SUMMARY STATEMENT

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(Privileged Communication)

Release Date: **03/19/2018**
Revised Date:

Application Number: **1 F31 HL144028-01**

REHM,GREGORY
The Regents of the University of California
(Davis
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Review Group:	**ZRG1 F16-L (20)** **Center for Scientific Review Special Emphasis Panel** **Fellowships: Risk, Prevention and Health Behavior**
Meeting Date:	**03/05/2018**
Council:	**MAY 2018** ***PCC:*** **LLLH N**
Requested Start:	**07/01/2018**

Project Title:	**A Real-Time Computational System for Detecting ARDS Using Ventilator Waveform Data**
	***Requested*: 2 Years 5 Months**
Sponsor:	**Adams, Jason Y**
Department:	**Engr Computer Science**
Organization:	**UNIVERSITY OF CALIFORNIA AT DAVIS**
City, State:	**DAVIS CALIFORNIA**
SRG Action:	**Impact Score:33 Percentile:28**
Next Steps:	**Visit https://grants.nih.gov/grants/next_steps.htm**
Human Subjects:	**48-At time of award, restrictions will apply**
Animal Subjects:	**10-No live vertebrate animals involved for competing appl.**
Gender:	**1A-Both genders, scientifically acceptable**
Minority:	**1A-Minorities and non-minorities, scientifically acceptable**
Children:	**3A-No children included, scientifically acceptable**

1F31HL144028-01 Rehm, Gregory

PROTECTION OF HUMAN SUBJECTS UNACCEPTABLE

RESUME AND SUMMARY OF DISCUSSION: This application requests support for training in computational and machine learning techniques relevant to intensive and critical care environments and research that focuses on the development of tools to detect acute respiratory distress syndrome (ARDS). In discussion, the reviewers emphasized application strengths of a talented applicant with an unusual background as a software engineer, outstanding graduate school academic performance, an emerging publication record, and enthusiastic letters of recommendation. The mentoring team has most of the needed expertise and experience to guide the applicant to successful completion of the research and training activities. The team is somewhat junior, however, and lacks sufficient depth in critical care and implementation and dissemination science. The research project addresses the critically important clinical issue of supporting physicians in identifying the devastating condition of ARDS so that treatment can be implemented. Concerns were raised regarding the apparent lack of consideration for multicollinearity and the absence of discussion of the validity of the exposure and independent variables. It also is not clear that the proposed sample sizes are sufficient to validly train the ARDS detection model and how patients who cycle on and off ventilation will be accounted for in the models. The training plan includes relevant activities and experiences to broaden the applicant's skills and expertise but some goals are under-specified and the plan lacks sufficient depth in scientific writing, grant writing, and formal course attendance. Overall, application strengths of a competent applicant, a committed team, and a clinically important research project were slightly offset by these concerns.

DESCRIPTION (provided by applicant): Acute respiratory distress syndrome (ARDS) is a severe form of acute hypoxemic respiratory failure affecting 10% of patients admitted to the intensive care unit (ICU) in the United States. In-hospital mortality of 35-46% has been reported across the spectrum of mild-severe ARDS, and one third of patients with initially mild ARDS will progress to moderate or severe ARDS. Over the last 20 years, multiple studies have reported improved outcomes for ARDS patients using specific ARDS targeted therapies. However, ARDS remains persistently under-recognized and challenging to diagnose. Only one third of ICU providers correctly identify ARDS on the first day when diagnostic criteria are met, and less than two thirds ever recognize the diagnosis in the ICU. This under recognition of ARDS may prevent some patients from receiving lifesaving therapies necessary for treating the disease. Attempts to automate ARDS diagnosis using rule- based algorithms have seen limited success, and require analysis of subjective data from patient histories, like chest scans, which limit diagnosis automation, timeliness, and study reproducibility. To improve the current state of the art of ARDS detection technology, we intend to utilize objective and readily available data including both ventilator waveform data, (VWD) and electronic health record (EMR) data to 1) improve the recognition of ARDS, and 2) identify high-risk ARDS patients most likely to benefit from additional ARDS treatments. For this task, we will make use of an existing dataset of VWD from over 500 patients receiving mechanical ventilation, including 156 patients with confirmed ARDS. Our preliminary analyses using a machine learned model and a subset of lung physiology features derived solely from VWD, suggest that ARDS can be diagnosed in the absence of a chest scan or medical history. In Aim 1 of this proposal, we will improve our existing model used for discriminating ARDS by adding objective EMR data, and additional features extracted from VWD, such as patient respiratory compliance and airway resistance. Our next focus will be to predict worsening of ARDS severity in intubated patients based on Berlin criteria. So in Aim 2, we will evaluate the best tools for predicting increases in ARDS severity, and which types of temporal information yield the best predictive results. We hypothesize that model development using additional objective data derived from VWD analysis and the EMR, along with advanced analytic techniques, will further improve ARDS diagnosis, and enable the prediction of clinical trajectories in patients with ARDS. The proposed work will yield innovative clinical decision support models that can be used to improve the state of the art in automated ARDS diagnosis. Our predictive modeling will also enable greater insight into the times when physicians can perform clinical

