The Regents of the University of California

COMPLIANCE AND AUDIT COMMITTEE
November 16, 2022

The Compliance and Audit Committee met on the above date at the UCSF-Mission Bay Conference Center, San Francisco campus and by teleconference meeting conducted in accordance with California Government Code §§ 11133.

Members Present: Regents Anguiano, Blas Pedral, Cohen, Elliott, Makarechian, Matosantos, Park, Pérez, Pouchot, and Sures; Ex officio member Leib; Advisory member Cochran; Chancellors Christ, Gillman, Hawgood, May, and Yang; Expert Financial Advisor Schini; Staff Advisor Mackness

In attendance: Regents Batchlor and Chu, Interim Secretary and Chief of Staff Lyall, General Counsel Robinson, Chief Compliance and Audit Officer Bustamante, Executive Vice President and Chief Financial Officer Brostrom, Executive Vice President Byington, Executive Vice President and Chief Operating Officer Nava, Vice President Leasure, Chancellor Wilcox, and Recording Secretary Johns

The meeting convened at 10:00 a.m. with Committee Chair Sures presiding.

1. **APPROVAL OF MINUTES OF PREVIOUS MEETING**

Upon motion duly made and seconded, the minutes of the meeting of September 21, 2022 were approved, Regents Anguiano, Blas Pedral, Cohen, Elliott, Leib, Matosantos, Park, Pouchot, and Sures voting "aye."[1]

2. **ETHICS, COMPLIANCE AND AUDIT SERVICES ANNUAL REPORT 2021–22**

[Background material was provided to Regents in advance of the meeting, and a copy is on file in the Office of the Secretary and Chief of Staff.]

Chief Compliance and Audit Officer Bustamante introduced the Office of Ethics, Compliance and Audit Services (ECAS) annual report for 2021–22. He briefly described the structure of ECAS, which is responsible for coordinating audit, compliance, and investigations efforts across the UC system. Internal audit directors and chief ethics and compliance officers at the UC locations report to local leadership and to the Regents through the Chief Compliance and Audit Officer. The same reporting relationship exists for healthcare compliance officers at the medical centers. ECAS maintains relationships with other campus compliance personnel to ensure ongoing coordination of compliance efforts.

[1] Roll call vote required by the Bagley-Keene Open Meeting Act [Government Code §11123(b)(1)(D)] for all meetings held by teleconference.

Mr. Bustamante presented the "three lines of defense" model, a widely used governance model for managing risk. The first line of defense is management, who are responsible for managing risks associated with the day-to-day operations of the University. The second line of defense, the risk management and compliance functions, identify emerging risks in daily operations. The third line of defense is the oversight function. These are units that operate independently of management and provide assurance that the organization is operating effectively and include the ECAS investigative and audit functions.

UC uses a risk management process to identify the highest-risk activities and the risks with the greatest impact on the system and the greatest likelihood of occurring. The goal is to design plans to control or mitigate these risks. These plans can include audit assessments, training, toolkits, and other items that ECAS develops with its campus partners. ECAS repeats this process annually to ensure that limited resources are always matched to the highest compliance risks throughout the UC system.

When ECAS performed the risk assessment process at the beginning of fiscal year 2021, it identified several high-risk areas. Although these risks often change from year to year, some are ongoing risks that continue to pose significant challenges to the organization. Cybersecurity had been one of the top risks to the University since Mr. Bustamante had joined UC. Similarly, research security had been a high risk area for several years and would continue to be so for the foreseeable future.

Regarding compliance, Mr. Bustamante noted that, as directed last year by this Committee, ECAS had broken out the required training completion rates by campus. Chief of Staff Irene Levintov underscored that training and awareness activities were a large part of the ECAS compliance portfolio. ECAS conducts its own training and monitors compliance with other mandatory training requirements across the UC system through the learning management system used by all locations.

All UC employees, faculty and staff, are assigned one of the two ethics and compliance briefings, and these courses must be completed within a designated time. Ms. Levintov presented a chart showing percentages of all UC employees as of October 2022 who were required to and completed these courses within the designated time frame. Ninety-two percent of all UC employees had completed the ethics and compliance briefing and 81 percent had completed the cyber security awareness course. The following chart represented the same information broken out by location and indicated some variability in timely completion rates.

