Testimony to the Subcommittee on Commerce, Manufacturing, and Trade

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Summary:

Chairman Burgess and members of the subcommittee, thank you for the opportunity to share this testimony on mobile health applications. I will focus on their value and limitations, including possible risk to patients, as they relate to my specialty of dermatology. I support the use of technology to improve patient access to high-quality dermatologic care as well as to improve early detection and diagnosis of skin cancer. My own research has shown that with easy distribution of apps to consumers, several poor-quality apps that claimed to be able to diagnose skin cancer were sold or made available for free to consumers and I am glad that our work helped the Federal Trade Commission to take these out of the marketplace. However, technology, properly tested and placed in the hands of physicians rather than provided directly to the consumer in a way that bypasses the physician-patient relationship, has the potential to improve early detection of skin cancer. In addition, mobile technology helps to deliver health care to patients who do not have access to the care and expertise of a dermatologist and to allow the current work force of dermatologists to more efficiently deliver care and reduce patient wait times to see a dermatologist.

My testimony will focus on the following points:

1. Direct-to-consumer apps that function as medical devices, make unsubstantiated claims, are not data-driven put patients at a high degree of risk and regulatory oversight should reflect this risk.
2. Telehealth applied to the field of dermatology has the potential to improve patient access to high-quality dermatologic care.
3. Mobile health applications that provide computer assistance in making a diagnosis are most appropriately and safely used by physicians and not directly by patients and the regulatory path to developing such technologies should take into consideration the difference in risk posed by a medical device in the hands of physicians vs. patients.

Appropriate regulation can help to keep patients safe; over regulation and lack of clarity in a changing landscape will stifle innovation.

Statement:

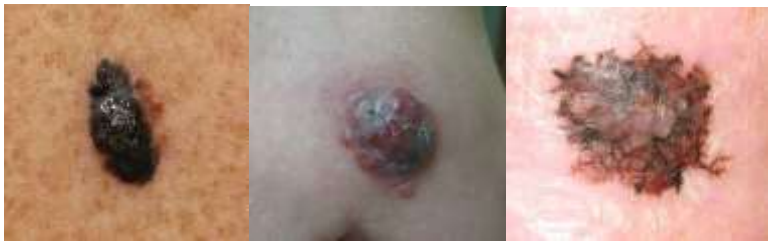
Because of the visual nature of the field of dermatology, we were among the first fields of medicine to experience the breadth of application of mobile health technology to patient care. I am here to share with you both the good and the bad that can result from this.

As a dermatologist at the University of Pittsburgh, a large part of my clinical practice and research is focused on the early detection of skin cancer. My interest in mobile health applications came from casual inquiries from my patients about apps available for their smartphones that claimed to be able to analyze a photograph that they had taken of a skin lesion and to give them information about if the lesions was benign, suggesting that they did not need to seek medical attention, or malignant, meaning they should see a doctor to determine if they had skin cancer and if a skin biopsy should be performed. My research team and I decided to test out some of these apps using photographs we had taken of skin lesions on our patients prior to biopsy and for which we thus knew the correct diagnosis. Three of these apps were inexpensive or free and gave an instantaneous answer, based on computer analysis,

Application No.	Evaluable Image, No. (%)	Sensitivity, % (95% CI)	Specificity, % (95% CI)
1	182 (96.8)	70.0 (56.6-80.8)	39.3 (30.7-48.6)
2	185 (98.4)	69.0 (55.3-80.1)	37.0 (28.7-46.1)
3	170 (90.4)	6.8 (2.2-17.3)	93.7 (87.0-97.2)
4	159 (84.6)	98.1 (88.8-99.9)	30.4 (22.1-40.3)

stating that the lesions was either at high or low risk of being skin cancer. None provided data about how they worked or if or how they had been validated. The fourth app sent the image to a board-certified dermatologist who then determined if that lesion was high or low risk but provided no care or guidance as to what to do from there. In our study, we found that the three automated apps missed 30-93% of the melanomas, the most deadly form of skin cancer, we presented to them. The board-certified dermatologist missed only one lesion (1.9%). Our results, are shown in this table (sensitivity is the proportion of melanomas that were correctly classified as melanoma; specificity is the percentage of benign lesions that were correctly classified as benign). [1]

Melanomas missed by automated apps:



This means that if a patient decided to save time and money by trusting their health to one of these apps that was easily available on their smartphone, at least a third of the time they would be dissuaded from seeking medical attention for a skin cancer that is generally curable when caught early and fatal when caught late. However, the user of one of these apps would not be aware of this because these apps did not provide data on their accuracy, nor did they adequately explain the consequence of a delay in the diagnosis of melanoma. These types of apps are no longer widely available to the public

due to actions by the Federal Trade Commission which charged app makers with making deceptive health claims. Mobile medical apps that interact with the patient directly, with no physician input, have the greatest potential to cause harm and thus require the greatest degree of oversight and should not be marketed with unsubstantiated claims directly to consumers.