interventions to arrest ARDS induced physiologic deterioration. Ultimately, these innovations could save lives by quickly detecting ARDS, and alerting physicians to begin or intensify ARDS focused therapies based on patient pathophysiologic state.

PUBLIC HEALTH RELEVANCE: Acute respiratory distress syndrome (ARDS) is a highly lethal disease contracted by over 100,000 Americans each year. We seek to address whether we can create automated technologies to detect onset and change in severity of ARDS in critically ill patients using widely available ventilator waveform data. With these automated diagnostic testing technologies, doctors can promptly deliver necessary treatments for ARDS before the disease worsens.

CRITIQUE 1

Fellowship Applicant: 3
Sponsors, Collaborators, and Consultants: 4
Research Training Plan: 4
Training Potential: 5
Institutional Environment & Commitment to Training: 3

Overall Impact/Merit: The applicant proposes a 29 month F31 fellowship at the Univ of California Davis with a sponsor and co sponsor examining the value of ventilator waveform and more general EHR data to improve recognition of ARDS and identify patients at high risk for ARDS. The applicant appears strong in past experience and current platform application to data management and mining, but needs development in academic deliverables and productivity. The sponsors are somewhat junior and with limited funding threads as examples for the applicant to emulate, somewhat below average mentoring experience cumulatively but with good capacity to cover some but not all areas of interest and need for the applicant. Additional expertise in secondary data analysis, late stage translational research and implementation science might enhance the application. The overall training potential and plan appear too heavily research focused and miss opportunities to truly develop expertise on a more balanced fashion between classroom exposure and application with very little class time or contact with implementation scientists. The research project represents a fairly good platform but does not seem to be fully mined for opportunity to apply computational approaches and machine learning, and thus loses some robustness in promoting the training goals outlined by the applicant. The overall impression is for an above average application with a fair probability of enhancing the applicant's career trajectory but with several minor to moderate remediable weaknesses that dampen enthusiasm predominantly in lost opportunities for learning and exposure to and incorporation of more diverse academic disciplines into the work.

1. Fellowship Applicant:

Strengths

- The applicant completes a BS in mathematics at Georgia State Univ and an MS at UC Davis, currently completing PhD in comp sci at UCDavis expected 12/2020.
- The applicant wishes to work in a team science setting with colleagues from medicine, computer science and informatics (p 20) and be a "leading scientist in computational and translational medicine".
- Brings experience as a software engineer and has already developed the platform for the VWD to be used in this project.
- Some challenges in undergrad academic performance followed by outstanding performance in grad school.

- Strong letters from 2-3 year relationships, consistently note capacity, internal drive and curiosity. A letter from industry would have strengthened application even more, but this represents a very good strength overall.

Weaknesses

- Little to no publication experience in traditional academic journals and would be expected to have a strong scientific writing training component as well as academic productivity expectations as part of training.