In addition to ethics and compliance briefings and cybersecurity awareness training, ECAS tracks the sexual violence and sexual harassment (SVSH) training courses for staff and supervisors/faculty. Ms. Levintov presented another chart representing the most current (as of July 2022) systemwide population of University faculty and staff who were required to take the SVSH training and completed the course on time. Due to a vendor issue, the SVSH courses were not available to learners from mid-July to September. During the time the courses were not available, many locations implemented some alternative, but both SVSH training modules were now available in the learning management system. The following

chart presented the same information by location, showing completion rates for staff and supervisors/faculty. There was variability in the timely completion of this training as well.

In addition to required training, ECAS collaborates with its compliance and risk partners on a number of projects and training activities that result in toolkits, infographics, templates, and alerts. These provide timely information on emerging issues and ensure that that compliance teams are aware of any new and current requirements.

In 2021, the National Security Presidential Memorandum 33 (NSPM-33) was issued, followed by some implementation guidance. These documents have a direct impact on the UC system as a major recipient of federally sponsored research funds. UC would now have to address different compliance requirements across the system. In order to ensure compliance and consistency, ECAS has formalized a research security program. The ECAS team monitors the latest developments and provides briefings and various tools for locations to ensure consistent compliance with requirements related to disclosure for recipients of federal funding, various cyber protocols, training requirements, and others.

One of ECAS' biggest collaborations during the last year was a UC research data privacy summit hosted in partnership with UC Legal, UC Health, and research policy analysis groups. The summit brought together Institutional Review Board directors, research compliance, health and campus privacy, legal counsel, and many other stakeholders. The discussion centered around their requirements, challenges, and best practices related to data privacy throughout the research lifecycle. UC created a strong community of practice and would continue these discussions to identify solutions for shared challenges in this area.

Systemwide Deputy Audit Officer Matthew Hicks discussed some of the significant projects that the internal audit program undertook in the last year. The cyber security audit team completed a systemwide audit to assess UC health locations' preparedness to respond to and recover from a significant cyber attack. The audit found that while UC health locations had taken significant steps to prepare for a cyber attack, opportunities existed at all locations to strengthen the plans and systems that support their ability to respond and recover. In the area of technology transfer, internal audit engaged with various subject matter experts to develop a new systemwide approach for identifying licensees for royalty audits. This new approach applied a data-driven risk-based methodology to flag licenses that are at higher risk for royalty underpayment. ECAS presented its proposed methodology the prior month to the Special Committee on Innovation Transfer and Entrepreneurship and, in the coming months, ECAS would be working with the campuses to implement the proposed approach. ECAS continued to serve as the independent compliance monitor responsible for assessing the implementation of corrective actions being taken at UCLA in response to allegations of sexual misconduct in the clinical environment.

Mr. Hicks presented a chart showing time spent on primary subject matter areas or functional areas. Nearly half of internal audit project hours were spent in the areas of financial management, health sciences operations, and information technology, which was generally consistent with prior years. The functional area with the largest increase in total effort compared to the prior year was governance and compliance.

Each year ECAS reviews the results of its audit and advisory services projects to identify the most prominent themes. Many of this year's themes had occurred in prior years, such as information technology security and information privacy, financial controls, and regulatory compliance. Mr. Hicks drew attention to a relatively new theme in the area of internal controls, which was talent management. Talent management has been an ongoing challenge for the University as departments continue to struggle to recruit and retain employees, particularly in areas requiring specialized skills. Departments with open positions were having difficulty maintaining effective controls while they were understaffed. ECAS was also observing instances of key process steps not being performed effectively due to employee turnover and loss of institutional knowledge.

Mr. Hicks then reviewed some key performance statistics. Regarding productivity, he presented a chart which indicated that the audit plan completion percentage had remained relatively stable over the past three years. It currently stood at 87 percent. The overall distribution of effort between the three lines of service—audits, advisory services, and investigations—had remained fairly consistent as well. The number of reports internal audit issued each year had declined in the past two years compared to fiscal year 2020. ECAS attributed this decline to the fact that it had completed some larger and more complex systemwide audits and special projects over the past few years, such as audits of admissions, foreign influence, and police complaints. In addition, some campus internal audit departments have been experiencing staffing difficulties and COVID-19-related disruptions to their audit projects.

ECAS continued to experience overall positive trends related to the Management Corrective Actions (MCAs) identified in internal audit projects. In the last fiscal year, ECAS was able to validate closure of 850 MCAs, bringing the overall count of open corrective actions to 334 as of the end of the fiscal year. The number of MCAs that are open for more than 300 days has remained low, below 30 for the past three years, down from over 100 in 2018. This was the result of continuing efforts from management and leadership to resolve corrective actions in a timely manner.

