

**BETH C. DRAIN, CA CSR NO. 7152**

BEFORE THE  
ACCESSIBILITY AND AFFORDABILITY WORKING GROUP OF THE  
INDEPENDENT CITIZENS' OVERSIGHT COMMITTEE  
TO THE  
CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE  
ORGANIZED PURSUANT TO THE  
CALIFORNIA STEM CELL RESEARCH AND CURES ACT  
REGULAR MEETING

LOCATION: VIA ZOOM

DATE: OCTOBER 11, 2022  
2 P.M.

REPORTER: BETH C. DRAIN, CA CSR  
CSR. NO. 7152

FILE NO.: 2022-37

**133 HENNA COURT, SANDPOINT, IDAHO 83864  
208-920-3543 DRAIBE@HOTMAIL.COM**

**BETH C. DRAIN, CA CSR NO. 7152**

**I N D E X**

<b>ITEM DESCRIPTION</b>	<b>PAGE NO.</b>
<b>OPEN SESSION</b>	
1. CALL TO ORDER	3
2. ROLL CALL	3
<b>DISCUSSION ITEMS</b>	
3. UPDATES ON MEDICAL AFFAIRS POLICY AND UPDATES ON PATIENT SUPPORT PROGRAM	4
4. PUBLIC COMMENT	NONE
5. ADJOURNMENT	25

**BETH C. DRAIN, CA CSR NO. 7152**

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

OCTOBER 11, 2022; 2 P.M.

CHAIRMAN TORRES: I'M GOING TO CALL THIS TO ORDER. AND WHY DON'T YOU CALL THE ROLL. IF WE DON'T HAVE A QUORUM, WE'LL LEAVE THE ROLL OPEN TILL WE DO. MARIANNE, IF YOU'D CALL THE ROLL, AND WE'LL GET TO AS CLOSE --

MS. DEQUINA-VILLABLANCA: I JUST WANT TO MAKE SURE THE RECORDING WAS ON.

DAN BERNAL.

MR. BERNAL: PRESENT.

MS. DEQUINA-VILLABLANCA: ANN BOYNTON.  
JAMES DE BENEDETTI.

MR. DE BENEDETTI: HERE.

MS. DEQUINA-VILLABLANCA: DANA DORNSIFE.  
DAVID GOLDMAN. TED GOLDSTEIN.

DR. GOLDSTEIN: HERE.

MS. DEQUINA-VILLABLANCA: DAVID HIGGINS.

DR. HIGGINS: HERE.

MS. DEQUINA-VILLABLANCA: HARLAN LEVINE.  
PAT LEVITT. ADRIANA PADILLA.

DR. PADILLA: HERE.

MS. DEQUINA-VILLABLANCA: AMMAR QADAN.

DR. QADAN: PRESENT.

MS. DEQUINA-VILLABLANCA: AL ROWLETT.

**BETH C. DRAIN, CA CSR NO. 7152**

1 MR. ROWLETT: PRESENT.

2 MS. DEQUINA-VILLABLANCA: MAHESWARI

3 SENTHIL. DAVID SERRANO-SEWELL. ADRIENNE SHAPIRO.

4 MS. SHAPIRO: HERE.

5 MS. DEQUINA-VILLABLANCA: JONATHAN THOMAS.

6 CHAIRMAN THOMAS: HERE.

7 MS. DEQUINA-VILLABLANCA: ART TORRES.

8 MR. TORRES: HERE. PRESENT.

9 ALL RIGHT. WE'LL LEAVE THE ROLL OPEN  
10 UNTIL WE HAVE NEW MEMBERS, AND THEN WE'LL DECLARE  
11 THAT WE HAVE A QUORUM. SO I'D LIKE TO PROCEED WITH  
12 THE UPDATES ON THE MEDICAL AFFAIRS POLICY. AND,  
13 SEAN, TAKE IT AWAY.

14 DR. TURBEVILLE: CERTAINLY. LET ME SHARE  
15 THE SLIDES, AND GIVE ME A THUMBS UP IF YOU CAN SEE  
16 THESE.

17 CHAIRMAN TORRES: I GOT 'EM.

18 DR. TURBEVILLE: ALL RIGHT. WONDERFUL.  
19 WELL, HAPPY TUESDAY, EVERYBODY. THANK YOU. I KNOW  
20 EVERYBODY IS INCREDIBLY BUSY. I DON'T ANTICIPATE TO  
21 USE THE ENTIRE TIME, BUT WE'LL SEE HOW THIS GOES.

22 COUPLE OF UPDATES. ONE, OF COURSE, WE HAD  
23 THE ICOC MEETING LAST WEEK, VERY ENGAGING, RECEIVED  
24 A LOT OF COMMENTS. A COUPLE UPDATES. OF COURSE,  
25 THE CONCEPT PLAN WAS APPROVED. THERE WERE A COUPLE

**BETH C. DRAIN, CA CSR NO. 7152**

1 OF VERY GOOD ASKS THAT WE ARE GOING TO INCORPORATE  
2 INTO THE RFP. ONE, OF COURSE, IS ANY APPLICANT THAT  
3 RESPONDS WHAT THEIR EXPERIENCE IS WITH THE  
4 COMMUNITY-BASED ORGANIZATION, CBO. SO THAT WAS  
5 CLEARLY EXPRESSED AS AN INTEREST AT THE ICOC.

6 AND THE OTHER ONE THAT'S VERY IMPORTANT,  
7 OF COURSE, IS THE DEI. SO WHAT'S THEIR EXPERIENCE  
8 AND THEIR POLICY WITH DEI, AND HOW DOES THAT MATCH  
9 OUR CULTURE AND OUR PHILOSOPHY HERE AT CIRM?

10 FROM THE PATIENT SUPPORT SIDE, TODAY I'D  
11 ACTUALLY LIKE TO TALK ABOUT SOMETHING DIFFERENT.  
12 AND THAT IS WITH RESPECT TO POLICY. SO, ONE, THIS  
13 IS AN AREA THAT CERTAINLY HAS BEEN MY AREA OF  
14 EXPERTISE, BUT THERE'S BEEN A LOT OF DISCUSSION ON  
15 ALL THE POLICY THAT'S TAKING PLACE RIGHT NOW, NOT  
16 ONLY UP IN CAPITOL HILL, BUT ALSO AT THE STATE  
17 LEVEL. AND SO I WAS HOPING FOR THIS PRESENTATION  
18 REALLY TO BE ONE OF MANY. AND THAT MEANING THAT  
19 THIS WOULD BE SORT OF AN UPDATE, WHAT WE'RE SORT  
20 LISTENING TO, WHAT'S OUT THERE WITH RESPECT TO  
21 LEGISLATION THAT MAY IMPACT ACCESS AND  
22 AFFORDABILITY, PARTICULARLY ON THE CELL AND GENE  
23 SIDE.