2. Sponsors, Collaborators, and Consultants:

Strengths

- Dr Adams is an MD with MS in health informatics, pulm/crit care provider with content well matched to applicant's project as they have worked together in the past. Publications are relevant but length of time past fellowship is relatively short as a F sponsor.
- Dr Anderson is a assoc prof of biomed informatics with emphasis in system usability, data sharing, and research engagement of participants, which is not very well matched to the project but the personal statement (p 29) notes a track record with algorithms using critical care and clinical outcomes data – this is relevant. Mentoring experience is average for an F sponsor of this career stage.

Weaknesses

- Dr Adams is an asst prof 5 years from fellowship with a single 1 year seed grant as PI – this is below average for an F primary sponsor. It also appears Dr Adams has only mentored 2 post docs previously (p 53) but will now have 3 simultaneous grad students (p 55) during the period of proposed fellowship. It is unclear if this may represent a threat to availability for the candidate's needs.
- Dr Anderson has several ending funded projects (CAIPM, UCD BCHE, p 31) that appear applicable but no long threads in PI-ships highly related to the project proposed.
- Given the applicant's interests to function in multidisciplinary translational teams, greater exposure to sponsors with longer academic track records and experience in implementation sciences and engineering applications in clinical medicine could improve the application.

3. Research Training Plan:

Strengths

- The applicant proposes to modify an existing machine learning model with VWD to determine performance changes and develop a time series machine learning model to predict deterioration of patients with early ARDS. Additional EHR data will be layered into analyses, which is appropriate.
- Conventionally accepted criteria for ARDS will be used and the cohort of 502 patients will be partitioned into development and validation cohorts.
- Contingency analyses are proposed and rational based on existing knowledge and available data, this is a strength.
- Attractive that several different approaches to modeling will be used and compared in aim 2, although given the training interests and availability of data, one wonders whether other additional approaches could not further stretch the applicant's training benefit.

Weaknesses

- There is no discussion of exposure and independent variable validity or issues of multicollinearity, suggesting additional epidemiologic and biostatistical expertise may be relevant to the training.
- What is the implication of ARDS patients representing only about 31% of patients in the cohort but almost 50% of the hourly data.
- Not clear that only 10 patients each of ARDS, COPD or other pathophysiology were sufficient to train the ARDS detection model as presented and without further specification as to comorbidities or other potentially relevant factors.
- It is not clear how patients who go on and off of ventilation and may share pathophysiologies will be handled in the models.
- Request for phone contact of surrogate decision makers is not sufficiently explained to reassure logistical standardization and completeness in recruitment without selection bias and possible distress to patient/family, including context of saved data before consent obtained. Further detail and prior experience summary is warranted (p 62).

4. Training Potential:

Strengths

- The applicant wishes to develop capacity to apply computational and machine learning to solve relevant problems in ICU and critical care. The desire to expand a network of collaborators and think along team science lines is excellent in this regard (p 39).
- Excellent goal of including development in communication and presentation work in industry, which was valuable but not what is sought necessarily in academics. Expectations for presentations annually are appropriate.

Weaknesses

- Seems to be research heavy in the first year (64%, p 40) given 75-80% research focus downstream relative to desired goals to learn more in informatics and machine learning – similarly, not nearly enough coursework to establish expertise in desired areas (6-16%, p 40, 4 courses outlined on p 41), esp since only one course is in machine learning and clinical epi and study design does not come until the graduating quarter of the last year of fellowship (p 41).
- No apparent scientific writing or grant writing seminar or course attendance expectations, which is a significant weakness given the applicant's experience to date and desire to function in academic team settings.

5. Institutional Environment & Commitment to Training:

Strengths

- There appear to be sufficient computing facilities, research experience and expertise, educational capacity, and clinical resources to successfully conduct the work.

Weaknesses

- There appear to be many more resources and opportunities for seminar attendance, clinical correlation, didactic experiences and research approaches that are not incorporated and thus represent an incomplete utilization of the resources available.