Systemwide Director of Investigations Molly Theodossy discussed ECAS' investigations function. The investigations unit in ECAS is responsible for providing a mechanism for reporting allegations of misconduct. Anyone, including members of the public, can submit reports and, as a result, many of the reports received do not rise to the level of significant policy violations. However, the goal is to ensure that ECAS receives reports of all suspected misconduct to ensure that it is able to appropriately address matters that are raised. Ms. Theodossy presented charts with investigation data for the past three years. In fiscal year 2021 there was a decrease in the number of reports received. This was an exception to the continuing trend of increasing reports year over year; the trend resumed in fiscal year 2022, when there was again an increase.

In fiscal year 2017 there were over 1,200 reports. In fiscal year 2018 there were nearly 1,400 reports and in fiscal year 2019 nearly 1,600 reports. The gradual increase in reporting tracked the population increases throughout the UC system. The percentage of reports submitted anonymously remained consistent at around 60 percent. Most reports are made

to ECAS directly through its whistleblower hotline, which can be done either online or over the phone rather than through other internal mechanisms such as e-mail or direct phone calls.

Another chart presented the three-year report data broken down by issue, with numbers of reports being investigated or reviewed; numbers of reports for which investigations were not warranted, when follow-up efforts by ECAS did not elicit enough information for ECAS to continue to an investigation or the allegations presented would not have constituted improper governmental activity or retaliation even if they were true; and numbers of reports that ECAS had referred to other departments such as human resources, to departmental managers for performance management, or to organizations such as Environment, Health and Safety for proper handling. There was a general decrease in reporting for all issues in fiscal year 2021, with two notable exceptions: medical misconduct and the health/safety/violence categories. Ms. Theodossy explained this circumstance by recalling that many UC employees were working remotely during that year, while the medical centers experienced a significant increase in patients during the height of the COVID-19 pandemic. The increase in these two areas demonstrated the impact of the pandemic on reporting.

The following chart illustrated the outcomes of cases investigated over the past three years broken down by categories. The substantiation rate generally hovered between 15 percent and 20 percent but was lower for reports of alleged retaliation. While one could not say with absolute certainty what the reason for this was, Ms. Theodossy noted that retaliation is a very specifically defined area, and many reports that ECAS receives demonstrate a general lack of understanding about what constitutes retaliation. Often individuals are already in a performance management process when they make a whistleblower report, or they are anticipating that retaliation might happen. To address this, ECAS was developing resources and training modules to increase understanding of UC whistleblower policies for both employees and managers, using videos and simplified language to make the process more understandable and accessible. ECAS' goal is to increase understanding and provide individuals with information about all the resources available to them to facilitate reporting that allows potential problems to be addressed in the best way possible.

Committee Chair Sures expressed concern about low completion rates for mandatory training—the ethics and compliance briefing for researchers, and training on SVSH prevention—on some campuses and requested a report in six months, at the March 2023 meeting. At that point, the numbers should be trending in the right direction.

Regent Leib referred to the data on outcomes of cases investigated over the past three years and asked about the category of "waste." Ms. Theodossy explained that this referred to any waste or misuse of UC resources, including improper use of technology, theft of time, use of resources for personal business, and wage and hour issues.

Regent Leib noted that the chart presented had shown a decrease in the numbers of substantiated cases of conflict of interest/commitment over the past three years. He asked if UC was doing enough to ascertain and detect these conflicts. Mr. Bustamante responded

that this category was related to research security efforts by ECAS' compliance team. There had been heightened training on what constitutes a conflict of interest or commitment and mandatory training for researchers. He believed there was some connection between this decrease and the enhanced work to make employees aware of their responsibilities and of the fact that there are certain actions they cannot undertake without least talking to UC legal counsel and others, actions that pose risks to the University's interests and might be violations of UC policy and federal laws.

Regent Leib expressed concern about the systemwide completion rate for cyber security awareness training of about 80 percent, not a good statistic. UC San Diego and UC Davis had managed to bring their completion rates closer to 90 percent. Completion rates needed to be examined and there needed to be improvement.