24 WE ARE NOW ATTENDING RIGHT NOW THE MEETING  
25 AT THE MESA. AND THIS MORNING'S PRESENTATION

**BETH C. DRAIN, CA CSR NO. 7152**

1 KICKOFF REALLY WAS ABOUT ACCESS AND AFFORDABILITY  
2 WITH ALL THESE NEW THERAPIES THAT ARE JUST NOW  
3 HITTING THE MARKETPLACE.

4 SO, FIRST, LET'S START OFF WITH A LITTLE  
5 BIT OF A BACKGROUND. I DO HAVE AN ASK FROM THE  
6 TEAM. SO THERE'S NO VOTING THAT'S GOING TO TAKE  
7 PLACE TODAY, BUT I DO WANT TO ASK THE TEAM TO  
8 PROVIDE US, MYSELF, GEOFF, MEDICAL AFFAIRS TEAM,  
9 GUIDANCE ON AREAS THAT WE SHOULD BE FOCUSING ON WITH  
10 RESPECT TO RESEARCH AND PERHAPS DOWN THE ROAD AS WE  
11 BECOME A LITTLE MORE ROBUST ON THIS SIDE IS PERHAPS  
12 A POLICY FOR CIRM IN TERMS OF ACTIVITIES THAT WE  
13 WANT TO SUPPORT AND THINGS THAT PERHAPS WE DON'T  
14 WANT TO SUPPORT FROM THE PATIENT PERSPECTIVE. SO  
15 REALLY NOT A WHOLE LOT OF AN ASK THIS PRESENTATION,  
16 BUT MORE ENGAGING THAN ANYTHING HOPEFULLY.

17 SO ALL OF YOU PROBABLY ALREADY KNOW THIS,  
18 AND THIS HAS ALREADY CHANGED THIS MORNING, BUT THERE  
19 ARE 24 APPROVED CELLULAR AND GENE PRODUCTS RIGHT NOW  
20 IN THE MARKETPLACE. AND ACCORDING TO THE  
21 PRESENTATION THIS MORNING, THEY ANTICIPATE, THEY  
22 BEING THE FDA, ANTICIPATE THAT 10 TO 25 WILL BE  
23 APPROVED EVERY YEAR MOVING FORWARD. SO THERE'S 2200  
24 ACTIVE CLINICAL TRIALS RIGHT NOW IN CELL AND GENE  
25 THERAPY, SEVERAL THERAPEUTIC AREAS, MUCH LIKE OUR

**BETH C. DRAIN, CA CSR NO. 7152**

1 PORTFOLIO.

2 AND IF YOU DO A LITERATURE REVIEW, IF YOU  
3 WILL, THERE'S SEVERAL FEDERAL, STATE LEGISLATIVE  
4 ACTIVITIES THAT WE'RE FOLLOWING HERE AT CIRM THAT  
5 COULD IMPACT PATIENTS, PARTICULARLY THE BARRIERS TO  
6 ACCESS AND AFFORDABILITY TO SOME OF THESE THERAPIES.

7 SO, AGAIN, THE PURPOSE OF THIS  
8 PRESENTATION IS REALLY JUST TO GIVE YOU A FLAVOR OF  
9 WHAT'S OUT THERE, WHAT WE'RE WATCHING, AND THEN GET  
10 SOME FEEDBACK ON WHERE WE NEED TO GO.

11 WE CONTINUE TO ADDRESS OR AT LEAST PROVIDE  
12 RECOMMENDATIONS, SOME SOLUTIONS TO LOWER THOSE  
13 BARRIERS WITH RESPECT TO ACHIEVING BROAD, EQUITABLE  
14 ACCESS TO REGENERATIVE MEDICINES. YOU'RE GOING TO  
15 SEE THE SLIDE PROBABLY OVER AND OVER AGAIN; AND AS  
16 WE DEVELOP MORE AND MORE PROGRAMS, HOPEFULLY THEY'RE  
17 GOING TO SUPPORT EACH ONE OF THE CONCEPTS.

18 WHEN YOU THINK ABOUT LEGISLATION, THAT  
19 COULD BE ANOTHER COMPONENT THAT IMPACTS ACCESS AND  
20 AFFORDABILITY. SO IF YOU THINK ABOUT IT, NOT IN ANY  
21 PARTICULAR ORDER, BUT, FOR EXAMPLE, THERE'S  
22 LEGISLATION RIGHT NOW ON TREATMENTS. WHO GETS  
23 TREATED? WHERE THEY GET TREATED? WHERE ARE THEY  
24 GOING TO BE INFUSED? THE POSTMARKETING COMPONENT.  
25 THAT'S AN AREA THAT WE'RE LOOKING INTO RIGHT NOW.

**BETH C. DRAIN, CA CSR NO. 7152**

1 ANOTHER AREA IS, AND I THINK THIS IS SORT  
2 OF A SLEEPER, IF YOU WILL, IS THE DISTRIBUTION. AND  
3 HAVING OBVIOUSLY WORKED ON THE INDUSTRY SIDE, I  
4 THINK A LOT OF PEOPLE UNDERAPPRECIATE WHAT A LIFT IT  
5 IS TO ACTUALLY DISTRIBUTE DRUGS TO PATIENTS, NOT  
6 ONLY JUST IN THE UNITED STATES, BUT OUTSIDE THE  
7 UNITED STATES. BUT THERE'S LEGISLATION RIGHT NOW  
8 ABOUT WHO WILL HAVE THE BLESSING, IF YOU WILL, TO BE  
9 ABLE TO DISTRIBUTE SOME OF THESE APPROVED,  
10 COMMERCIALY APPROVED, PRODUCTS, NOT ONLY IN  
11 CALIFORNIA, BUT ALSO OUTSIDE CALIFORNIA. WHAT ARE  
12 THOSE DISTRIBUTION PATHWAYS GOING TO LOOK LIKE?

