITTEE.

22 CHAIRMAN KESSLER: WHAT IS STAFF  
23 RECOMMENDING?

24 MR. KLEINSCHMIDT: I WOULD RECOMMEND THAT THE  
25 INDIVIDUAL FILLS IT OUT SO THEY KNOW THEIR SITUATION.

1                   CHAIRMAN KESSLER:  THE NOMINEE.  SO BY THE  
2  22D WE WOULD HAVE TO HAVE --

3                   MR. SHESTACK:  THIS IS ACTUALLY THE FORM THAT  
4  THEN GOES TO THE CHAIR'S OFFICE.  SO NOMINATORS GET IT  
5  TO THEIR NOMINEES, PUBLIC MEMBERS.

6                   CHAIRMAN KESSLER:  OR IF WE GET NOMINATIONS,  
7  WE COULD SEND THAT OUT.

8                   MR. KLEINSCHMIDT:  GET A NAME.

9                   CHAIRMAN KESSLER:  WE GET A NAME, WE SEND IT  
10 OUT, AND SAY ARE YOU INTERESTED.

11                  MR. SHESTACK:  OKAY.

12                  CHAIRMAN KESSLER:  AGAIN, FEBRUARY 22D IS HOW  
13 MANY WORKING DAYS FROM TODAY?

14                  DR. SAMUELSON:  TWENTY-TWO.

15                  CHAIRMAN KESSLER:  IT'S NOT -- HOW MANY  
16 WORKING DAYS, ABOUT 17.  NOW, POINT OF DISCLOSURE.  THE  
17 GRANTS WORKING GROUP GAVE TEN DAYS.

18                  MR. SHESTACK:  WHICH IS UNREALISTIC.

19                  CHAIRMAN KESSLER:  WE'RE GOING TO BE BEHIND  
20 THEM.  WHEN WE TELL PEOPLE ON THURSDAY, WE MAY BE  
21 VIEWED AS SOMEWHAT TAKING A LITTLE TIME, BUT ARE YOU --

22                  MR. SHESTACK:  I THOUGHT TEN DAYS WAS  
23 OPTIMISTIC ON THE GRANTS WORKING GROUP.

24                  CHAIRMAN KESSLER:  THIS IS WHEN WE GET THE  
25 INFORMATION BACK.  LET ME OPEN DISCUSSION AMONG MEMBERS

1 OF THE SUBCOMMITTEE ABOUT THIS TIME LINE. ESPECIALLY  
2 INTERESTED IN YOUR THOUGHTS ON THE DUE DATE FOR  
3 RECEIVING INFORMATION FORMS. I MADE THE POINT OF  
4 INFORMATION ABOUT TEN DAYS FROM THE GRANT SUBCOMMITTEE.  
5 COMMENTS FROM THE SUBCOMMITTEE?

6 DR. SAMUELSON: I'M WONDERING WHERE A  
7 DISCUSSION OF THE COMPOSITION OF THE WORKING GROUP  
8 AND/OR AD HOC ADJUNCTS TO IT, DEPENDING ON THE SCOPE OF  
9 THE WORKING GROUP, HOW THAT GETS FOLDED INTO THIS  
10 BECAUSE PRESUMABLY --

11 MR. SHESTACK: THAT'S TO BE DUE IN MARCH.  
12 THAT'S THE MEETING THAT HAPPENS IN MARCH. WE HAVE A  
13 MIX AND THEN FIGURE OUT WHAT YOU LIKE THE BEST MIX IS.

14 DR. SAMUELSON: BUT IF WE RESOLVE AS A FULL  
15 ICOC THAT, LET'S SAY, IP IS UNDER THE AMBIT OF THIS  
16 WORKING GROUP, THEN DON'T WE NEED TO THINK ABOUT HOW WE  
17 BEST HANDLE THAT WITH THE CONSTRAINTS OF THE ACT AND SO  
18 ON? FIGURE THAT OUT BEFORE WE --

19 MR. SHESTACK: EVEN IF IT WERE -- I THOUGHT  
20 THE ASSUMPTION HERE WAS THERE WOULD HAVE TO BE AN AD  
21 HOC COMMITTEE TO DEAL WITH IP BECAUSE THE AREAS OF  
22 EXPERTISE THAT WE WANT REPRESENTED COULDN'T POSSIBLY  
23 FIT ON THIS, THEN REPORTED TO THIS COMMITTEE AS A  
24 SEPARATE MATTER.

25 DR. SAMUELSON: I WOULDN'T WANT THAT TO

1 DILUTE THE IMPORTANCE OF THAT.

2 CHAIRMAN KESSLER: NO.

3 MR. SHESTACK: IT'S TOTALLY SEPARATE.

4 CHAIRMAN KESSLER: MAY I ASK IF THERE'S  
5 PUBLIC COMMENT ON THE PROPOSED TIMETABLE? NO PUBLIC  
6 COMMENT.

7 THE FOURTH DOCUMENT IN THE PACKET IS THE  
8 INFORMATION FORM THAT WAS JUST ALLUDED TO. THE  
9 INFORMATION REQUEST TO ALLOW US TO SCREEN FOR  
10 QUALIFICATIONS AND PROVIDE ADDITIONAL INFORMATION,  
11 INCLUDING A SELF-RATING OF EXPERTISE IN PERTINENT  
12 SUBJECT AREAS AND A TIME COMMITMENT PROVISION. THIS  
13 FORM WILL HELP TO DOCUMENT OUR PROCESS FOR SELECTING  
14 MEMBERS, AS ALREADY DISCUSSED. AFTER INITIAL SCREENING  
15 FOR BASIC QUALIFICATIONS, THE INFORMATION FORMS WOULD  
16 BE DIVIDED AMONG OUR SUBCOMMITTEE MEMBERS TO NARROW  
17 DOWN THE POTENTIAL WORKING GROUP MEMBERS INTO A SUBSET  
18 TO BE DISCUSSED OPENLY BY THE SEARCH SUBCOMMITTEE.

19 MR. SHESTACK: ONE THING HERE IS JOB  
20 DESCRIPTION SAYS LENGTH OF TERMS IS SIX YEARS. AS WE  
21 WERE LOOKING AT NOMINEES, IN THE OTHER GROUP IT WAS  
22 DETERMINED YOU MIGHT SERVE SIX YEARS, BUT YOU DIDN'T  
23 HAVE TO. IT'S NOT REALISTIC TO ASK THEM TO SERVE SIX  
24 YEARS.

25 MR. KLEINSCHMIDT: IT'S A STATUTE THING FOR



1 SIX-YEAR TERMS, BUT SOMEONE COULD RESIGN.

2 MR. SHESTACK: IT'S ONEROUS.

3 CHAIRMAN KESSLER: OTHER COMMENTS ABOUT THE  
4 INFORMATION FORM FROM SUBCOMMITTEE MEMBERS? ANY PUBLIC  
5 COMMENT ON THE INFORMATION FORM OF POTENTIAL MEMBERS?

6 MS. DARNOVSKY: IS THE MAY 1ST TARGET DATE  
7 SET?

8 CHAIRMAN KESSLER: EVERYONE SEES THIS IS  
9 POINT 3. YES, ON THE SECOND PAGE OF THE INFORMATION.  
10 WE MAY NOT HAVE TO INCLUDE THAT. THE POINT HERE WAS  
11 THE SPECIFIC TIME FRAME IN GIVING A SENSE.