Regent Elliott referred to the differences in training completion rates among the campuses for ethics and compliance briefings, cyber security awareness, and SVSH. He asked if there were practical reasons or other reasons why the rates at certain campuses would be as low as they were. Mr. Bustamante responded that there were a number of factors involved. He noted that there were different types of training occurring at the campuses; not all of them were tracked and included in these aggregate numbers. Different campuses were experimenting with different ways to ensure high rates of compliance. ECAS was in communication with all the campus chief ethics and compliance officers, who report to Mr. Bustamante and to the chancellors, about these completion rates. Campus leaders were engaged and taking this matter seriously. ECAS was trying to identify best practices to be able to provide the campuses with tools for increasing these rates. Mr. Bustamante acknowledged that the completion percentages should be in the low 90s to indicate solid compliance in these areas.

Regent Elliott asked about the frequency of training. Mr. Bustamante responded that this depended on the subject. Individuals were given a deadline and if they did not complete training within that deadline, this was recorded as non-compliance in that area, whether the training was required annually or every two years. Regent Elliott expressed agreement with Committee Chair Sures' concerns and looked forward to a future report and updated numbers. If the numbers were not moving toward desired levels, one or two campuses might present information at a future meeting explaining the situation.

Regent Pérez asked if, in cases when an employee has not completed training by the deadline, it is possible to take a second look to determine if that employee has become compliant within ten, 15, or 20 days, within a reasonable time. He suggested that the completion rate on a campus might be at 80 percent on the day of the deadline but significantly higher a week or two later, after people had been alerted. He asked if there was a pattern of quick catching up. Mr. Bustamante responded that he did not have this information.

Regent Chu referred to the three-year report data broken down by issue and the numbers of reports for which investigations were not warranted. She asked about the controls in place to ensure that there are multiple checks to close out cases. She also asked to what

extent investigations are completed in a timely manner. Responding to Regent Chu's second question, Mr. Bustamante explained that time to completion would depend on the complexity of the investigation, including the number of allegations and the area to be investigated. Investigations in areas such as foreign influence can be quite complex, requiring retrieval of information from various sources. Some investigations require only a few interviews to complete.

Regent Chu commented that she understood the differences in complexity and how long different kinds of investigation might take. Her question was whether investigations were being completed in a timely manner and resolved in a way that the University would want them to be resolved. Mr. Bustamante responded that this was related to Regent Chu's first question, which concerned how the University triages and reviews these matters. Each UC location has an investigative group whose core members are investigators, representatives of UC Legal, and a director of investigations. Depending on the issues, experts are brought into the group to review allegations and to determine an appropriate path. Ultimately a decision is made is by the Locally Designated Official as to whether or not a matter warrants investigation. For example, when a report comes to ECAS, it is triaged by the Director of Investigations, Ms. Theodossy, who consults with UC Legal to determine if there are any other individuals who need to be consulted. Following these discussions, the matter is brought to the Locally Designated Official, an individual separate from the investigative group who has the ability to raise questions and suggest further investigation or a specific direction. There are multiple reviews of the matter from different vantage points, and when a matter is closed out, there has been a unanimous determination that there is insufficient evidence to go forward or, even if everything that an individual states is true, the matter would nevertheless not constitute a policy violation.

Regent Chu commented that training was just one way to mitigate risk. While this is an important component of risk mitigation, she asked that the Regents hear about other components of how UC locations mitigate risk in areas such as cyber security.

Chancellor Gillman remarked that the campuses have certain groups of employees who need to complete the training but are unlikely to do this through the electronic learning system, such as groundskeepers and custodial staff who rarely interact with computers. To address this, campuses organize in-person training. Chancellor Gillman asked if the employees receiving this type of in-person training outside of the learning modules are captured in these data. Mr. Bustamante responded that ECAS tries to capture as much of this information as it can and works with each of the campuses in to include this information in the finalized, aggregated data. He acknowledged that ECAS and the campuses needed to find better ways to capture all this information.

Chancellor Gillman stated his view that the statistical data presented on compliance rates did not capture the current state of affairs, the actual rates of training completion. For example, the charts that had been shown presented rates of 85 percent or 89 percent for some campuses, while the actual percentages might be higher.

Committee Chair Sures stated that he was aware of and appreciated this factor. He was not concerned about completion rates in the range of 85 percent to 89 percent, but about campuses with rates of 65 percent to 70 percent.