13 YOU WOULD THINK THAT AFTER, AND THERE'S  
14 PROBABLY SOME TRUTH TO THIS, BUT AFTER THE PANDEMIC,  
15 THE DISTRIBUTION CHANNELS BECAME A LITTLE BIT MORE  
16 ROBUST, BUT THE REALITY IS THERE ARE SOME  
17 ORGANIZATIONS THAT TRULY WANT TO OWN THE  
18 DISTRIBUTION ROUTES. SO THAT'S SOMETHING THAT  
19 OBVIOUSLY MAY IMPACT ACCESS AND AFFORDABILITY. SO  
20 WE ARE KEEPING AN EYE ON THAT AREA OF LEGISLATION.

21 AND, OF COURSE, THE BIG ELEPHANT IN THE  
22 ROOM IS THE PRICE AND REIMBURSEMENT. EVERYBODY IS  
23 TALKING ABOUT THIS, WHETHER IT'S THOSE VALUE-BASED  
24 CONTRACTS, WHICH I GAVE A PRESENTATION ON A COUPLE  
25 OF WEEKS AGO. WHAT DOES THAT LOOK LIKE FROM A



**BETH C. DRAIN, CA CSR NO. 7152**

1     METHODOLOGICAL STANDPOINT FOR PAYORS, NOT ONLY FOR  
2     PRIVATE, BUT ALSO FOR PUBLIC PAYORS? WE'LL TALK  
3     ABOUT THAT IN A FEW MINUTES.

4             FINALLY, NOT MY AREA OF EXPERTISE, THIS IS  
5     PROBABLY MORE ON SHYAM'S SIDE, BUT MANUFACTURING.  
6     THERE'S A LOT OF LEGISLATION RIGHT NOW ON THE  
7     MANUFACTURING SIDE FOR CELL AND GENE. OF COURSE,  
8     THIS IS REALLY TO INCENTIVIZE POSTPANDEMIC, A LOT OF  
9     THE CREATION OF SOME OF THE RAW MATERIALS IN THE  
10    UNITED STATES AS OPPOSED TO OUTSIDE THE UNITED  
11    STATES. SO LOTS OF AREAS THAT ARE QUITE ACTIVE.

12            SO HERE'S JUST A SNAPSHOT OF THE SELECTED  
13    POLICY EXAMPLES. AND GEOFF AND I JUST TOOK A COUPLE  
14    OF THESE JUST TO BRING THE TEAM UP TO SPEED. ONE,  
15    OF COURSE, THE CALIFORNIA CANCER EQUITY ACT THAT WAS  
16    SIGNED IN LAW EXPANDS PATIENT'S ACCESS TO  
17    SPECIALIZED CANCER CARE, PARTICULARLY NCI  
18    INSTITUTIONS FOR MEDI-CAL PATIENTS. SO THAT'S A BIG  
19    WIN.

20            WE'RE ALL FAMILIAR WITH THE INFLATION  
21    REDUCTION ACT WAS SIGNED INTO LAW JUST RECENTLY, OF  
22    COURSE, BY PRESIDENT BIDEN. AND WHAT'S INTERESTING  
23    ABOUT THIS, THERE'S A LOT TO UNCOVER HERE, BUT IT  
24    DOES ALLOW MEDICARE TO NEGOTIATE WHAT'S CALLED A  
25    BEST PRICE AND PERFORMANCE-BASED CONTRACTS. NOW,

**BETH C. DRAIN, CA CSR NO. 7152**

1 THESE ARE SOMEWHAT LIMITED, NOT WHAT YOU WOULD SEE  
2 ON THE PRIVATE SIDE, AND STILL WON'T TAKE EFFECT  
3 UNTIL 2023 OR 2024. SO CMS IS PUTTING TOGETHER A  
4 POWERHOUSE OF A TEAM TO START THINKING THROUGH WHAT  
5 THEIR POLICY IS GOING TO BE WITH RESPECT TO  
6 VALUE-BASED CONTRACTS.

7 ANOTHER THING THAT'S INTERESTING IS HELP  
8 INSURE LOWER PATIENT CO-PAYS. SO THIS HR 5801.  
9 THIS IS LEGISLATION THAT'S ATTEMPTING TO ADDRESS THE  
10 DIFFERENCE IN MEDICARE'S PAYMENT AMOUNTS BETWEEN  
11 INPATIENT AND OUTPATIENT SITES.

12 OTHERS INCLUDE INFECTIOUS DISEASE  
13 THERAPIES RESEARCH AND INNOVATION. THERE'S THE MORE  
14 CURES ACT, WHICH, AGAIN, INCENTIVIZES COMPANIES BY  
15 TAX CREDITS BY MANUFACTURING HERE IN THE UNITED  
16 STATES. CMS ALSO HAS SOME ENGAGEMENT RIGHT NOW.  
17 THEY HAVE SOME POLICY THAT'S ATTEMPTING TO BE  
18 APPROVED. THIS IS REGARDING INPATIENT PAYMENT AND  
19 UPDATED NTAP REIMBURSEMENT FOR GENE-EDITED  
20 TECHNOLOGIES.

21 HR 6000 IS THE PANDEMIC PREPAREDNESS AND  
22 GENETIC TESTING, ANOTHER ONE THAT HAS QUITE A BIT OF  
23 INFORMATION. AND THEN, OF COURSE, THERE'S THE  
24 AMERICAN MADE MEDICINE ACT, HR 7410, THAT PROVIDES,  
25 AGAIN, MORE TAX INCENTIVES FOR COMPANIES TO

**BETH C. DRAIN, CA CSR NO. 7152**

1 MANUFACTURE HERE ON OUR HOME SOIL.

2 SO THIS IS JUST A SNAPSHOT. MANY OF YOU  
3 ARE PROBABLY MORE FAMILIAR WITH THIS SPACE THAN WE  
4 ARE. THERE'S OTHERS OUT THERE. WHAT WE'RE  
5 ATTEMPTING TO DO IS REALLY JUST CAST A WIDE NET AND  
6 START TO CATEGORIZE THESE IN A WAY THAT WE CAN  
7 CONTINUE TO PRESENT TO THE AAWG AND BRING EVERYBODY  
8 UP TO SPEED AND FIND AREAS THAT WE THINK MIGHT  
9 IMPACT PATIENTS ON THE ACCESS AND AFFORDABILITY  
10 STANDPOINT.