Protections for Human Subjects:

Unacceptable Risks and/or Inadequate Protections

- Unclear that obtaining and storing research information without consent with subsequent promise to delete if unable to contact patient or surrogate and obtain consent is an acceptable approach to the consent process, further detail and experience is warranted

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- Inclusion/Exclusion of Children under 18: Excluding ages < 18 not justified scientifically
- excluding children and pregnant women as vulnerable populations, but these patients can and may still develop ARDS, thus scientific justification should be provided.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Training in the Responsible Conduct of Research:

- Acceptable

Comments on Format (Required):

- Small group and didactic training as well as online resources

Comments on Subject Matter (Required):

- Appears appropriate (p 51)

Comments on Faculty Participation (Required):

- CLH 204 led by faculty

Comments on Duration (Required):

- 3 credits and 49.5 total hours for CKH 204 alone

Comments on Frequency (Required):

- classes and online recerts occur annually and once every three years, respectively

Resource Sharing Plans:

Acceptable

- Appears appropriate, will share software, p 70

Budget and Period of Support:

Recommend as Requested

CRITIQUE 2

Fellowship Applicant: 2
Sponsors, Collaborators, and Consultants: 4
Research Training Plan: 4
Training Potential: 2
Institutional Environment & Commitment to Training: 2

Overall Impact/Merit: Mr. Rehm's proposal, "A real-time computational system for detecting ARDS using ventilator waveform data," intends to utilize object and readily available ventilator and electronic health record data to improve recognition of ARDS and identify high-risk ARDS patients most likely to benefit from additional ARDS treatments. The proposed science has significant potential to improve this devastating condition by utilizing and packaging available clinical information for physicians. Mr. Rehm has published a first-authored manuscript of the fundamental preliminary work for this proposal in a top-tier journal (JAMIA). His letters of support suggest he is a strong candidate for achieving his proposed career goal of computational and translational research. Weaknesses of this proposal include specificity around training goals and objectives.

1. Fellowship Applicant:

Strengths

- As a masters student, and under the same mentorship as proposed, Mr. Rehm's successfully published two manuscripts (one first-authored), with two more (as first author) in progress. He has a first authored manuscript in JAMIA on the development of the system for collecting mechanical waveform data, to be used in the proposed study.
- Mr. Rehm has a unique background in computer science and has already begun to successfully engage in interdisciplinary research.

Weaknesses

- None noted.

2. Sponsors, Collaborators, and Consultants:

Strengths

- Dr. Adams (Primary Sponsor) recently completed a K12 career development award to develop informatics infrastructure to allow the study of patient-ventilator interactions. This expertise, combined with his clinical background as a pulmonary and critical care physician, provide excellent background for Mr. Rehm.
- Dr. Anderson (Co-Sponsor) has expertise in investigating integrating clinical and outcomes data for research and clinical care.

Weaknesses

- Dr. Adams is an assistant professor and does not have any current research support, with his last funding ending in June 2017. However, Dr. Anderson offers to provide necessary resources to Mr. Rehm, through his funding on multiple projects, including as Co-I on a P30 and Biomedical Informatics Core Director for the UC-Davis CTSA. Dr. Adams does have several proposals pending, including a DOD proposal as Co-PI.
- Although the mentors have outstanding strengths in the applicant's interest areas, identifying a more senior mentor with active related research funding is recommended to provide additional expertise.

3. Research Training Plan:

Strengths

- Mr. Rehm's career goal is to be "a leading scientist in the field of computational and translational medicine." His training goals include: (1) expand network of clinical collaborators; (2) strengthen underlying skills in machine learning; (3) become an expert informaticist; (4) improve leadership skills; (5) improve communication and presentation skills; and (6) find preliminary data for later studies. Overall, these objectives are appropriate but lack specificity.
- The proposed research plan is innovative and Mr. Rehm has already published in this area, suggesting success in his ability to move this work forward. In addition, the preliminary models have demonstrated sensitivity comparable or superior to clinician recognition, without need for a chest radiograph, ABG or other clinical information. This suggests tremendous potential utilization, given the rise of telemedicine, in caring for patients at risk for developing this devastating illness.