Regent Anguiano echoed Regent Chu's request for data on risk mitigation activities besides employee training. She reflected that cyber security requires that one have appropriate resources, staff, and technology infrastructure. She asked how these compliance findings lead to management discussions and are then translated into actions. Mr. Bustamante responded that this could be provided in future reports. The University has a layered approach to risk mitigation, in which training is only one component. There are many communication channels on the campuses to ensure that information is brought forward in a timely manner. Audits and investigations are also parts of the layered approach. He could provide more information to respond to Regent Anguiano's question.

Regent Makarechian asked if the University knew which employees were not completing required training modules. He asked if there were consequences for not completing training, and if people were failing to do this out of idleness or refusing to complete the training. Mr. Bustamante responded that UC tracks completion, is able to identify who has not completed the training, and provides this information to the campuses. Cases of non-compliance were dealt with at the campus level and the approach might differ among the campuses.

Regent Makarechian reiterated his question about the consequences for employees who do not complete required training. Chancellor Gillman responded that there might be a variety of circumstances. Some people have difficulty with access to the training modules, and the campus would reach out to address this. Some situations might necessitate a manager-employee conversation and there might be a decision to prevent that person from being eligible for merit increases, and other steps beyond that. Chancellor Gillman affirmed that there is a process and consequences for people who refuse to complete required training.

3. **ANNUAL REPORT OF EXTERNAL AUDITORS FOR THE YEAR ENDED JUNE 30, 2022**

[Background material was provided to Regents in advance of the meeting, and a copy is on file in the Office of the Secretary and Chief of Staff.]

PricewaterhouseCoopers (PwC) representative Will Cobb reported that PwC was in a position to issue unqualified opinions for the University and the medical centers. PwC also issued an unqualified opinion related to the retirement system. PwC had provided a completion results report, which included various required communications that PwC is obligated to make to the Regents under professional standards. Mr. Cobb stated that PwC received full cooperation from management and there were no disagreements. There were certain required communications concerning internal controls and accounting misstatements.

Committee Chair Sures asked if there was any issue in the systemwide audit that fell outside the norm and that Mr. Cobb felt the Board should be aware of. Mr. Cobb responded that there was nothing abnormal or outside the norm. There was a matter concerning internal controls, but he noted that this matter had been reported in the past and discussed with management. In response to another question by Committee Chair Sures, he confirmed that there were no "red flags" to report to the Committee since the last report.

Regent Cohen referred to the required communications document, which reported an identified misstatement in 2022. The University had concluded that the error was not material. He requested more detail on the incident and asked if UC had made any changes to improve controls to prevent this from happening again. Mr. Cobb responded that this was a prior year classification misstatement that was brought to PwC's attention by management. Management performed its own assessment of the materiality of the item. In the UC financial statements, items can sometimes be mis-mapped among different line items. Associate Vice President and Systemwide Controller Barbara Cevallos explained that this issue arose at one campus that had implemented Oracle last year. Financial statement mapping work was ongoing during the Oracle implementation, and this led to the error.

Regent Cohen asked if there were any campuses implementing Oracle in the current year where similar issues might arise. Ms. Cevallos noted that there had been a productive summit meeting in October where campuses that would be implementing Oracle learned from those who already had. Work was being done to ensure that campuses were implementing the lessons learned. Executive Vice President and Chief Financial Officer Brostrom added that, at this time, UC San Diego, UC Merced, and the Office of the President had shifted over to the Oracle financial system. Several more locations would make this change in the next three to four years, and UC would make sure it did not repeat the mistakes of the past.

4. **FOSTERING A FAIR AND ACCOUNTABLE CULTURE TO PROMOTE HIGH RELIABILITY IN HEALTH CARE**

[Background material was provided to Regents in advance of the meeting, and a copy is on file in the Office of the Secretary and Chief of Staff.]

General Counsel Robinson began the discussion by recalling that one important function of the Compliance and Audit Committee in evaluating reports and settlements brought before it is to review the corrective action recommendations to address any deficiencies or errors discovered during the course of litigation. This presentation would describe an evidence-based approach to responding to unexpected adverse events and developing corrective actions. The approach is known as CANDOR, which stands for "communication and optimal resolution." It is supported by the Agency for Healthcare Research and Quality, an agency of the U.S. Department of Health and Human Services, and is widely embraced throughout the healthcare industry. Among other matters, CANDOR assesses individual accountability together with systemic deficiencies and/or opportunities for improvement and its objective is to encourage open communication and consistent and fair

evaluation of work/clinical outcomes. Mr. Robinson introduced Timothy McDonald, M.D., Chief Patient Safety and Risk Officer at RLDatix, who previously served as the Chief Patient Safety and Risk Officer at the University of Illinois where he was responsible for medical oversight of a $300 million self-insurance fund. He also worked with a national group of experts to design the CANDOR process and had worked with UC since 2016 through UC's risk management program.