11 LET ME PAUSE THERE TO SEE IF THERE'S ANY  
12 QUESTIONS. SO I TALKED ABOUT PERFORMANCE-BASED  
13 AGREEMENTS. THESE ARE INTERESTING. SO AREAS THAT  
14 WE CAN CONSIDER, CERTAINLY AAWG AND CIRM IN GENERAL  
15 ARE PERFORMANCE-BASED AGREEMENTS. THESE ARE FOR  
16 PRIVATE AS WELL AS PUBLIC PAYORS. NOW, WHAT WE ARE  
17 OBSERVING IS THAT THEY'RE GENERALLY WELL ACCEPTED  
18 RIGHT NOW BY SOME OF THE PAYORS. SOME PAYORS ARE  
19 PUSHING BACK. MEDICARE, OF COURSE, AT THIS POINT  
20 DOESN'T HAVE A WHOLE LOT OF STATUTORY PUSHBACK RIGHT  
21 NOW. SO IT'S REALLY INDUSTRY SAYS, "HERE'S WHAT WE  
22 ARE CHARGING, AND THIS IS WHAT IT'S GOING TO COST  
23 FOR THE PATIENT" AS OPPOSED TO PRIVATE PAYORS HAVE A  
24 LITTLE BIT MORE LEEWAY IN TERMS OF WHAT THOSE  
25 NEGOTIATIONS LOOK LIKE.

**BETH C. DRAIN, CA CSR NO. 7152**

1 SO JUST TO GIVE YOU AN IDEA OF HOW  
2 SOMEWHAT COMPLICATED THIS IS, MANY OF THE CLINICIANS  
3 HERE OBVIOUSLY PROBABLY WOULD BE INFUSING SOME OF  
4 THESE PATIENTS WITH THESE GENE THERAPIES. INSURANCE  
5 COMPANIES AREN'T PUSHING BACK, AT LEAST WHAT WE'RE  
6 FINDING, FOR THAT FIRST INFUSION. WHAT THEY WANT  
7 MORE CLARITY ON IS ACTUALLY THE SUBSEQUENT  
8 FOLLOW-UPS. SO THOSE CONTRACT-BASED PAYMENTS ARE  
9 VALUE BASED. IF THAT PATIENT DEMONSTRATES  
10 DURABILITY AND EFFICACY AND SAFETY OVER TIME, THAT'S  
11 HOW THE ORGANIZATION, THE MANUFACTURER, WILL GET  
12 PAID. SO THERE IS SOME DISCUSSION ABOUT WHAT THAT  
13 METHODOLOGY LOOKS LIKE. NOT ALL THE PAYORS ARE IN  
14 AGREEMENT IN TERMS OF WHAT THOSE BIOLOGICAL MARKERS  
15 ARE, WHETHER THEY'RE VALID, HOW LONG THE PATIENT  
16 NEEDS TO BE FOLLOWED UP. SO ALL OF THAT IS STILL IN  
17 DISCUSSION, QUITE FRANKLY.

18 I DO THINK WHAT YOU SEE UNIVERSALLY IS  
19 THAT PAYORS ARE STEPPING UP TO THE PLATE AND  
20 CERTAINLY STARTING THAT FIRST INFUSION. THE  
21 SUBSEQUENT FOLLOW-UP WITH REGARDS TO PAYMENT  
22 THEREAFTER IS STILL SORT UP FOR DISCUSSION.

23 ANOTHER THING THAT WE MIGHT BE ABLE TO  
24 IMPACT IS THE ACTUAL FORMULARY REVIEWS. SO LET'S  
25 SAY AMCP DOSSIER, SO THAT GOES OUT TO 80 OR 90

**BETH C. DRAIN, CA CSR NO. 7152**

1 PAYORS RIGHT OUT OF THE GATE ONCE A DRUG IS  
2 APPROVED. AND THOSE DOSSIERS TAKE TIME TO REVIEW BY  
3 A PT COMMITTEE, WHETHER IT'S GET MEDICARE, STATE  
4 LEVEL, OR EVEN PRIVATE. THE GENE THERAPY SEEMS TO  
5 BE TAKING A LITTLE BIT MORE TIME. I DON'T KNOW IF  
6 THAT'S SIMPLY BECAUSE IT'S A NEW STATE OF SCIENCE  
7 FOR PT COMMITTEES, THEY'RE A LITTLE MORE CAUTIOUS,  
8 OR THEY WANT MORE INFORMATION COMPARED TO A  
9 TRADITIONAL SORT OF THERAPEUTIC. SO MAYBE THERE'S  
10 WAYS THAT WE, CIRM, CAN HELP IN TERMS OF, I DON'T  
11 KNOW, MAYBE FROM A PAYOR STANDPOINT OR EDUCATIONAL  
12 STANDPOINT REDUCE THE TIME FOR THESE FORMULARY  
13 REVIEWS.

14 ANOTHER CONCERN IS THAT MANY PATIENTS WILL  
15 REQUIRE THERAPY ACROSS STATE LINES. THIS IS  
16 FASCINATING. SO WE JUST TALKED ABOUT THIS AT THE  
17 MEETING ON THE MESA THIS MORNING, AND THIS SEEMS TO  
18 BE A CONCERN TO SOME OF THE ORGANIZATIONS, THAT  
19 WHERE THE PATIENT IS GOING TO BE TREATED. THEY  
20 THINK THERE'S GOING TO BE SOME STATES THAT WILL BE  
21 DISPROPORTIONATELY TREATING MORE PATIENTS THAN  
22 OTHERS, CERTAIN CENTERS OF EXCELLENCE. QUESTIONS  
23 ABOUT, WELL, WILL SATELLITE INSTITUTIONS BE ABLE TO  
24 INFUSE SOME OF THESE THERAPIES? THAT'S ALL OPEN FOR  
25 DISCUSSION AND, QUITE FRANKLY, SITTING ON THE HILL

**BETH C. DRAIN, CA CSR NO. 7152**

1 RIGHT NOW WITH RESPECT TO SOME POTENTIAL  
2 LEGISLATION.

3 THERE'S ALWAYS CONCERN ABOUT DIFFERENTIAL  
4 REIMBURSEMENT FOR OUTPATIENT VERSUS INPATIENT, WHICH  
5 IS IMPACTING PATIENT COPAYS. ONE OF THE QUESTIONS  
6 THAT GEOFF AND I WERE KIND OF FLOATING AROUND WAS  
7 WILL CALIFORNIA REQUIRE ACCREDITATION FOR HOSPITALS,  
8 EITHER LIMITING GENE THERAPY ADMINISTRATION TO  
9 CERTAIN SITES OR PERHAPS OPENING IT UP TO MORE  
10 FACILITIES, AND THEREBY MORE PATIENTS WILL HAVE  
11 ACCESS.