12 MR. KLEINSCHMIDT: IT'S JUST A NUMBER THAT --  
13 DATE THAT BOB KLEIN HAS MENTIONED AS A TARGET DATE.

14 CHAIRMAN KESSLER: IT'S NOT -- I THINK IT'S  
15 PROBABLY BETTER. IT'S A GOOD COMMENT. LET'S TAKE IT  
16 OFF THIS FORM SINCE IT'S NOT BEEN FORMALLY ADOPTED. WE  
17 CAN TAKE OFF THAT TIME. WE'LL JUST SAY INTERIM  
18 STANDARDS ARE BEING ADOPTED BY THE ICOC. IT GIVES A  
19 SENSE THAT WE REFER SPECIFICALLY TO MAY 1ST.

20 MR. SHEEHY: ONE THING THAT I MISSED. ON  
21 THIS NO. 2, WE SHOULD INCLUDE THE NEW STANDARDS THAT WE  
22 PUT IN. MAYBE THAT'S NOT CLEAR. REMEMBER WE ADDED.

23 CHAIRMAN KESSLER: WE ADDED SOME OTHERS.  
24 WE'LL DO THOSE. THAT'S A GOOD POINT.

25 MR. SHEEHY: MAKE SURE THAT'S CLEAR.

1 CHAIRMAN KESSLER: ANY OTHER COMMENTS FROM  
2 THE PUBLIC ON THIS?

3 THE FIFTH DOCUMENT IS A DRAFT JOB  
4 DESCRIPTION. THE JOB DESCRIPTION GIVES POTENTIAL  
5 MEMBERS OF THE WORKING A GROUP A SUMMARY OF THE  
6 EXPECTATIONS BASED ON THE SPECIFICS OF PROP 71. THIS  
7 DOCUMENT WAS CREATED TO PROVIDE POTENTIAL WORKING GROUP  
8 MEMBERS WITH MORE INFORMATION ABOUT THE DUTIES OF THE  
9 WORKING GROUP.

10 LET ME ASK THE MEMBERS OF THE SUBCOMMITTEE TO  
11 DISCUSS THIS JOB DESCRIPTION.

12 MR. SHESTACK: THAT'S FINE.

13 CHAIRMAN KESSLER: MUCH OF IT IS TAKEN FROM  
14 THE STATUTE. WHILE THE SUBCOMMITTEE MEMBERS ARE  
15 REVIEWING THIS, LET ME ASK IF THERE'S PUBLIC COMMENT ON  
16 THE JOB DESCRIPTION? GIVE EVERYONE A FEW MOMENTS TO  
17 READ IT.

18 COMMENTS FROM THE MEMBERS OF THE SUBCOMMITTEE  
19 ON THE JOB DESCRIPTION? COMMENTS FROM THE PUBLIC ON  
20 THE JOB DESCRIPTION?

21 DR. SAMUELSON: WHAT I'M SEEING LOOKS FINE.  
22 IT WOULD BE NICE TO HAVE A LITTLE MORE TIME TO REVIEW  
23 IT. PERHAPS WE COULD HAVE SOME OPPORTUNITY TO PROVIDE  
24 INDIVIDUAL RECOMMENDATIONS OR SOMETHING.

25 CHAIRMAN KESSLER: WHY DON'T I -- I THINK

1 THAT THAT'S FAIR. LET ME, THEN, ASK FOR A MOTION TO  
2 ACCEPT THE PROCESS THAT WE'VE DISCUSSED TO SELECT  
3 MEMBERSHIP AND RECOMMENDATIONS FOR THE SCIENTIFIC AND  
4 MEDICAL ACCOUNTABILITY STANDARDS WORKING GROUP WITHIN  
5 THE CONFINES THAT WE'RE GOING TO HAVE TO STAY WITH THE  
6 STATUTE, THE LANGUAGE OF THE STATUTE, AND THE JOB  
7 DESCRIPTION IN ITSELF. IF THERE ARE SUGGESTIONS THAT  
8 HELP CLARIFY THAT, WE CAN -- STAFF CAN CERTAINLY, I  
9 THINK, HELP CLARIFY CERTAIN WORDS IF YOU HAVE THOSE  
10 COMMENTS.

11 CAN I ASK FOR A MOTION? IS ANYONE WILLING TO  
12 PROPOSE A MOTION TO ACCEPT THE PROCESS AS WE JUST  
13 OUTLINED IT?

14 DR. STEWARD: I'LL MOVE.

15 MR. SHESTACK: SECOND.

16 CHAIRMAN KESSLER: LET ME ASK FOR A PUBLIC  
17 COMMENT.

18 AGAIN, I'VE GONE THROUGH EACH OF THE  
19 ELEMENTS. LET ME ASK ON THE WHOLE PROCESS, IS THERE  
20 PUBLIC COMMENT ON THE PROCESS WE JUST DISCUSSED?

21 MS. DARNOVSKY: INCLUDING THE JOB  
22 DESCRIPTION.

23 CHAIRMAN KESSLER: THIS IS INCLUDING THE JOB  
24 DESCRIPTION.

25 MS. DARNOVSKY: SIMILAR TO MY LAST QUESTION,

1 I NOTICE THE CONFLICT OF INTEREST PARAGRAPH. IT SAYS  
2 THAT CONFLICT OF INTEREST STANDARDS WILL BE ADOPTED BY  
3 THE ICOC BASED ON THE STANDARDS APPLICABLE TO MEMBERS  
4 OF THE SCIENTIFIC REVIEW COMMITTEE OF NIH. IS THAT A  
5 DECISION BY THE ICOC, THAT CONFLICT OF INTEREST  
6 STANDARDS WOULD BE BASED ON THAT?

7 CHAIRMAN KESSLER: IF I'M, AND COUNSEL CAN  
8 HELP ME, AS I UNDERSTAND IT, WE ARE -- THERE'S A  
9 PRESUMPTION OF THOSE STANDARDS IN THE STATUTE. WE HAVE  
10 TO ADOPT THEM, BUT WE HAVE TO LOOK TOWARD THOSE  
11 STANDARDS.

12 MR. SHESTACK: IT'S SORT OF A MINIMAL  
13 PRESUMPTION.

14 DR. SAMUELSON: IT'S RECOMMENDED.

15 MR. SHESTACK: IT'S RECOMMENDED TO WORK SO  
16 KEEP -- TO WORK, SO WE CAN KEEP WORKING, RIGHT?

17 CHAIRMAN KESSLER: RIGHT. SO IT IS -- SO IT  
18 IS TRUE THE MEMBERS OF THIS WORKING GROUP ARE GOING TO  
19 HAVE TO COMPLY WITH CONFLICT OF INTEREST AND IS  
20 DETERMINED BY THE ICOC BASED ON. I THINK THAT'S  
21 PROBABLY CONSISTENT WITH THE STATUTORY LANGUAGE.

22 MR. HARRISON: STATUTORY LANGUAGE SAYS THE  
23 ICOC SHALL ADOPT CONFLICT OF INTEREST RULES BASED ON  
24 STANDARDS APPLICABLE TO MEMBERS OF THE SCIENTIFIC  
25 REVIEW COMMITTEES OF THE NATIONAL INSTITUTES OF HEALTH.

1                   CHAIRMAN KESSLER:   SO WE'RE JUST PARROTING  
2   THE STATUTE THERE.

3                   MS. DARNOVSKY:   SO IT'S NOT THAT THIS WILL BE  
4   A MINIMUM STANDARD.   IT'S SOMETHING THAT COULD BE  
5   CONSTRUED AS BASED ON.