Dr. McDonald explained that he was a physician and an attorney and related that one of his past responsibilities had been to present liability cases to the Board of Trustees at the University of Illinois. Some settlements were massive, since the State of Illinois and Cook County did not have something like the Medical Injury Compensation Reform Act (MICRA) cap, and the Board wanted to know what would be done to prevent this in the future and if there were any needs for corrective action. Over time, one had learned that less than five percent of liability cases that are settled involve what one would consider punishable behavior. There are best practices and ways to identify cases in which corrective action is needed. Dr. McDonald emphasized the importance of building high reliability in healthcare systems and pursuing zero percent preventable harm.

It is important to review harm events to understand what happened and why. One cannot eliminate human error. It is a mistake to think that one can punish people and that this will lead to high reliability. Punishment provokes secrecy, collusion, and repression. It is also important to ask what was responsible for an event rather than who was responsible. A fair, accountable approach is one that seeks a middle ground between shaming and blaming people on the one hand and no accountability on the other. A culture of accountability distinguishes between human error, at-risk behavior, and reckless behavior. It is essential to develop a culture of accountability; an organization can have excellent strategy, but without the right culture, it is hard to improve. A culture of accountability looks at human behavior along a continuum. In cases of human error, a slip or a lapse, the people who commit errors should be consoled and supported. In cases of at-risk behavior, people break rules because they think it is acceptable or safe to break them. Reckless behavior occurs when people intentionally disregard the rules; and this results in harm. Other important factors are knowledge and purpose. An example would be the case of a Health Insurance Portability and Accountability Act (HIPAA) violation. If someone knowingly and inappropriately accesses a medical record it is leadership's responsibility to ensure that, if this was done with knowledge and purpose, that individual is held accountable.

Based on patient safety studies, Dr. McDonald asserted that 95 percent of the cases brought to the Regents would involve human error or at-risk behavior, neither of which should require firing or significant issues related to corrective action. Reckless behavior requires significant corrective action.

Dr. McDonald presented an "unsafe acts algorithm," adapted from work by James Reason, professor emeritus of psychology at the University of Manchester, United Kingdom, an expert on safety and error management in various industries. Some of the questions asked in this algorithm were: Were the actions as intended? Was there any evidence of illness or substance use on the part of the clinician? Did they knowingly violate safe procedures? If

so, were these procedures available, workable, intelligible, correct, and routinely used? Does an action pass the substitution test, or, in other words, could this happen to someone else? Does the individual have a history of these unsafe acts? The questions in the algorithm lead to a conclusion about whether one needs to apply some sort of corrective action.

Dr. McDonald outlined a case from his experience that led to a significant financial settlement in order to demonstrate the application of these principles. A 70-year-old patient was admitted with palpitations and abnormal heart rhythm. The patient had an episode of witnessed loss of consciousness. The need for defibrillation was identified. The defibrillator was attached to the patient. When the nurse tried to defibrillate and shock the patient, the device turned off. Four minutes elapsed before they could properly restart the machine and shock the patient; unfortunately, the patient suffered brain damage. The equipment was sent for review and analysis, and it was found to be working perfectly, so that operator error must have been involved. When the case came up for a decision regarding financial settlement, the question was raised about whether there was a need to review process or if individual corrective action was needed for the individual involved. Dr. McDonald presented a photograph of the defibrillator. One presses a green button to turn on the machine, selects the energy, charges it up, and then shocks the patient. In this case, when the individuals involved tried to shock the patient the machine shut off for some reason. Process reviewers ran 20 simulation tests with the machine and found that 20 percent of the time a nurse or a doctor using this device, because they are nervous and trying to resuscitate a patient, and because of the general perception that "green is good and red is bad," would inadvertently press the green button, which shuts off the device. One found that there was in fact a design defect in the defibrillator, and there were discussions related to the manufacturer; to err is human, and there should have been some warning signal or prompt asking the operator if they were certain they wanted to turn off the machine. Initially, some people wanted to fire the nurse who had pressed the wrong button. She did not intend for this to happen, she was a good nurse, she did not knowingly violate a safe procedure, and this incident would pass the substitution test in that, as it turns out, 20 percent of the time other people do the same thing that she did. The nurse had no history of unsafe acts. This was a blameless error, and the nurse needed to be consoled, not fired. Too often, within a punitive healthcare system, one would fire a nurse like this for being human. This was a classic example of human error which can happen to anyone. It was not at-risk behavior.

