Exploring Legal Challenges to Fulfilling the Potential of mHealth in a Safe and Responsible Environment

Workshop I: Regulation

Convened and Hosted by AAAS

June 16-17, 2014

Goal: The workshop will assist AAAS in setting forth the principles and requirements for a regulatory framework that promotes development of mHealth devices and apps to improve patient health, while at the same time protecting the public from undue risk.

To achieve that goal AAAS will:

- Gather the views of a wide range of experts and affected populations to contribute to the preparation of a AAAS report on the topic of mHealth regulation;
- Commission papers from among those attending the workshop to trigger discussion on specific agenda topics;
- Build on the advanced dissemination of those commissioned papers and relevant guidance/policies to inform the workshop deliberations;
- Use the workshop deliberations to engage in post-workshop electronic discussions among the participants to elaborate on and fine-tune a set of findings and recommendations;
- Release a AAAS report on the findings and recommendations related to the regulation of mHealth; and
- Use social media to gather views from a public beyond the workshop attendees.

Conference Agenda

Day I: June 16

8:00-8:30  Continental Breakfast

8:30-9:15  Welcome, Goal of Project, and Introductions

Speakers:  Mark S. Frankel, AAAS
          Deborah Runkle, AAAS

9:15-10:00  State of the Art, Part I: Technologies. This session will focus on an overview of the types of mHealth applications that are currently part of health care practice and the newer technologies that are expected to be realized in the near- to medium-future.

Moderator:  Deborah Runkle

Speakers:  Santosh Kumar, University of Memphis/Wendy Nilsen, National Institutes of Health
10:00-10:30  **Break**

10:30-12:30  **State of the Art, Part II: Regulations, Guidelines and Policies.** This session will focus on how our regulatory, legislative, and other policy-making bodies are addressing these rapidly-developing mobile health technologies. What actions are they taking? What plans do they have on the drawing board?

**Moderator:** James Kelly, *Food and Drug Law Institute (emeritus)*

**Speakers:** Bakul Patel, *U.S. Food and Drug Administration*
Matthew Quinn, *Federal Communications Commission*
Cora Tung Han, *Federal Trade Commission*
Wendy Nilsen, *National Institutes of Health*

12:30-1:30  **Lunch**

1:30-3:30  **Opportunities and Challenges: Stakeholder Perspectives.** This session will enable a variety of stakeholders to respond to the information from the previous sessions.

**Moderator:** Carol Ley, *3M*

**Speakers:** Richard Katz, *George Washington University*
Jason Brooke, *Vasoptic Medical*
Kent Dicks, *Alere Inc*
Robert Jarrin, *Qualcomm Inc.*
Gail Gibson Hunt, *National Alliance for Caregiving*
Nithya Ramanathan, *UCLA/Nexleaf*

3:30-4:00  **Break**

4:00-5:30  **Regulatory Landscape I.** This session will explore state-specific regulations, covering standard of care, electronic prescribing, and related issues. To what degree do states differ in their approaches to regulating mHealth? Is a state-by-state regulatory scheme advancing or hindering mHealth applications?

**Moderator:** Kyle Peterson, *Calgary Scientific*

**Speaker:** Alexis Gilroy, *Jones Day*

5:30  **Adjourn**
Day II: June 17

8:30-9:00  Continental Breakfast

9:00-10:30  Regulatory Landscape II: Looking Forward. This session will focus on the next steps in regulation, guidelines, and policies. What, if any, new regulations or guidelines are needed? What type of regulatory framework will strike the right balance between facilitating innovation and deployment of new technologies, while at the same time protecting patient safety?

Moderator:  Elisabeth Belmont, Maine Health
Speakers:  Melissa Goldstein, George Washington University/Frank Pasquale, University of Maryland School of Law
          Bradley Thompson, Epstein Becker Green

10:30-11:00  Break

11:00-12:30  Recommendations. What should government regulating and policy-making bodies do to create a supportive regulatory environment for the development of new mHealth devices and apps? What principles should guide government agencies? What role is there for non-governmental bodies? How can these principles be operationalized so that industry will know what is expected of it?

Moderator:  Mark S. Frankel, AAAS

12:30-1:30  Lunch

1:30-3:00  Recommendations (con’t)

Moderator:  Deborah Runkle, AAAS

3:00  Wrap-up and Adjourn

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