6                   CHAIRMAN KESSLER:   BASED ON IS THE OPERATIVE  
7   STATUTORY LANGUAGE, AND WE'RE ADOPTING THAT.

8                   ANY OTHER PUBLIC COMMENTS ON THE PROCESS AS  
9   IDENTIFIED?

10                  MS. MCMURRY:   JUST A QUICK QUESTION.  
11   MICHELLE MCMURRY.   IS THE TIME LINE FOR THIS IN LINE  
12   WITH THE TIME LINE FOR THE MEDICAL RESEARCH GRANTS  
13   COMMITTEE GROUP, THAT THEY'LL HAVE INTERIM STANDARDS IN  
14   PLACE TO START AWARDING GRANTS?   IS THAT EVEN NEEDED?

15                  MR. KLEINSCHMIDT:   YES.   IT'S MY  
16   UNDERSTANDING.

17                  CHAIRMAN KESSLER:   IT'S NOT EXACTLY THE SAME  
18   BECAUSE OF, AS I POINTED OUT, THE DIFFERENCE BETWEEN  
19   TEN DAYS AND ABOUT 17 DAYS HERE.   SO IT'S --

20                  MR. KLEINSCHMIDT:   ALL OF THIS HAS TO GO TO  
21   THE ICOC, SO THOSE MEETINGS ARE GOING TO BE THE MOMENT  
22   WHERE THE BIG DECISION IS GOING TO BE MADE.

23                  CHAIRMAN KESSLER:   COULD I CALL FOR A VOTE ON  
24   THE MOTION TO ADOPT THE PROCESS AS WE DISCUSSED IT?  
25   AND CAN WE HAVE A ROLL CALL VOTE?

1 MR. KLEINSCHMIDT: DAVID KESSLER.  
2 CHAIRMAN KESSLER: AYE.  
3 MR. KLEINSCHMIDT: DAVID SERRANO SEWELL.  
4 MR. SERRANO SEWELL: AYE.  
5 MR. KLEINSCHMIDT: JEFF SHEEHY.  
6 MR. SHEEHY: AYE.  
7 MR. KLEINSCHMIDT: JOAN SAMUELSON.  
8 DR. SAMUELSON: AYE WITH A COMMENT. I DO  
9 FEEL THAT THERE IS A BIT OF HASTE, AND PERHAPS IT'S IN  
10 THE END GOING TO BE CONSIDERED NECESSARY, BUT I THINK  
11 WE NEED TO BE CAREFUL. AND IT DOES CONCERN ME  
12 SOMEWHAT. I'D LIKE TO MAKE A RECORD OF THAT.  
13 MR. KLEINSCHMIDT: JONATHAN SHESTACK.  
14 MR. SHESTACK: AYE.  
15 MR. KLEINSCHMIDT: OSWALD STEWARD.  
16 DR. STEWARD: AYE.  
17 CHAIRMAN KESSLER: WITH THAT ONE CAVEAT. I'M  
18 ALWAYS -- I HAVE NO PROBLEMS WITH BEING ACCUSED OF  
19 GOING TOO FAST. I'M ONE OF THE FOREMOST DISEASE  
20 ADVOCATES. WE'RE IN REVERSE ROLES A LITTLE.  
21 DR. SAMUELSON: THAT'S TRUE.  
22 CHAIRMAN KESSLER: LET US TURN TO THE  
23 FOURTH -- IF I CAN DO THAT OFF THE RECORD.  
24 LET US NOW TURN TO THE FOURTH ITEM ON THE  
25 AGENDA AS YOU SEE IT IN FRONT OF YOU. THE LANGUAGE OF

1 PROPOSITION 71 IS CLEAR THAT ALL THREE WORKING GROUPS  
2 ARE ADVISORY AND HAVE NO FINAL DECISION-MAKING  
3 AUTHORITY, THUS ARE NOT CONSIDERED PUBLIC OFFICIAL  
4 EMPLOYEES OR CONSULTANTS FOR THE PURPOSE OF THE  
5 POLITICAL REFORM ACT. HOWEVER, PROP 71 ALSO STATES  
6 THAT THE ICOC SHALL ADOPT CONFLICT OF INTEREST RULES  
7 BASED ON STANDARDS APPLICABLE TO MEMBERS OF SCIENTIFIC  
8 REVIEW COMMITTEES OF THE NATIONAL INSTITUTES OF HEALTH  
9 TO GOVERN THE PARTICIPATION OF NON-ICOC WORKING GROUP  
10 MEMBERS.

11 ICOC CHAIRMAN BOB KLEIN ASKED ME TO BRING  
12 THIS ISSUE UP AT TODAY'S MEETING TO GET THE  
13 SUBCOMMITTEE'S RECOMMENDATIONS ON HOW TO DEVELOP  
14 CONFLICT OF INTEREST POLICY FOR POTENTIAL WORKING GROUP  
15 MEMBERS AS IT IS IN THE JURISDICTION OF ETHICAL  
16 CONSIDERATIONS. I'VE RESEARCHED THE ISSUE, AND I WANT  
17 TO SHARE WITH YOU A COPY OF THE RELEVANT NIH  
18 GUIDELINES. ANYONE WHO HAS PARTICIPATED WITH THE STUDY  
19 SECTION OF THE NIH IS FAMILIAR WITH THESE GUIDELINES,  
20 BUT I REALIZE THAT MANY OF THE MEMBERS OF THIS  
21 SUBCOMMITTEE, CERTAINLY THE PUBLIC, MAY NOT BE FAMILIAR  
22 WITH THEM.

23 MY SUGGESTION IS THAT THIS SUBCOMMITTEE, IF I  
24 MAY, REQUEST THAT THE ICOC AUTHORIZE AN INDEPENDENT  
25 NON-NIH CONSULTANT WHO IS FAMILIAR WITH THE CURRENT NIH

1 STANDARDS TO DEVELOP SPECIFIC CONFLICT OF INTEREST  
2 GUIDELINES FOR THE WORKING GROUP MEMBERS. THAT  
3 CONSULTANT CAN THEN BRING THOSE RECOMMENDATIONS TO THE  
4 WHOLE ICOC.

5 NOW, ONE PERSON TO BE CONSIDERED FOR THIS  
6 ROLE IS SOMEBODY WHO PRESENTED, I BELIEVE, AT IRVINE,  
7 WHOSE NAME IS JAMES WRIGHT, WHO SERVES AS A GENERAL  
8 COUNSEL FOR THE NATIONAL ACADEMIES OF SCIENCE. I THINK  
9 HE DEMONSTRATED HIS EXPERTISE IN CONFLICT OF INTEREST  
10 IN GENERAL AND SPECIFICALLY IN NIH CONFLICT OF INTEREST  
11 POLICIES IN PARTICULAR AT THAT BEST PRACTICES MEETING  
12 FOR PROPOSITION 71 HELD IN DECEMBER 2004. THAT IS JUST  
13 ONE NAME. WE WANTED TO DO SOME HOMEWORK AND BE ABLE TO  
14 BRING YOU, BUT WE BY NO MEANS WANT TO BE EXCLUSIVE.  
15 THIS WOULD BE SOMEBODY WHO COULD CONSULT ON WHAT THE  
16 POLICY SHOULD BE.

17 ARE THERE COMMENTS FROM THE MEMBERS OF THE  
18 COMMITTEE ABOUT HIRING A CONSULTANT TO ADVISE THE ICOC  
19 ON MATTERS OF CONFLICT OF INTEREST?

20 MR. SERRANO SEWELL: THIS IS FOR ADOPTING  
21 CONFLICT OF INTEREST GUIDELINES, NOT ADVISING THE  
22 MEMBERS ABOUT A CONFLICT OF INTEREST?

23 CHAIRMAN KESSLER: NO.

24 MR. SERRANO SEWELL: WE WOULD LOOK TO THE  
25 ATTORNEY GENERAL'S OFFICE OR OUR COUNSEL FOR THAT.



1                   CHAIRMAN KESSLER:  OR YOU WOULD LOOK TO  
2                   SPECIFIC COUNSEL.  THAT WILL BE SOMEBODY ELSE.  THIS IS  
3                   THE POLICY.