12 THIS ALSO PLAYS INTO DISTRIBUTION. I AM  
13 AWARE OF SOME DISTRIBUTION LANGUAGE RIGHT NOW THAT'S  
14 TRYING TO BE PASSED IN THE STATE THAT WOULD LIMIT  
15 THE DISTRIBUTION TO A NUMBER OF DISTRIBUTORS, JUST  
16 IN CALIFORNIA.

17 SO THESE ARE ALL THE THINGS TO BRING TO  
18 THE AAWG'S ATTENTION. I CERTAINLY DON'T HAVE THE  
19 ANSWERS TO ALL THESE, BUT HOPEFULLY THROUGH THIS  
20 DISCUSSION, WE CAN AT LEAST GET SOME GUIDANCE FROM  
21 THE TEAM IN TERMS OF WHAT WE SHOULD BE FOLLOWING AND  
22 ADDITIONAL INTEL AND RESEARCH WE SHOULD BE ENGAGED  
23 IN.

24 SO HERE ARE A COUPLE OF QUESTIONS THAT  
25 MAYBE I COULD POSE TO THE AAWG. ONE IS HOW CAN WE

**BETH C. DRAIN, CA CSR NO. 7152**

1 FURTHER ASSIST CANCER PATIENTS UNDER CALIFORNIA'S  
2 CANCER CARE EQUITY ACT? AND LET ME PAUSE THERE TO  
3 SEE IF THERE'S ANY SORT OF RESPONSE TO THIS THAT  
4 MIGHT PROVIDE AT LEAST GEOFF AND I AND MEDICAL  
5 AFFAIRS SOME GUIDANCE.

6 DR. GOLDSTEIN: SO QUESTION. MOST CANCER  
7 CARE IS DELIVERED IN THE INFUSION SETTING IN CLINICS  
8 THAT ARE TYPICALLY NEAR, BUT NOT NECESSARILY  
9 ADJACENT TO EMERGENCY ROOMS. THERE ARE  
10 COMPLICATIONS THAT OCCUR, AND SO SOMEONE MAY -- BUT  
11 MOST PEOPLE IN POVERTY GET THEIR CARE IN EMERGENCY  
12 ROOMS. AND SO ONE QUESTION I HAVE IS HOW DO WE  
13 MANAGE PATIENTS WHOSE PRIMARY SOURCE OF CARE IS NOT  
14 A REGULAR DOCTOR, BUT IS IN AN EMERGENT SITUATION?

15 AND THINKING OF THIS BOTH IN TERMS OF  
16 EQUITY UNDER THE CCC, BUT ALSO FOR NONCANCER  
17 DISEASES, SUCH AS -- AGE IS CATCHING UP TO ME --  
18 SICKLE CELL DISEASE. AND MOST IMPOVERISHED PATIENTS  
19 RECEIVE THEIR CARE IN THE EMERGENCY ROOM SETTING.  
20 SO ONE QUESTION IS CAN WE FACILITATE CARE IN THE ER?

21 DR. TURBEVILLE: GOOD. THAT'S HELPFUL.  
22 ANY OTHER COMMENTS? MARIANNE, I DON'T SEE ANY.  
23 OKAY. GOOD.

24 WELL, ANOTHER QUESTION GEOFF AND I BROUGHT  
25 UP WAS HOW DOES CMS REGULATIONS AUTHORIZING ACCESS

**BETH C. DRAIN, CA CSR NO. 7152**

1 AND REIMBURSEMENT FOR CLINICAL TRIALS PROVIDE ACCESS  
2 TO CELL AND GENE THERAPIES? ANY COLLEAGUES HAVE ANY  
3 RESPONSE TO THAT QUESTION? WE'LL COME BACK TO THAT  
4 ONE.

5 ANOTHER ONE WAS HOW CAN THE ALPHA CLINICS  
6 NETWORK STREAMLINE ACCESS AND ASSIST PATIENTS WITH  
7 THE REIMBURSEMENT IN THIS EVOLVING POLICY LANDSCAPE?

8 MR. TORRES: I THINK THE RESPONSE TO THAT  
9 ALSO IS GOING TO DETERMINE JUST -- AND I KNOW I'VE  
10 TRIED TO PUT YOU IN TOUCH WITH ASSEMBLYMAN WOODS'  
11 OFFICE IN RESPECT TO THE AFFORDABILITY OFFICE THAT'S  
12 GOING TO START TO BE EFFECTIVE JANUARY 1. I THINK  
13 THAT INTERACTION WITH OURS AND THEM IS GOING TO BE  
14 VERY CRUCIAL TO LOOKING AT A LOT OF THESE ANSWERS.

15 DR. TURBEVILLE: YEAH, ART. IN TERMS OF  
16 MEDI-CAL, IS HARLAN ON THE CALL? I DON'T THINK HE'S  
17 ON THE CALL. I'D LIKE TO GET A LOT OF INSIGHT FROM  
18 HIM ON HOW -- AND GEOFF WAS TALKING ABOUT THIS  
19 EARLIER ABOUT WE UNDERSTAND WHAT'S GOING ON OUT  
20 THERE ON THE HILL, AND THERE'S ONLY SO MUCH WE CAN  
21 DO. WE CAN JUST FOLLOW IT AND PROVIDE GUIDANCE FROM  
22 OUR EXPERIENCE. IN THE STATE, OUR STATE, I'D LIKE  
23 TO SEE IF IT'S POSSIBLE WE CAN GET MORE ENGAGED WITH  
24 MEDICAID, IF POSSIBLE.