Weaknesses

- Some of the training goals lack specificity in how they will be achieved. For example, "become an expert informaticist" will be achieved through courses and "collaborating with members of the clinical information technology group to create systems that can more rapidly gather EMR data." Greater detail about these collaborations can help identify how these will be thoughtfully integrated into Mr. Rehm's training (major weakness).
- The timeline of research could be better presented as a Gantt chart than a table (minor weakness).
- The research plan is still limited to a single institution, which as described, has limited the generalizability of other ARDS models.

4. Training Potential:

Strengths

- Mr. Rehm's letters of support suggest he has the necessary skills to be successful in interdisciplinary research: "more and more [Mr. Rehm] is functioning as the semantic glue between groups and entities that traditionally did not have common ground."
- Mr. Rehm's unique background in computer science has enabled him to make connections between disciplines and has resulted in more productivity in both topics researched and scholarly product.

Weaknesses

- None noted.

5. Institutional Environment & Commitment to Training:

Strengths

- UC-Davis has a CTSA which provides resources to junior researchers. In addition, there is also a nationally recognized Graduate Group in Computer Science, with strong ties to UC-Davis Medical Center.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

- Risks to human subjects are minimal and protections described adequately.

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable
- Inclusion/Exclusion of Children under 18: Excluding ages <18; justified scientifically
- This secondary data analysis appropriately includes women and minorities. Children are excluded, which is scientifically justified.

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Training in the Responsible Conduct of Research:

- Acceptable

Comments on Format (Required):

- Formal coursework in the responsible conduct of research will be completed, in addition to web-based tutorials.

Comments on Subject Matter (Required):

- Subject matter covers appropriate material.

Comments on Faculty Participation (Required):

- Course is taught by faculty member, who is also the primary contact for ethics consults for research.

Comments on Duration (Required):

- Course consists of nearly 50 hours of training.

Comments on Frequency (Required):

- Web-based tutorials and coursework will occur throughout proposed project period.

Resource Sharing Plans:

Acceptable

- Reviewed and acceptable.

Budget and Period of Support:

Recommend as Requested

CRITIQUE 3

Fellowship Applicant: 1
Sponsors, Collaborators, and Consultants: 2
Research Training Plan: 2
Training Potential: 1
Institutional Environment & Commitment to Training: 2

Overall Impact/Merit: The candidate, Gregory Rehm, already has a MSC in Computer Science from UC-Davis and is currently a PHD student in the same program at the same institution. His project is a real-time computation system for detecting ARDS using ventilator waveform data. Preliminary data suggests that this can be done with some degree of accuracy without any clinical or X-ray data. Experienced ICU clinicians miss this diagnosis most of the time. He proposes to use an existing dataset of 500 ICU patients, 156 of whom have adjudicated ARDS according to Berlin criteria, and merge their ventilator waveform data with selected data from the HER to determine if the combined models better discriminate between those with and without ARDS; next he will use machine learning algorithms (Deep Learning, Hidden Markov Models) to discriminate between which patients with ARDS do and do not progressively worsen. The ultimate goal – and seemingly an absolutely on-target scientific effort – is to develop an automated algorithm for the recognition of the highly lethal condition, ARDS, that can be more effectively treated if recognized. There is a very high level of enthusiasm for this project, the candidate, his mentors and the environment that he is in.

1. Fellowship Applicant:

Strengths

- Very strong letters of recommendation.
- Candidate is noted to not only to be a quick study in areas of science where he has no solid background but he also has high emotional intelligence.
- He has three years of non-academic, industry work experience.
- Overall, he has a good publication record and has published already in the area of his proposed project.
- Academic record is above average, mostly As in graduate school.

Weaknesses

- None noted.

2. Sponsors, Collaborators, and Consultants:

Strengths

- A solid team of sponsors has been assembled.

Weaknesses

- Prior training records are not uniformly extensive.
- Consider broadening the sponsor/mentor team to expand the training milieu of the candidate – critical care physician, dissemination scientist, etc.