4                   NOW, THE STATUTE, AS I UNDERSTAND IT, AND AS  
5                   COUNSEL JUST READ IT, IT GIVES US GUIDANCE.  IT SHOULD  
6                   BE BASED UPON THE NIH, BUT THERE MAY BE OTHER THINGS  
7                   THAT MAY WANT TO BE CONSIDERED.  AND WE NEED SOMEBODY  
8                   WHO HAS SOME EXPERTISE WHO CAN BRING THOSE ISSUES AND  
9                   MAKE SOME RECOMMENDATIONS TO THE ICOC.  SO I WAS  
10                  LOOKING FOR SOME EXPERTISE ON THIS ISSUE.

11                  DR. STEWARD:  SO JUST -- I'M NOT SURE I  
12                  UNDERSTAND THE PROCESS HERE.  THE STANDARDS WORKING  
13                  GROUP THAT WE'RE IN THE PROCESS OF BEING THE SEARCH  
14                  COMMITTEE FOR ARE RESPONSIBLE FOR DEVELOPING CONFLICT  
15                  OF INTEREST GUIDELINES AND MAKING RECOMMENDATIONS TO  
16                  THE ICOC.  SO ARE YOU SUGGESTING THIS PERSON BE  
17                  SEPARATE FROM THAT GROUP, ADVISOR TO THAT GROUP?  I'M  
18                  NOT SURE WHERE WE ARE ON THIS.

19                  CHAIRMAN KESSLER:  WE NEED TO HAVE CONFLICT  
20                  OF INTEREST GUIDELINES FOR THE MEMBERS WHO SERVE ON  
21                  BOTH -- ALL THESE WORKING GROUPS.  SO YOU CAN'T BE A  
22                  MEMBER OF THE WORKING GROUP AND SET YOUR OWN CONFLICT  
23                  OF INTEREST GUIDELINE.  LET ME MAKE SURE.  IN ORDER TO  
24                  BE ON THESE WORKING GROUPS, WE'VE DETERMINED THAT THERE  
25                  HAS TO BE CONFLICT OF INTEREST POLICY.  THE STATUTE

1 SAYS THEY SHOULD BE BASED UPON, BUT THEY STILL HAVE TO  
2 BE VOTED UPON BY THE ICOC. THEY CAN BE MODIFIED. THEY  
3 CAN BE ADDED TO, BUT THEY HAVE TO BE BASED ON.

4 I JUST WANTED TO BRING SOME ADDITIONAL  
5 EXPERTISE, PEOPLE WHO KNOW THE NIH GUIDELINES,  
6 INDEPENDENCE HERE. AND THE THOUGHT WAS THE NATIONAL  
7 ACADEMIES OF SCIENCES HAS THAT KIND OF EXPERTISE IN  
8 THIS INDIVIDUAL WHO COULD MAKE A RECOMMENDATION AS TO  
9 WHAT POLICY WE SHOULD FOLLOW. IF WE'RE GOING TO  
10 FINE-TUNE, CHANGE, AMEND THE NIH GUIDELINES, THAT COULD  
11 THEN BROUGHT TO THE ICOC AS A WHOLE, PUBLIC CAN COMMENT  
12 ON THOSE RECOMMENDATIONS, AND THEN THE WORKING GROUPS  
13 WOULD HAVE TO LIVE UNDER THOSE CONFLICT OF INTEREST  
14 POLICIES. THAT WAS THE GOAL.

15 DR. STEWARD: I'M SORRY. JUST LET ME  
16 UNDERSTAND. I THINK I UNDERSTAND WHAT YOU SAID. SO  
17 WE'RE NOW TALKING ABOUT CONFLICT OF INTEREST GUIDELINES  
18 FOR THE MEMBERS OF THE WORKING GROUPS.

19 CHAIRMAN KESSLER: YES.

20 DR. STEWARD: NOT THE CONFLICT OF INTEREST  
21 GUIDELINES THAT WILL BE DEVELOPED FOR GRANTEES AND SO  
22 FORTH.

23 CHAIRMAN KESSLER: NO. THAT'S CORRECT.

24 MR. SHEEHY: MY ONLY QUESTION IS THE  
25 APPLICATION OF THESE CONFLICT OF INTEREST RULES TO THE

1 PEOPLE THAT WE'RE PICKING TO BE. IN OTHER WORDS, TWO  
2 COMMITTEES ARE GOING TO BE REVIEWING THE PEOPLE WHO ARE  
3 GOING TO BE APPOINTED FOR SIX YEARS. UNDER WHAT  
4 CONFLICT OF INTEREST RULES IS THAT VETTING TAKING  
5 PLACE? NIH CONFLICT OF INTEREST RULES? THE SECOND  
6 PROCEDURE THAT YOU JUST ELABORATED.

7 IT SEEMS TO ME THE TIME LINE HAS US APPROVING  
8 THESE BEFORE WE MEET AGAIN.

9 MR. SERRANO SEWELL: I WOULD SAY TO THAT  
10 POINT, IT'S A GOOD POINT, BUT WHOEVER IS INTERESTED IN  
11 SERVING ON THIS WORKING GROUP, THERE'S GOING TO BE THIS  
12 CAVEAT, I THINK, THAT THE ICOC HAS RETAINED A  
13 CONSULTANT THAT IS REVIEWING THE CONFLICT OF INTEREST  
14 RULES THAT WILL BE APPLICABLE TO EVERYONE, ALL THE  
15 WORKING GROUP MEMBERS. IF YOU ARE SELECTED TO SERVE ON  
16 THIS WORKING GROUP, YOU WILL BE SUBJECT TO THOSE  
17 CONFLICT OF INTEREST RULES AS WELL. WE'RE LOOKING AT  
18 DIFFERENT EXAMPLES. HERE'S WHAT ONE LOOKS LIKE.  
19 YOU'RE PROBABLY GOING TO BE FAMILIAR WITH IT. AND  
20 THAT'S THE WAY -- IF THEY CAN'T LIVE IT, THEY'LL HAVE  
21 TO RESIGN.

22 CHAIRMAN KESSLER: YOU WILL REMEMBER ON THE  
23 JOB DESCRIPTION WE SAID EXACTLY THAT. THE ICOC IS  
24 GOING TO BE ADOPTING THEM BASED ON THE NIH, AND WE EVEN  
25 SAID IN THE ITALICS NOTE, THESE RULES HAVE NOT YET BEEN

1 ADOPTED BY THE ICOC.

2 MR. SHEEHY: BECAUSE WE'RE GOING TO BE  
3 PUTTING FORWARD -- I MEAN EVERYBODY IS GOING TO BE  
4 PICKED BEFORE THESE. ARE YOU GOING TO SCREEN --

5 CHAIRMAN KESSLER: NO. NO. I THINK WE HAVE  
6 TO FIND PEOPLE WHO MEET THOSE CRITERIA. ICOC HAS TO  
7 ADOPT POLICIES. AND THEN I THINK WE NEED THE ICOC AND  
8 THE INSTITUTE NEED TO HAVE A FORMAL VETTING PROCESS OF  
9 NAMES AGAINST THAT CONFLICT OF INTEREST POLICY. THAT  
10 WOULD BE MY GUESS, BUT THAT'S LATER ON IN THE PROCESS.