Dr. McDonald presented another case which illustrated the importance of communication after harm and of promoting a just culture within an institution, and which had had a significant impact on University of Illinois physicians. A patient with severe cancer was prescribed a significant amount of chemotherapy and radiation. Unfortunately, when she was in the hospital for other reasons and she had received chemotherapy, this was not communicated to the outpatient electronic medical record. When she was discharged and went into the outpatient arena she received a second dose of chemotherapy, eight weeks early. This put the patient in a dire state, with bleeding from every mucous membrane. She needed to be admitted to the intensive care unit with a central line to maintain hydration.

The head of oncology realized the mistake, used the CANDOR hotline, and asked how to communicate with the patient. A team trained in patient communication reached out to this patient with advice from a safety risk manager and the doctor explained to the patient that she was in the hospital because of a mistake he made for which he was sorry, that he knew what he had done, and he knew what needed to be put in place to prevent this from happening in the future. He was completely honest with her. The patient hugged the doctor and said that it must have been hard for him to tell her the truth. She also said that, because the doctor had been honest with her, this gave her the courage to continue with the chemotherapy treatment; earlier, she had felt that she would rather die than continue the treatment. The patient was now an 11-year cancer survivor. It was significant that hospital leadership supported this doctor in being open and honest with this patient. In terms of the above-mentioned algorithm, the doctor did not intend this, he did not knowingly violate a safe procedure, this could have happened to anyone when electronic medical records are disconnected, and he was an outstanding physician with no history of unsafe acts. In this case, there was not a need for corrective action; the institution needed to support the doctor and to fix its processes. The Board of Trustees agreed to a relatively small financial settlement since the patient ultimately recovered but there was a process redesign for the electronic medical records.

Dr. McDonald then discussed the case of RaDonda Vaught, an intensive care unit nurse at Vanderbilt University Medical Center who made an error in medication, giving a patient a paralytic agent instead of a sedative prior to an MRI scan. The patient was paralyzed but awake during the scan and then suffered brain death. Vanderbilt fired the nurse, did not apply the standards of a fair and accountable culture, and made significant mistakes. Vanderbilt did not report the truth on the patient's death certificate, did not report to the State Department of Public health as it should have, and did not report truthfully to the Centers for Medicare and Medicaid Services (CMS). An internal whistleblower informed the State and CMS, who performed an audit and found that untruthful information had been submitted by leadership. Vanderbilt almost lost its payments from Medicare as a result of this case.

The State of Tennessee charged Ms. Vaught with a crime, not using the fair and accountable or just culture principles, and this has had a significant impact around the country. Many nurses and physicians were now terrified about submitting reports of mistakes that they have made for fear of this. Dr. McDonald emphasized that, in this case, it was the leadership of the medical center that caused this outcome. A complaint was filed with the U.S. Office of Inspector General against Vanderbilt for concealing the deadly patient safety event. The just culture approach can be applied not only to frontline nurses and doctors but all the way up the chain of command.

Dr. McDonald concluded that the fair and accountable approach to harm in health care can improve culture and outcomes. Among hospital workers, those who feel that they will be treated fairly have the safest units. The single greatest impediment to error prevention is punishing people for being human and making mistakes. This methodology can be applied beyond health care as a fundamental human resources approach to compliance and misconduct in the workplace.

Committee Chair Sures referred to the idea that punishing people for making mistakes is an impediment to error prevention and noted that there is an aviation safety reporting system, administered by the National Aeronautics and Space Administration (NASA), which allows pilots to file reports of errors they have made immediately after landing. If a pilot files a report, the chances of being punished are low. The system encourages self-reporting and allows NASA to learn from the mistakes people make. He asked if there was a process like this at the UC medical centers. Dr. Byington responded in the affirmative. Deputy General Counsel Rachel Nosowsky explained that UC Health has an incident reporting system, managed by Risk Services. All the information in this system, along with information from other California hospitals, is reported to a patient safety organization whose sole purpose is to look for trends and identify opportunities for safety improvement. Dr. Byington observed that it is important that employees feel free to report errors. The UC Health system would not improve unless one understood where mistakes were being made and which systems and processes needed to be changed.