25 CHAIRMAN TORRES: YOU MEAN MEDI-CAL.



**BETH C. DRAIN, CA CSR NO. 7152**

1 DR. TURBEVILLE: SAY AGAIN.

2 CHAIRMAN TORRES: MEDI-CAL IN OUR STATE.

3 DR. TURBEVILLE: CORRECT, MEDI-CAL.

4 SORRY. I DON'T HAVE THOSE CONNECTIONS, BUT  
5 CERTAINLY WOULD LOVE TO GET AN OPPORTUNITY TO  
6 INTERACT WITH THEM AND DISCUSS SOME COLLABORATIONS,  
7 IF POSSIBLE.

8 CHAIRMAN TORRES: I THINK THE FIRST STEP  
9 IS TO MAKE SURE YOU FOLLOW UP WITH ASSEMBLYMAN  
10 WOODS' OFFICE AND SEE WHAT THEY'VE BEEN DOING UP TO  
11 THIS POINT. AND I CAN CERTAINLY HOOK YOU UP WITH  
12 HEAD OF MEDI-CAL WHO SECRETARY OF HHS GAVE ME, MARK  
13 KELLY, A FEW WEEKS AGO. WE'LL FOLLOW UP. IT'S JUST  
14 A MATTER OF DETERMINING JUST WHAT THE QUESTIONS ARE  
15 SO WE MAKE THE BEST USE OF THEIR TIME AND OURS.

16 DR. TURBEVILLE: YEAH. OKAY. GEOFF AND I  
17 WILL THINK ABOUT THAT. THANK YOU, SENATOR.

18 CHAIRMAN TORRES: I'LL WAIT TO HEAR FROM  
19 YOU GUYS.

20 DR. TURBEVILLE: GOOD. SO MOVING  
21 FORWARD --

22 DR. PADILLA: I HAD A COMMENT. BECAUSE  
23 I'M A FAMILY PHYSICIAN, SO ANY MEDICATION THAT  
24 DOESN'T GET REIMBURSED OR IS INVESTIGATIONAL, FOR  
25 THAT MATTER, NEEDS TO GO THROUGH A PERSON'S

**BETH C. DRAIN, CA CSR NO. 7152**

1 HEALTHCARE INSURANCE, WHETHER THAT BE MEDI-CAL,  
2 MEDICARE PART D, PRIVATE INSURANCE, WHATEVER  
3 BASICALLY. ONCE THAT GETS DENIED, THEN THERE'S A  
4 PROCESS FOR AUTHORIZATIONS, AND THEN IT GOES INTO  
5 NEGOTIATIONS ABOUT WHO PAYS WHAT.

6 SO I THINK THERE'S GOT TO BE A LOT OF  
7 DISCUSSION OF HOW INSURANCE COMPANIES ARE GOING TO  
8 TAKE THIS ON BECAUSE IT'S GOING TO GO THROUGH  
9 INSURANCE COMPANIES TO BEGIN WITH. IT DOESN'T  
10 MATTER. THE ONLY FREEFALL IS GOING TO BE PEOPLE WHO  
11 HAVE NO INSURANCE BASICALLY. AND THEN THERE'S GOING  
12 TO BE A COST, AND THAT NEEDS TO BE DECIDED HOW  
13 THAT'S GOING TO BE REIMBURSED, WHETHER IT'S GOING TO  
14 GO THROUGH THE ACTUAL RESEARCH PROJECT THEMSELVES,  
15 OR IS IT GOING TO GO THROUGH A CENTRAL WORKING  
16 STATION THAT YOU'RE DEVELOPING OR WHATNOT.

17 DR. TURBEVILLE: OKAY. THAT'S HELPFUL.  
18 LET US FOLLOW UP ON THAT. THAT MIGHT BE AN ACTION  
19 ITEM WE CAN EXPLORE FURTHER. THANK YOU.

20 DR. LOMAX: I JUST WANTED TO ADD, BECAUSE  
21 I KNOW PART OF THE RATIONALE ON THAT PREVIOUS LIST  
22 OF QUESTIONS WAS, A, TO SORT OF POTENTIALLY SOLICIT  
23 FEEDBACK; BUT, B, TO KIND OF POINT TO THE WORKING  
24 GROUP THAT THESE ARE THINGS THAT WE'VE ACTUALLY KIND  
25 OF KEYED IN ON AND WE THINK ARE IMPORTANT QUESTIONS

**BETH C. DRAIN, CA CSR NO. 7152**

1 TO CONTINUE TO PURSUE. SO I JUST WANTED TO KIND OF  
2 PUT THAT OUT THERE IN CASE THERE WAS SOME SENSE THAT  
3 WE ARE ON THE WRONG TRACK.

4 BUT PARTICULARLY THIS INTERACTION BETWEEN  
5 THE MEDICAID AUTHORIZATION THAT'S ALLOWING FOR  
6 CLINICAL TRIAL COSTS TO BE COVERED BECAUSE THAT  
7 ACTUALLY CAN POTENTIALLY IMPACT OUT-OF-STATE  
8 PATIENTS COMING TO CALIFORNIA AS WELL, AND THEN SOME  
9 OF THE MORE RECENT THINGS IN CALIFORNIA,  
10 PARTICULARLY THE CANCER CARE ACT. SO THERE SEEMS TO  
11 BE A KIND OF NEXUS THERE OF A STRONG LANE FOR MAKING  
12 SURE WE CAN REALLY UNDERSTAND AND BRING PEOPLE IN  
13 ALONG THIS SORT OF CLINICAL TRIAL PATHWAY, AND THEN  
14 CONSIDERING THE PUBLIC PAYOR REIMBURSEMENT ASPECTS  
15 OF THAT. AGAIN, MAKING SURE THAT IF WE CHOOSE TO  
16 SPEND OUR TIME LOOKING AT THAT, THE WORKING GROUP  
17 BELIEVES WE ARE ON THE RIGHT TRACK. SO I JUST  
18 WANTED TO ADD THAT.