11 MR. HARRISON: YES.

12 CHAIRMAN KESSLER: I'M NOT READY TO RECOMMEND  
13 ANYTHING, BUT I WOULD HOPE THAT WE WOULD HAVE EXPERTISE  
14 TO BE ABLE TO DO THE VETTING. WHAT WE'RE ASKING FOR IS  
15 THE ABILITY TO RECOMMEND THAT WE HIRE A CONSULTANT TO  
16 HELP GUIDE US IN ADOPTING THE POLICY.

17 MR. SERRANO SEWELL: ONE LAST QUESTION,  
18 DAVID. IS IT ALL THE WORKING GROUPS THAT HAVE -- NOT  
19 THE WORKING GROUPS, BUT THE SEARCH COMMITTEES FOR THE  
20 WORKING GROUP MEMBERSHIP THAT HAVE MET THUS FAR, THE  
21 SAME ISSUE HAS BEEN RAISED AND THE SAME NAME'S BEEN  
22 RECOMMENDED, I ASSUME, RIGHT?

23 CHAIRMAN KESSLER: BOB HAS GIVEN US THE  
24 CHARGE TO MAKE THAT RECOMMENDATION, THIS COMMITTEE,  
25 BECAUSE IT'S THE STANDARDS, THE ETHICAL. SO WE DO IT.

1 I HAVE BEEN -- I HAVE TALKED, FULL DISCLOSURE, WITH ED  
2 HOLMES, WHO CHAIRS THE GRANT, EARLIER AND TOLD HIM I  
3 WAS GOING TO RAISE THIS, AND HE WAS SUPPORTIVE OF THIS  
4 PROCESS.

5 I FORGET, I APOLOGIZE, IS THERE PUBLIC  
6 COMMENT ON THE ISSUE OF HIRING A CONSULTANT TO ADVISE  
7 US ON CONFLICT OF INTEREST POLICIES?

8 DR. REED: I THINK THIS IS EXCELLENT. IT'S  
9 EXACTLY NEEDED. PROPOSITION 71 IS BEING PUT UNDER  
10 UNPRECEDENTED SCRUTINY, AND EVERY SINGLE STEP THAT YOU  
11 GUYS DO IS BEING WATCHED AND WATCHED AND WATCHED. SO I  
12 THINK THIS IS ONE MORE LAYER, ONE MORE WAY WE CAN SAY,  
13 LOOK, WE'RE TAKING EVERY POSSIBLE PRECAUTION TO  
14 PRECLUDE EXACTLY THE OBJECTIONS THAT HAVE BEEN MADE.  
15 EXCELLENT IDEA.

16 CHAIRMAN KESSLER: OTHER PUBLIC COMMENT? DO  
17 WE HAVE A MOTION TO --

18 MS. DARNOVSKY: I AGREE. I THINK IT'S A  
19 REALLY GOOD IDEA, BUT I DON'T KNOW IF YOU'RE ASKING  
20 SPECIFICALLY ABOUT JAMES WRIGHT. I DON'T KNOW  
21 MR. WRIGHT. QUESTION IS DO THE OTHER COMMITTEE MEMBERS  
22 KNOW JAMES WRIGHT?

23 CHAIRMAN KESSLER: WE'RE NOT MAKING A  
24 SPECIFIC RECOMMENDATION ON JAMES WRIGHT. I JUST GAVE  
25 HIM AS ONE POTENTIAL NAME. THERE IS IN THE IRVINE

1 DOCUMENTS, THERE IS A LITTLE BIOGRAPHY. BUT AGAIN, I  
2 DON'T WANT TO FOCUS ON ANY ONE INDIVIDUAL. I WAS JUST  
3 GIVING AN EXAMPLE OF SOMEONE THE ACTUAL INSTITUTE COULD  
4 HIRE. WE'RE RECOMMENDING THAT THERE BE A CONSULTANT.

5 DO WE HAVE A MOTION TO RECOMMEND THE ICOC  
6 EMPLOY A CONSULTANT TO MAKE RECOMMENDATIONS ON ADOPTION  
7 OF THE NIH CONFLICT OF INTEREST GUIDELINES?

8 MR. SHESTACK: SO MOVED.

9 CHAIRMAN KESSLER: IS THERE A SECOND?

10 DR. STEWARD: SECOND.

11 CHAIRMAN KESSLER: IS THERE ANY FURTHER  
12 PUBLIC COMMENT ON THIS QUESTION? SEEING NONE, LET ME  
13 CALL FOR A VOTE ON THE MOTION.

14 DR. SAMUELSON: BEFORE YOU DO, LET ME JUST  
15 MAKE A COMMENT. I'M NOT GOING TO CONDITION MY VOTE ON  
16 IT. BUT I THINK IT MAY BE IMPORTANT FOR US TO HAVE  
17 SOME GREATER EXPERTISE UNDER OUR OWN BELTS AS WELL AS  
18 HAVING THE EXPERTISE OF WHATEVER PERSON WE HAVE CONSULT  
19 WITH US. BUT I THINK THIS IS A WAY TO GET THE THING  
20 GOING.

21 CHAIRMAN KESSLER: COULD I ASK FOR A VOTE ON  
22 THE MOTION, AND HAVE A ROLL CALL, PLEASE.

23 MR. KLEINSCHMIDT: DAVID KESSLER.

24 CHAIRMAN KESSLER: AYE.

25 MR. KLEINSCHMIDT: DAVID SERRANO SEWELL.

1 MR. SERRANO SEWELL: AYE.

2 MR. KLEINSCHMIDT: JEFF SHEEHY.

3 MR. SHEEHY: I'LL ABSTAIN.

4 MR. KLEINSCHMIDT: JOAN SAMUELSON.

5 DR. SAMUELSON: AYE.

6 MR. KLEINSCHMIDT: JONATHAN SHESTACK.

7 MR. SHESTACK: AYE.

8 MR. KLEINSCHMIDT: OSWALD STEWARD.

9 DR. STEWARD: AYE.

10 CHAIRMAN KESSLER: MOTION PASSES WITH THE ONE

11 ABSTENTION.

12 LET ME NOTE THAT IT IS 6 O'CLOCK. ACTUALLY

13 MY WATCH, PEOPLE HAVE DIFFERENT TIMES? ANYONE WANT TO

14 BE THE OFFICIAL WATCH KEEPER? YOU HAVE 5:55. THAT

15 GIVES ME FIVE MORE MINUTES BEFORE I HAVE TO ASK THE

16 QUESTION.

17 LET ME TURN TO ITEM 5 ON THE AGENDA. BEFORE

18 WE BEGIN TO DISCUSS THIS ITEM, LET ME BRING TO YOUR

19 ATTENTION TWO DOCUMENTS THAT WERE POSTED WITH THIS

20 AGENDA ITEM. ONE IS ASSEMBLY CONCURRENT RESOLUTION 252

21 AND THE ACTUAL LANGUAGE, NO. 2 A LETTER FROM THE

22 CALIFORNIA COUNCIL ON SCIENCE TECHNOLOGY TO PARTICIPATE

23 WITH THEIR COMMITTEE TO DEVELOP RECOMMENDATIONS ON

24 INTELLECTUAL PROPERTY CREATED WITH STATE FUNDS.

25 AS CHAIRMAN BOB KLEIN EXPLAINED AT THE FIRST

1 TWO MEETINGS OF THE ICOC, THERE HAS BEEN A REQUEST FOR  
2 NOMINATIONS OF TWO MEMBERS OF THE ICOC TO SERVE ON THIS  
3 STATE COMMITTEE.

4 I WOULD LIKE TO SUGGEST THAT WE ASK MEMBERS  
5 OF THE ICOC WITH EXPERTISE IN INTELLECTUAL PROPERTY  
6 ISSUES TO IDENTIFY THEMSELVES AT THE NEXT ICOC MEETING  
7 AND DISCUSS WHO WOULD BE BEST SUITED TO SERVE ON THE  
8 ACR-252 COMMITTEE.