Our findings also showed that store and forward telemedicine was actually quite accurate in detecting of melanomas, a finding repeated by other studies as well which show that show a high correlation between in-person and telemedicine evaluation in the evaluation of skin lesions .[2] However, unlike other telehealth applications that provide an extension of the existing patient-physician relationship, the app in our study provided a single assessment from a physician who has no relationship with the "patient" on the other end of the app. Currently, many similar such apps are still widely available. In such apps, often the physician's credentials are not available to the patient (and in some cases the doctor is not licensed in the US) and the physician does not have access to the patient's medical history and would not be able to perform the counseling or arrange in-person follow up that may be an essential part of patient care. A patient with one of the lesions pictured above does not just need someone to decide if a biopsy should be performed; that patient needs a physician who can explain the consequences of opting not to do have the lesion biopsied, who will follow up with a phone call if the patient initially declines a biopsy, and who will ultimately help guide them through their treatment when they are diagnosed for melanoma. An app that simply provides a reading of "high risk," even if it is correct, is easier to ignore than a physician who can explain the consequences of a delayed diagnosis of melanoma.

Teledermatology provided in the context of a legitimate physician-patient relationship can improve patient access to dermatologists, particularly in underserved populations.[3, 4] There are currently multiple platforms that allow for the delivery of teledermatology. Reimbursement for appropriate teledermatology services would expand access to this service, which has the potential to result in the

earlier diagnosis of skin cancer[5] in addition to improving access for patients with a variety of skin diseases. Reimbursement for high-quality teledermatology services, provided by a licensed physician and within a physician-patient relationship or as part of physician-to-physician consultation, will allow for the growth of these services. Such services should augment but not be intended to replace or be a requirement for ultimately obtaining face-to-face care from a dermatologist when either the patient or the physician feels this is the best option.

While my initial work highlighted some of the potential pitfalls of technology released directly to patients too quickly and without evidence or physician involvement, I see great promise in the use of technology to improve patient care, particularly in the field of the early diagnosis of skin cancer. I have been working with collaborators at Carnegie Mellon University to develop a system that applies computer vision to skin cancer diagnosis. We have developed a program that accurately identified 97% of melanomas using images taken with a small device called a dermatoscope that can be attached to a smartphone which can then send that image to a server where the image can be processed and a score can be given to help to determine how likely that lesion is to be malignant.[6] Others have developed similar technologies that use computer-assisted diagnosis to provide more information about skin lesion that can ultimately aid in making a diagnosis. [7] While we can make a claim of performance based upon published data, our vision for this technology has never been to put it directly in the hands of patients. We see this as a tool that gives a non-dermatologist medical professional, such as a primary care physician, additional information, to use along with their clinical judgement, to better triage which lesions need to be seen by a dermatologist immediately and which can be evaluated later- either through a teledermatology consult or in person. The important factor here is that this is a tool for physician-to-physician communication that will be used only when both the dermatologist and the primary care physician are comfortable that the evidence supports its use. As physicians, we use data to determine how we interpret test results and we are trained to understand the limitations of tests.

We are trained to think in terms of sensitivity, specificity, and positive and negative predictive value. We take these into consideration when we use tests and tools. One of the hurdles we face in advancing the development of our technology is the uncertain future landscape of telehealth and how the FDA will classify and oversee such tools as medical devices. If is important to distinguish such a tool and the potential risk it may pose, used in physician to physician communication and triage, which provides data but not a stand-alone diagnosis, from the apps that are directly marketed to patients that attempt to make a stand-alone diagnosis. This technology and many others like it are likely to be halted in development without clear guidance on their classification and path to regulatory approval. This path is best laid out in a collaborative relationship between the FDA, technology innovators, patients, and physicians.

In summary, while I was invited to testify based upon my work showing the potential harms of technology that is made available directly to patients, with claims not substantiated by research or data, and cutting the physician out of the relationship, I am also a strong believer in the value that technology can bring to health care. I encourage you to provide clear guidance that will allow us to move ahead with developing new technologies, making existing technologies more robust, and finding new, more efficient ways of delivering health care. Technology should enhance the physician-patient relationship and opens up new treatment options for patients and should first of all do no harm by promising more than can safely be delivered.

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