3. Research Training Plan:

Strengths

- 2-year training program is proposed that continues course work in various aspects of machine learning (deep learning, hidden Markov Models) necessary for the execution of his proposed project.
- The training appears to be incremental to that required for his PhD.
- Timeline and approach is well described.
- The research training proposed is for sure a vexing important issue in critical care medicine that will not be solved by traditional critical care-based clinical research because most clinicians, even experienced ones, do not recognize (or at least strongly suspect) this condition in real-time; thus, the proposed is extremely timely, important and is best carried out by a team with the credentials as the one put forth in this application.

Weaknesses

- Scholarly output benchmarks are not explicitly defined.
- More emphasis should be placed on things like grant/manuscript writing, multi-disciplinary collaborations.

4. Training Potential:

Strengths

- Outstanding.

Weaknesses

- None noted.

5. Institutional Environment & Commitment to Training:

Strengths

- Strong.

Weaknesses

- None noted.

Protections for Human Subjects:

Acceptable Risks and Adequate Protections

- no concerns

Data and Safety Monitoring Plan (Applicable for Clinical Trials Only):

Not Applicable (No Clinical Trials)

Inclusion of Women, Minorities and Children:

- Sex/Gender: Distribution justified scientifically
- Race/Ethnicity: Distribution justified scientifically
- For NIH-Defined Phase III trials, Plans for valid design and analysis: Not applicable

- Inclusion/Exclusion of Children under 18: Excluding ages <18; justified scientifically
- no concerns

Vertebrate Animals:

Not Applicable (No Vertebrate Animals)

Biohazards:

Not Applicable (No Biohazards)

Training in the Responsible Conduct of Research:

- Acceptable

Comments on Format (Required):

- didactic, small group discussion, online CITI training,

Comments on Subject Matter (Required):

- animal subjects in research, misconduct, conflict of interest, human subjects in research, etc.

Comments on Faculty Participation (Required):

- demonstrated

Comments on Duration (Required):

- 1.8 hours/week over 9 weeks

Comments on Frequency (Required):

- every quarter for a year

Budget and Period of Support:

Recommend as Requested

THE FOLLOWING SECTIONS WERE PREPARED BY THE SCIENTIFIC REVIEW OFFICER TO SUMMARIZE THE OUTCOME OF DISCUSSIONS OF THE REVIEW COMMITTEE, OR REVIEWERS' WRITTEN CRITIQUES, ON THE FOLLOWING ISSUES:

PROTECTION OF HUMAN SUBJECTS: UNACCEPTABLE. It is not clear that obtaining and storing research information without consent with subsequent promise to delete if unable to contact patient or surrogate and obtain consent is an acceptable approach to the consent process; greater detail and explanation of potential risks and benefits of this procedure is required.

INCLUSION OF WOMEN PLAN: ACCEPTABLE

INCLUSION OF MINORITIES PLAN: ACCEPTABLE

INCLUSION OF CHILDREN PLAN: ACCEPTABLE

COMMITTEE BUDGET RECOMMENDATIONS: The budget was recommended as requested.

Footnotes for 1 F31 HL144028-01; PI Name: Rehm, Gregory B

NIH has modified its policy regarding the receipt of resubmissions (amended applications). See Guide Notice NOT-OD-14-074 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-074.html. The impact/priority score is calculated after discussion of an application by averaging the overall scores (1-9) given by all voting reviewers on the committee and multiplying by 10. The criterion scores are submitted prior to the meeting by the individual reviewers assigned to an application, and are not discussed specifically at the review meeting or calculated into the overall impact score. Some applications also receive a percentile ranking. For details on the review process, see http://grants.nih.gov/grants/peer_review_process.htm#scoring.

MEETING ROSTER

Center for Scientific Review Special Emphasis Panel
CENTER FOR SCIENTIFIC REVIEW
Fellowships: Risk, Prevention and Health Behavior
ZRG1 F16-L (20)
03/05/2018 - 03/06/2018

Notice of NIH Policy to All Applicants: Meeting rosters are provided for information purposes only. Applicant investigators and institutional officials must not communicate directly with study section members about an application before or after the review. Failure to observe this policy will create a serious breach of integrity in the peer review process, and may lead to actions outlined in NOT-OD-14-073 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-073.html and NOT-OD-15-106 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-106.html, including removal of the application from immediate review.

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