9 FURTHERMORE, I BELIEVE THAT IT WOULD BE  
10 ADVISABLE TO SELECT ONE MEMBER WITH ACADEMIC IP  
11 EXPERIENCE AND ANOTHER WITH INDUSTRY IP EXPERIENCE TO  
12 FORM THE TWO-MEMBER TEAM REPRESENTING THE ICOC.

13 POINT OF INFORMATION. DR. SUSAN HACKWOOD,  
14 WHO IS EXECUTIVE DIRECTOR OF THE CALIFORNIA COUNCIL ON  
15 SCIENCE AND TECHNOLOGY, SUPPORTS ICOC MEMBERS SUSAN  
16 BRYANT AND MICHAEL GOLDBERG AS REPRESENTATIVES ON THIS  
17 COMMITTEE. SUSAN BRYANT HAS ACADEMIC EXPERTISE AND  
18 MICHAEL GOLDBERG HAS INDUSTRY EXPERTISE.

19 LET ME ASK FOR OPEN DISCUSSION AMONG MEMBERS  
20 OF THE SUBCOMMITTEE ABOUT OUR RECOMMENDATIONS TO SELECT  
21 TWO ICOC MEMBERS TO PARTICIPATE IN THE ACR 252 PROCESS.  
22 COMMENTS FROM THE MEMBERS.

23 MR. SHEEHY: COULD I -- DIDN'T WE KIND OF  
24 DISCUSS THIS EARLIER AND ADOPT A MOTION? IS THIS GOING  
25 TO BE RECOMMENDING IP? IT SEEMS TO ME THAT WE KIND OF



1 THOUGHT THAT IP OUGHT TO COME FROM AN AD HOC COMMITTEE  
2 THAT WOULD RECOMMEND TO THE --

3 MR. SHESTACK: THAT'S NOT WHAT THIS DOES.  
4 THIS IS AN ODD THING WE HAVE TO DEAL WITH. THIS IS  
5 SORT OF INTEGRATING, YOU KNOW --

6 CHAIRMAN KESSLER: CAN I JUST ASK A FAVOR?  
7 YOU WANT TO STRIKE THE WORD "ODD" FOR THE RECORD. THIS  
8 IS -- I THINK BOB HAS AGREED TO COOPERATE FULLY WITH  
9 THIS.

10 MR. SHESTACK: IT HELPS TIE IN ALL THESE  
11 INSTITUTIONS IN CALIFORNIA THAT ARE MAKING POLICY ON  
12 THESE ISSUES. IT DOESN'T --

13 CHAIRMAN KESSLER: DOES NOT BIND.

14 MR. SHESTACK: -- BIND THEM OR US.

15 MR. SHEEHY: THAT ANSWERS MY QUESTION.

16 MR. SHESTACK: SEEMS LIKE A GOOD THING TO DO  
17 TO HAVE THE COMMUNITIES --

18 CHAIRMAN KESSLER: HOW SHOULD WE COME UP WITH  
19 THE TWO ICOC?

20 MR. SERRANO SEWELL: ARE YOU RECOMMENDING,  
21 DAVID, THAT WE POLL THE ICOC MEMBERS AT THE THURSDAY  
22 MEETING? YOU IDENTIFIED MICHAEL AND SUSAN.

23 CHAIRMAN KESSLER: THOSE ARE NAMES THAT WERE  
24 BROUGHT TO US. I'M TAKING NO POSITION. WE HAVEN'T  
25 ASKED. ONLY SUSAN HACKWOOD --

1                   MR. SERRANO SEWELL: WHO IDENTIFIED THEM  
2 THEN?

3                   CHAIRMAN KESSLER: SUSAN HACKWOOD RECOMMENDED  
4 THOSE NAMES, AND I DON'T WANT ANYTHING NOT TO BE IN  
5 FULL PUBLIC VIEW. SOMEBODY RECOMMENDS --

6                   MR. SHESTACK: WE KNOW IF THOSE GUYS ARE  
7 WILLING TO DO IT?

8                   CHAIRMAN KESSLER: NO. IT DOESN'T  
9 NECESSARILY HAVE TO BE. I THINK MY SENSE IS IP ISSUES,  
10 I THINK THERE'S THREE BROAD POINTS. ONE, YOU WANT  
11 BROADER PUBLIC INTEREST, MEDICAL ETHICS VIEW, BUT THERE  
12 ALSO IS THE WORLD OF ACADEMIC IP, WORLD OF BIOTECH IP,  
13 AND I THOUGHT SOME BALANCE ALSO. I THINK EVERYONE ON  
14 THE ICOC REPRESENTS, I HOPE, THE PUBLIC INTEREST HERE.

15                   DR. STEWARD: JUST A QUESTION OF PROCEDURE.  
16 IS IT POSSIBLE TO SEND THAT REQUEST FOR VOLUNTEERS OUT  
17 BEFORE THURSDAY'S MEETING, OR IS THAT SOMETHING THAT  
18 CANNOT BE SENT OUT UNDER BAGLEY-KEENE RULES UNTIL THE  
19 MEETING ITSELF?

20                   MR. HARRISON: IT'S POSSIBLE TO SEND THE  
21 REQUEST OUT, BUT WE NEED TO CONSIDER WHETHER THE ICOC  
22 CAN ACTUALLY MAKE THE APPOINTMENT AT THE MEETING.

23                   CHAIRMAN KESSLER: IT'S NOT BEEN AGENDAD WITH  
24 SPECIFICITY. WE CAN CERTAINLY GET A SENSE OF WHO WOULD  
25 BE WILLING TO SERVE. WE COULDN'T FORMALLY ADOPT THAT

1 UNTIL THE FOLLOWING MEETING WHEN IT'S AGENDAD PROPERLY.

2 MR. HARRISON: THAT'S CORRECT.

3 DR. STEWARD: I WOULD JUST SAY IT WOULD BE  
4 NICE TO BE ABLE TO SEND IT OUT SO PEOPLE CAN BE  
5 THINKING ABOUT SERVING.

6 CHAIRMAN KESSLER: STAFF, BEFORE THURSDAY, IF  
7 ANYONE WOULD BE WILLING TO SERVE. AND IS IT OKAY IF WE  
8 RELAY SUSAN HACKWOOD'S RECOMMENDATION FOR WHAT IT IS  
9 AND PEOPLE CAN DECIDE? SHE'S THE DIRECTOR OF THAT  
10 CALIFORNIA COUNCIL. OKAY.

11 SO COMMENTS FROM THE PUBLIC ON THIS ITEM? NO  
12 COMMENTS.

13 LET ME TURN TO AGENDA NO. 6. BEFORE -- I  
14 DON'T THINK WE NEED IT. JUST WE'RE GOING -- THIS IS  
15 AGENDAD FOR DISCUSSION.

16 AGENDA ITEM 6, BEFORE WE BEGIN TO DISCUSS  
17 THIS ITEM, I WANT TO BRING YOUR ATTENTION TO A DOCUMENT  
18 THAT WAS POSTED WITH THE AGENDA ITEM, THE LANGUAGE OF  
19 SENATE BILL 322. SENATE BILL 322 HAS BEEN MENTIONED BY  
20 CHAIRMAN BOB KLEIN AT THE FIRST TWO ICOC MEETINGS AS  
21 SOMETHING TO BE AWARE OF AND TO COOPERATE WITH TO THE  
22 EXTENT POSSIBLE. SENATE BILL 322 REQUIRES THE  
23 CALIFORNIA DEPARTMENT OF HEALTH SERVICES TO DEVELOP  
24 GUIDELINES FOR RESEARCH INVOLVING THE DEVIATION OR USE  
25 OF -- DERIVATION OR USE OF -- DERIVATION OR USE OF

1 HUMAN EMBRYONIC STEM CELLS IN THE STATE.

2 THESE GUIDELINES ARE TO BE DEVELOPED BY AN  
3 APPOINTED 13-MEMBER TASK FORCE. SENATE BILL 322 WAS  
4 PASSED WHEN THERE WAS NO GUIDELINES FOR EMBRYONIC STEM  
5 CELL RESEARCH. WE NOW KNOW THAT THE NATIONAL ACADEMIES  
6 ARE SCHEDULED TO RELEASE STANDARDS IN APRIL OF THIS  
7 YEAR.