Committee Chair Sures asked if it was the case that individuals were not punished for reporting. Dr. McDonald responded that he had conducted about 2,000 interviews with UC Health employees. About 40 percent of those interviewed felt that they would be punished if they reported a mistake. There was a reporting system, but the institutional culture must respond in a fair and accountable way. There were plans for broad training at UCSF about these principles of fairness and accountability. Chancellor Hawgood added that UCSF encourages self-reporting not only of errors but also of "near misses," situations when no error occurred but could have. Regarding punishment, under California law, when there is a medical malpractice settlement, there must be a process of allocation of responsibility to a system or a person.

Committee Chair Sures asked Chancellor Hawgood for his views about the self-reporting system. Chancellor Hawgood responded that he believed that the legal requirement to allocate blame was a problem. There were other ways of dealing with reckless behavior. Dr. McDonald added that, at the University of Illinois, the issues were almost always system issues. In those cases, the University did not report the physicians or nurses to the State licensing board or the national practitioner databank. This led to an increase in event reporting. Chancellor Hawgood commented that this was the case across the UC system. Allocation to an individual was a rare event.

Regent Pérez expressed appreciation for this approach to improving patient safety but had misgivings about the presentation. The situation was presented in a way that would normalize deviance. He referred to Dr. McDonald's assertion that 95 percent of the cases brought to the Regents would involve human error or at-risk behavior, while five percent would involve reckless behavior. He asked if these percentages were based on number of incidents or cost of settlements. Dr. McDonald clarified that this referred to number of incidents.

Regent Pérez commented that, in the cases that come before the Regents, there were patterns of problematic activity that were not consistent with the examples in this presentation. He was concerned that this presentation had minimized the importance of the

five percent of cases with reckless behavior, and he had concerns about how UC approaches accountability outside the individual provider. In cases involving high dollar amounts, whistleblowers had come forward, but campuses did not respond to the whistleblower reports. There had been decreases in whistleblower reporting because a different message seemed to have been transmitted, which was that the institution would not investigate and take the reports seriously. Regent Pérez did not dispute Dr. McDonald's numbers but stressed UC's obligation for apportionment of responsibility when there are patterns of concern. The effort to create a culture of self-reporting was important, but the Regents had a different responsibility above and beyond that to hold themselves and the administration accountable when patterns of reckless behavior kept repeating themselves. He asked what UC should do if there was a pattern over time of a campus under-responding to whistleblower complaints. Dr. McDonald responded by emphasizing that individuals who commit reckless acts with knowledge and purpose must be held accountable and fired in cases such as a HIPAA violation. The fair and accountable culture in this presentation would require this.

In response to another question by Regent Pérez, Dr. McDonald affirmed that, in cases of reckless behavior, this culture would require a thorough investigation at every level to determine who knew what and what they did, and to assess their behavior. Regent Pérez asked that this matter be discussed further in closed session in connection with litigation the University was facing.

President Drake referred to the cited percentages of 95 and five percent; he accepted the survey figures, but noted that, based on his experience of approving settlements, he would have estimated that the proportion of cases with human error or at-risk behavior accounted for 98 or 99 percent of cases, while reckless behavior was present in one or two percent of cases. It was extraordinarily rare that there was purposeful, repetitive bad action; cases were almost always the result of human error. He expressed agreement with Regent Pérez's concerns and concurred that, in cases of repeated activity or when a person has acted knowingly, termination is a proper response. President Drake shared experiences from his own career as a medical practitioner, such as weekly meetings with colleagues to discuss mistakes, problems, and bad outcomes. This was a positive practice that allowed people to discuss and share these issues. He reflected that, when there is a bad outcome for a patient, this is often painful for a physician, even if no punishment is warranted or received, and that it is important to have a supportive culture for physicians. He recalled a panel of UCSF physicians, about 20 years prior, who shared their worst mistakes in recent years. In all these cases, the physicians had been honest with patients and their families about the mistakes and had apologized. None of these cases resulted in lawsuits. Today, some of these cases would be litigated no matter what because there was injury, and the system would require this. A sincere apology by the physician, taking responsibility for one's actions, made a difference.

Dr. McDonald added that part of the CANDOR system is providing peer support to the doctors and nurses involved in these harm events. Some UC campuses were actively reaching out to practitioners involved in these events.

The meeting adjourned at 11:25 a.m.

Attest:

Secretary and Chief of Staff