19 DR. TURBEVILLE: GOOD CLARIFICATION.  
20 THANK YOU.

21 DAN.

22 MR. BERNAL: REGARDING THE SECOND QUESTION  
23 ABOUT CMS, I'M NOT DEEPLY FAMILIAR WITH SOME OF  
24 THESE ISSUES, BUT I DO KNOW THAT THERE IS A NEW  
25 REIMBURSEMENT METHOD THAT WAS PUT IN PLACE BY CMS

**BETH C. DRAIN, CA CSR NO. 7152**

1 FOR CAR-T TREATMENTS. AND THERE ARE SOME QUESTIONS  
2 ABOUT WHAT THE IMPLICATIONS WOULD BE FOR SOME  
3 PIPELINE CELL AND GENE THERAPIES THAT HAVE HIGH  
4 UPFRONT COSTS. I'M NOT SURE THERE'S ANYTHING THAT'S  
5 HAPPENED SINCE THEN. THESE WENT INTO EFFECT IN  
6 2021, BUT I CAN SEND YOU AN ARTICLE ABOUT THAT IF  
7 YOU WANT.

8 DR. TURBEVILLE: THAT WOULD BE GREAT.  
9 THANK YOU. I DON'T SEE ANY OTHER COMMENTS.

10 MR. ROWLETT: I HAVE A COMMENT. IF YOU'RE  
11 INTERESTED, THERE IS A POPULATION HEALTH MANAGEMENT  
12 GROUP THAT THE STATE HAS ADVANCED IN RESPONSE TO THE  
13 IMPLEMENTATION OF CAL-AIM THAT'S BEEN IN EXISTENCE  
14 FOR A BIT. AND THOSE OF US WHO HAVE BEEN ASKED TO  
15 PARTICIPATE ON THAT, WE'RE LOOKING SPECIFICALLY AT  
16 ACCESS AND AFFORDABILITY FOR MEDI-CAL PATIENTS.  
17 THERE'S SOME SIGNIFICANT LEADERSHIP THERE, NOT DR.  
18 GULLY OR ANY OF THOSE FOLKS, BUT INDIVIDUALS WHO  
19 MIGHT BE ABLE TO PROVIDE YOU WITH SOME INSIGHT  
20 AROUND SPECIFICALLY HOW THERE MAY BE AREAS OF  
21 COMMONALITY BETWEEN WHAT YOU'RE TRYING TO DO AND  
22 WHAT CAL-AIM IS DESIGNED TO ACCOMPLISH IN TERMS OF  
23 ACCESS AND AFFORDABILITY FOR MEDI-CAL PATIENTS.

24 AND SO IF THAT RESOURCE IS HELPFUL FOR  
25 YOU, I'LL PROVIDE YOU WITH SOME INFORMATION, AND YOU

**BETH C. DRAIN, CA CSR NO. 7152**

1 CAN REACH OUT TO THOSE FOLKS.

2 DR. TURBEVILLE: YEAH. THAT WOULD BE VERY  
3 HELPFUL. THANK YOU.

4 ALL RIGHT. I DON'T SEE ANYBODY ELSE. HOW  
5 ABOUT THIS? THIS IS SOMETHING THAT GEOFF AND I  
6 THOUGHT ABOUT DOING, AND MOVING FORWARD, WE'D LIKE  
7 TO START PRODUCING A DASHBOARD OF ALL THE POLICY AND  
8 LEGISLATION THAT'S TAKEN PLACE. WE'D LIKE TO BE  
9 ABLE TO PUT THAT INTO OBVIOUSLY A PRESENTATION,  
10 MAYBE ON A MONTHLY BASIS, MAYBE EVERY SIX WEEKS TO  
11 ON THE AAWG, GETTING EVERYBODY UP TO SPEED WHERE THE  
12 STATUS OF MANY OF THE BILLS ARE, WHAT THEIR IMPACT  
13 FACTOR IS FOR PATIENTS, FOR PAYORS, ET CETERA. SO  
14 WE WOULD BE LOOKING AT NOT ONLY LEGISLATIVE BILLS,  
15 POLICY BRIEFS, PROFESSIONAL SOCIETY GUIDELINES, AND  
16 REPORTS, PUBLISHED LITERATURE, STATE AND FEDERAL  
17 GUIDANCE DOCUMENTS. AND IF YOU CAN THINK OF  
18 ANYTHING ELSE THAT WE COULD PERHAPS ADD TO THIS  
19 DASHBOARD, FEEL FREE TO GIVE US RECOMMENDATION TODAY  
20 OR PERHAPS SEND US AN EMAIL.

21 CHAIRMAN TORRES: I'LL GIVE YOU ONE RIGHT  
22 NOW. U.S. SUPREME COURT DECISIONS BECAUSE THERE'S  
23 ONE COMING DOWN THE ROAD IN OCTOBER OF THIS YEAR  
24 THAT THE COURT IS GOING TO HEAR, WHICH IS THE  
25 UNIVERSITY OF NORTH CAROLINA AND HARVARD BEING SUED

**BETH C. DRAIN, CA CSR NO. 7152**

1 BY STUDENTS FOR ADMISSION STANDARDS, WHICH DEALS  
2 DIRECTLY WITH EQUITY DISTRIBUTION AND MAY HAVE AN  
3 IMPACT ON HOW WE CONDUCT OUR DES SURVEYS.

4 DR. TURBEVILLE: OKAY. TAKING NOTES.  
5 THAT'S GOOD.

6 BUT TO THE TEAM, DOES THAT SEEM REASONABLE  
7 EVERY MONTH, MAYBE SIX WEEKS WE'LL BE ABLE TO DO A  
8 DEEP DIVE ON EVERYTHING THAT'S GOING ON OUT THERE  
9 AND IMPACTING OUR PATIENTS, IMPACTING ACCESS AND  
10 AFFORDABILITY? MAYBE I COULD ASK FOR A THUMBS UP,  
11 NOT NECESSARILY -- IF THAT SEEMS REASONABLE.

12 CHAIRMAN TORRES: WE WON'T HAVE ANYTHING  
13 AVAILABLE ON LEGISLATIVE BILLS AND ISSUES UNTIL  
14 JANUARY 1, IF THEN, AND THAT WILL BE JUST FOR  
15 INTRODUCTION OF BILLS PURPOSES, NOT ANY UPDATES ON  
16 WHERE THEY'RE MOVING.

17 DR. TURBEVILLE: OKAY. GOOD.

18 THAT IS ALL I HAD TO UPDATE TODAY. I  
19 THINK WE HAVE A COUPLE QUESTIONS, BUT CERTAINLY ANY  
20 MORE COMMENTS, SUGGESTIONS, WE ARE ACCEPTING  
21 EVERYTHING.