8 FIRST A BIT OF HISTORY ON THIS MEASURE.  
9 SENATOR DEBRA ORTIZ, A STRONG PROPONENT AND CHAMPION OF  
10 STEM CELL RESEARCH SPONSORED THIS BILL IN THE 2003  
11 LEGISLATIVE SESSION. AFTER PASSING THE LEGISLATURE, IT  
12 WAS SIGNED INTO LAW BY THEN GOVERNOR GRAY DAVIS IN  
13 SEPTEMBER 2003. THE BILL REQUIRES THAT GUIDELINES WERE  
14 TO BE ISSUED BY JANUARY 1, 2005. HOWEVER, AT THE TIME  
15 OF THE SIGNING, NO NEW FUNDING WAS INCLUDED FOR  
16 STAFFING THE EFFORT. IN LAST YEAR'S LEGISLATIVE  
17 SESSION, MONEY FOR STAFFING THAT CREATED THE TASK FORCE  
18 WAS INCLUDED IN THE STATE BUDGET. SINCE LAST SUMMER  
19 DHS STAFF HAVE BEEN IDENTIFIED -- IDENTIFIED POTENTIAL  
20 MEMBERS, BUT AT THIS TIME NONE OF THE 13 MEMBERS HAVE  
21 BEEN NAMED, NOR HAS THE TASK FORCE MET. NEEDLESS TO  
22 SAY, THE JANUARY 2005 DEADLINE WAS NOT MET.

23 WHILE I BELIEVE THE ICOC AND THE STANDARDS  
24 WORKING GROUP SHOULD FULLY COOPERATE WITH SENATE BILL  
25 322 TASK FORCE, IT'S MY RECOMMENDATION THAT WE SHOULD

1 SEND A LETTER TO THE GOVERNOR TO GET A FORMAL PROGRESS  
2 REPORT ON SENATE BILL 322 TASK FORCE. UNTIL WE KNOW  
3 THIS INFORMATION, IT IS UNCLEAR HOW TO PROCEED TO  
4 COOPERATE. AT A MINIMUM, I'D LIKE TO RECOMMEND THAT  
5 THE APPROPRIATE INSTITUTE STAFF ATTEND THE MEETINGS OF  
6 SENATE BILL 322 TASK FORCE WHEN THEY ACTUALLY HAPPEN  
7 AND REPORT BACK TO THE ICOC.

8 DR. GEORGE CUNNINGHAM, WHO HAS BEEN APPOINTED  
9 THE HEAD OF THIS TASK FORCE IS PRESENT AT THIS MEETING.  
10 DR. CUNNINGHAM, DO YOU HAVE ANYTHING TO ADD ON THIS  
11 PARTICULAR POINT?

12 DR. CUNNINGHAM: ONLY TO GIVE YOU WHAT I CALL  
13 EUPHEMISTICALLY PROGRESS REPORT. WE HAVE -- I HAVE  
14 SENT FORWARD 14 NAMES TO THE DIRECTOR. SINCE WE HAD A  
15 COMMUNICATION FROM SENATOR ORTIZ' OFFICE THAT SHE  
16 WANTED REPRESENTATIVES FROM WOMEN'S HEALTH GROUP, AND  
17 THAT WAS ADDED TO IT. OUR GROUP IS STATUTORILY  
18 REQUIRED TO HAVE TWO LAWYERS, TWO RELIGIOUS  
19 PERSPECTIVES, AND TWO BIOETHICISTS, AND SEVEN MEDICAL  
20 SCIENTISTS.

21 WE HAVE -- WE HAVE TWO POSITIONS, A  
22 PROFESSIONAL POSITION AND A CLERICAL POSITION. WE'VE  
23 HIRED A CLERK. WE HAVE BEEN UNABLE YET TO FILL THE  
24 CIVIL SERVICE POSITION FOR THE PROFESSIONAL. I HAVE --  
25 I CAN'T -- I THINK YOUR SUGGESTION IS AN EXCELLENT ONE

1 BECAUSE WE'RE NOT AT LIBERTY TO RELEASE NAMES UNTIL  
2 THEY'RE OFFICIALLY APPOINTED. AND THAT'S ONE WAY TO  
3 GET THE OFFICIAL NAMES.

4 I HAVE MEETING CALENDARS FOR FEBRUARY AND  
5 MARCH FOR THE COMMITTEE ONCE THEY'RE APPOINTED. AND  
6 WE'RE READY TO START OUR ORIENTATION MEETING AS SOON AS  
7 THEY'RE APPOINTED. AND I AM IN COMMUNICATION WITH KIRK  
8 AND STAFF ABOUT OUR ACTIVITIES, AND I PLAN TO ATTEND  
9 THE FEBRUARY MEETING TO KEEP ABREAST OF WHAT THIS GROUP  
10 IS DOING.

11 CHAIRMAN KESSLER: THANK YOU, DR. CUNNINGHAM.  
12 I'D LIKE TO ASK MEMBERS OF THE SUBCOMMITTEE --

13 DR. CUNNINGHAM: LET ME JUST MAKE ONE COMMENT  
14 JUST SO YOU UNDERSTAND THE DIFFERENCE. THE DIFFERENCE  
15 IS IF YOUR PROJECT IS FUNDED WITH PROP 71, YOU HAVE  
16 EXEMPTIONS FROM THE GUIDELINES THE STATE DEVELOPS.

17 THERE IS ONE SECTION OF THE CODE THAT YOU DO  
18 HAVE TO FOLLOW. THAT IS THE GUIDELINES WE DEVELOP WITH  
19 RESPECT TO DONATION OF EMBRYOS AND OVUM. IF YOU GET  
20 YOUR FUNDING FROM PRIVATE FUNDING, FROM FEDERAL  
21 FUNDING, FROM OTHER STATES, THEN OUR GUIDELINES ARE  
22 APPLICABLE. AND THAT'S THE REASON WE WANT TO MAKE SURE  
23 TO THE EXTENT POSSIBLE THAT THE GUIDELINES ARE  
24 ESSENTIALLY THE SAME.

25 CHAIRMAN KESSLER: THANK YOU, DR. CUNNINGHAM,

1 FOR THAT CLARIFICATION.

2 LET ME OPEN DISCUSSION UP TO MEMBERS OF THE  
3 SUBCOMMITTEE ABOUT SENDING A LETTER TO THE GOVERNOR TO  
4 REQUEST A PROGRESS REPORT ON SENATE BILL 322 TASK  
5 FORCE. COMMENTS FROM THE MEMBERS.

6 ARE THERE COMMENTS FROM THE PUBLIC ON THIS  
7 ITEM?

8 CAN I ASK FOR A MOTION TO WRITE A LETTER TO  
9 THE GOVERNOR REQUESTING A REPORT ON THE PROGRESS OF THE  
10 COMMITTEE CREATED BY SENATE BILL 322?

11 DR. SAMUELSON: WHAT'S THE PURPOSE OF SENDING  
12 A LETTER? ARE WE NUDGING?

13 CHAIRMAN KESSLER: WE WANT TO COOPERATE, BUT  
14 THERE'S NOTHING WE CAN COOPERATE WITH RIGHT NOW BECAUSE  
15 WE DON'T KNOW THE MAKEUP. SO THAT WOULD BE THE  
16 PURPOSE. AGAIN, IT'S IN THE SPIRIT OF COOPERATION.  
17 THAT WOULD BE HOW THE LETTER IS, WE WANT TO COOPERATE  
18 WITH. ONCE YOU TELL US THE PROGRESS, WE WILL BE READY  
19 TO COOPERATE.

20 DR. STEWARD: I'M SORRY. ALONG THOSE LINES,  
21 THEN, COULD MAYBE WE JUST SORT OF REPHRASE THAT LETTER  
22 A LITTLE BIT AS AN INVITATION TO COOPERATE RATHER THAN  
23 A REQUEST FOR A PROGRESS REPORT?

24 DR. SAMUELSON: YEAH. YEAH. YEAH.

25 CHAIRMAN KESSLER: THAT'S FINE. CAN WE HAVE

1 THAT -- ARE YOU WILLING TO PUT THAT IN A MOTION?

2 DR. STEWARD: THAT'S THE MOTION.

3 CHAIRMAN KESSLER: DO WE HAVE A SECOND?

4 DR. SAMUELSON: SECOND.

5 CHAIRMAN KESSLER: CAN I ASK WHETHER THERE'S

6 ANY PUBLIC COMMENT ON THAT MOTION? CAN I ASK THAT,

7 KIRK, WOULD BE KIND ENOUGH TO CALL THE ROLL.

8 MR. KLEINSCHMIDT: DAVID KESSLER.

9 CHAIRMAN KESSLER: AYE.

10 MR. KLEINSCHMIDT: DAVID SERRANO SEWELL.

11 MR. SERRANO SEWELL: AYE.

12 MR. KLEINSCHMIDT: JEFF SHEEHY.

13 MR. SHEEHY: AYE.

14 MR. KLEINSCHMIDT: JOAN SAMUELSON.

15 DR. SAMUELSON: AYE.

16 MR. KLEINSCHMIDT: JONATHAN SHESTACK.

17 MR. SHESTACK: AYE.

18 MR. KLEINSCHMIDT: OSWALD STEWARD.

19 DR. STEWARD: AYE.

20 CHAIRMAN KESSLER: IT'S UNANIMOUS.

21 ITEM NO. 7 ON THE AGENDA, THIS I JUST WOULD

22 LIKE TO AS LOUD AS WE CAN SEND THIS MESSAGE FROM EVERY

23 HILLTOP IN THIS CITY AND IN THIS STATE, LET US REMIND

24 ANY INTERESTED PARTY TO EITHER URGE THEM TO APPLY FOR

25 MEMBERSHIP TO THE STANDARDS WORKING GROUP OR TO



1 NOMINATE QUALIFIED CANDIDATES FOR MEMBERSHIP.

2 AS DISCUSSED EARLIER, OUR INFORMATION FORM  
3 AND JOB DESCRIPTION WILL BE POSTED ON CIRM.CA.GOV. FOR  
4 WEBSITE INFORMATION ABOUT THE CANDIDATES -- ACTUALLY  
5 THE INFORMATION FORM IS GOING TO BE DUE ON FEBRUARY  
6 22D, SO YOU NEED TO GIVE US ENOUGH TIME TO BE ABLE TO  
7 GET THOSE INFORMATION FORMS FILLED OUT BY ANY NOMINEES.  
8 SO AS SOON AS POSSIBLE, BUT THE WORD NEEDS TO GO FORTH  
9 THAT WE NEED NOMINATIONS TO BE ABLE TO ASK THEM TO FILL  
10 OUT THE INFORMATION FORM OR TO SELF-NOMINATE.

11 MR. VOELKER: SO AGAIN, WHERE'S THAT WEBSITE  
12 WHERE WE CAN GET THE CRITERIA?

13 CHAIRMAN KESSLER: CIRM.CA.GOV.

14 ARE THERE ANY COMMENTS FROM THE MEMBERS ON  
15 THE CALL FOR NOMINATIONS?

16 DR. SAMUELSON: WHAT WAS THAT DEADLINE?

17 CHAIRMAN KESSLER: THE DEADLINE FOR THE  
18 INFORMATION FORMS IS FEBRUARY 22D.

19 MR. VOELKER: AND THAT'S RECEIVED BY YOU GUYS  
20 BY FEBRUARY 22D OR POSTMARKED?

21 CHAIRMAN KESSLER: WHY DON'T WE SAY  
22 POSTMARKED, FAX DATED, E-MAIL DATED BY MIDNIGHT ON THE  
23 22D.

24 ARE THERE COMMENTS FROM THE PUBLIC ON THIS  
25 ITEM ON THE CALL FOR NOMINATIONS ON THIS REQUEST?

1                   MR. BARGLOW: IS THIS THE LAST OPPORTUNITY  
2 FOR THE PUBLIC TO COMMENT BEFORE WE ADJOURN?

3                   CHAIRMAN KESSLER: IF I MAY, LET'S MAKE IT  
4 THAT, IF THAT'S OKAY.

5                   MR. BARGLOW: I WANT TO INTRODUCE MYSELF TO  
6 YOU ALL. I'M RAYMOND BARGLOW, AND I'M ON THE ADVISORY  
7 BOARD OF STEM CELL ACTION NETWORK, WHICH IS A NATIONWIDE  
8 PATIENT ADVOCACY ORGANIZATION. WE DO HAVE SOME  
9 COMMENTS ABOUT THE PROCEEDINGS TODAY. I KNOW WE'D HAD  
10 A HECK OF A PACKED AGENDA, AND WE'VE ACCOMPLISHED ONE  
11 HECK OF A LOT. I WONDER IF MY COMMENTS, IF THEY COULD  
12 BE SOMEHOW READ INTO THE PROCEEDINGS. I CAN E-MAIL  
13 THEM, OR I CAN GIVE THE TRANSCRIBER A SHEET SO THAT --  
14 ALSO, I HANDED IT OUT TO EVERYONE ANYWAY.

15                   CHAIRMAN KESSLER: THE HANDOUT, I BELIEVE, IS  
16 THE --

17                   MR. BARGLOW: IF SOMEONE DOESN'T HAVE IT.

18                   CHAIRMAN KESSLER: SO WHY DON'T WE ASK.  
19 HEARING NO OBJECTION, THIS IS INCLUDED IN THE RECORD.  
20 IS THAT PERMISSIBLE, COUNSEL?

21                   MR. HARRISON: ABSOLUTELY.

22                   CHAIRMAN KESSLER: ANY OTHER COMMENTS FROM  
23 THE PUBLIC?

24                   ITEM NO. 8 ON THE AGENDA IS ADJOURNMENT. I  
25 APOLOGIZE FOR BEING A LITTLE OVER. IS THERE A MOTION

1 TO ADJOURN?

2 DR. STEWARD: SO MOVED.

3 CHAIRMAN KESSLER: IS THERE A SECOND?

4 MR. SERRANO SEWELL: SECOND.

5 CHAIRMAN KESSLER: ALL IN FAVOR. DO I NEED A  
6 ROLL CALL? ALL IN FAVOR OF ADJOURNMENT. IF YOU GET UP  
7 AND LEAVE, I TAKE THAT AS A SIGN. THANK YOU ALL VERY  
8 MUCH FOR COMING TODAY.

9 (THE MEETING WAS THEN ADJOURNED AT 06:12  
10 P.M.)

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