22 CHAIRMAN TORRES: THANK YOU, GEOFF, AND  
23 THANK YOU, SEAN, FOR KEEPING ME IN THE LOOP WITH  
24 YOUR EMAILS BECAUSE THEY'RE VERY INFORMATIVE. AND I  
25 DO SOME FOLLOW-UP AS WE'VE BEEN ABLE TO ON THE

**BETH C. DRAIN, CA CSR NO. 7152**

1 FEDERAL LEVEL, INCLUDING ON THE STATE LEVEL.

2 IS THERE ANY PUBLIC COMMENT? MARIANNE, DO  
3 YOU SEE ANY PUBLIC COMMENT?

4 MS. DEQUINA-VILLABLANCA: ADRIENNE SHAPIRO  
5 HAD HER HAND UP.

6 MS. SHAPIRO: I DON'T KNOW EXACTLY WHERE  
7 THIS FITS IN, BUT RIGHT NOW WE'VE JUST RECEIVED WORD  
8 THAT ICER IS GOING TO BE CONDUCTING THEIR REVIEW FOR  
9 STEM CELL FOR SICKLE CELL. AND WE WENT THROUGH THIS  
10 PROCESS WITH THEM ON TRYING TO GET OUR TREATMENT,  
11 AND EVERYBODY SAID DON'T THINK ABOUT IT, DON'T WORRY  
12 ABOUT IT. IT'S NOT GOING TO REALLY AFFECT THINGS  
13 WHEN WE ARE CONSTANTLY HEARING FROM PAYORS WHERE  
14 THEY'RE FIGHTING THE ICER REVIEW AS FAR AS THE  
15 TREATMENTS BEING COST-EFFECTIVE.

16 I DON'T KNOW IF WE WANT THEM ON OUR RADAR,  
17 BUT IT IS SOMETHING THAT REALLY DOES IMPACT THE  
18 COMMUNITY. AND I DON'T KNOW EXACTLY WHERE IT NEEDS  
19 TO BE, BUT WE ARE ONE OF THE FIRST. AND WE ARE VERY  
20 TRANSPARENT ABOUT OUR DEALINGS WITH THEM AND  
21 EVERYTHING, BUT I THINK WE NEED TO SOMEHOW KEEP AN  
22 EYE ON THEM BECAUSE IT KEEPS COMING UP AND THE WHOLE  
23 CONCEPT OF QUALS WHICH YOU WILL SEE CRAWLING THROUGH  
24 MANY STATE LEGISLATOR'S DOCKETS WHERE THEY'RE  
25 TALKING ABOUT THAT SORT OF THING.

**BETH C. DRAIN, CA CSR NO. 7152**

1 SO, AGAIN, I DON'T KNOW IF THAT FITS IN  
2 UNDER OUR MANDATE. IT'S JUST SOMETHING THAT I KNOW  
3 THAT WE, AS A DISEASE COMMUNITY, HAVE TO BE AWARE  
4 OF.

5 CHAIRMAN TORRES: THANK YOU. JUST KEEP US  
6 IN THE LOOP SO THAT WE'RE ON TOP OF IT FROM OUR END  
7 AS WELL.

8 ANY OTHER QUESTIONS FROM MEMBERS OF THE  
9 WORKING GROUP? ANY PUBLIC COMMENT?

10 MS. DEQUINA-VILLABLANCA: TED HAS HIS HAND  
11 UP.

12 CHAIRMAN TORRES: I DIDN'T SEE YOU, TED.  
13 GO AHEAD.

14 DR. GOLDSTEIN: SO PROBABLY NOT IN  
15 LEGISLATIVE MATTERS, BUT IT WOULD, I THINK, BE GREAT  
16 TO HAVE A DASHBOARD OF LEADING THERAPIES AND WHERE  
17 THEY ARE.

18 CHAIRMAN TORRES: AH.

19 DR. GOLDSTEIN: JUST TO TRACK WHERE THEY  
20 ARE SO THAT WE KNOW IN PROGRESS, PASSED, BEING  
21 DEPLOYED, HOW MANY PATIENTS. WE NEED TO, I THINK,  
22 CLOSELY WATCH THE FIRST DOZEN OR SO.

23 CHAIRMAN TORRES: YOU'RE TALKING ABOUT  
24 THERAPIES THAT ARE FUNDED BY CIRM?

25 DR. GOLDSTEIN: CIRM THERAPIES.



**BETH C. DRAIN, CA CSR NO. 7152**

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

CHAIRMAN TORRES: GOOD.

ANY OTHER COMMENTS? THANK YOU, SEAN.

THANK YOU, GEOFF. THANK YOU, MARIANNE. AND THANK  
YOU, MEMBERS OF THE WORKING GROUP. WE'LL BE IN  
TOUCH AND CONTINUE TO HOPEFULLY RECEIVE YOUR INPUT  
WHENEVER IT COMES TO YOUR ATTENTION AND BRING IT TO  
MY ATTENTION. HAVE A GOOD WEEKEND, AND WE'LL TALK  
TO YOU SOON.

(THE MEETING WAS THEN CONCLUDED AT 2:37

P.M.)

**REPORTER'S CERTIFICATE**

I, BETH C. DRAIN, A CERTIFIED SHORTHAND REPORTER IN AND FOR THE STATE OF CALIFORNIA, HEREBY CERTIFY THAT THE FOREGOING TRANSCRIPT OF THE VIRTUAL PROCEEDINGS BEFORE THE ACCESSIBILITY AND AFFORDABILITY WORKING GROUP OF THE INDEPENDENT CITIZEN'S OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE IN THE MATTER OF ITS REGULAR MEETING HELD ON OCTOBER 11, 2022, WAS HELD AS HEREIN APPEARS AND THAT THIS IS THE ORIGINAL TRANSCRIPT THEREOF AND THAT THE STATEMENTS THAT APPEAR IN THIS TRANSCRIPT WERE REPORTED STENOGRAPHICALLY BY ME AND TRANSCRIBED BY ME. I ALSO CERTIFY THAT THIS TRANSCRIPT IS A TRUE AND ACCURATE RECORD OF THE PROCEEDING.

BETH C. DRAIN, CA CSR 7152  
133 HENNA COURT  
SANDPOINT, IDAHO  
(208) 920-3543