September 8, 2014

The Honorable Fred Upton
Chairman
Energy & Commerce Committee
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Diana DeGette
Member
Energy & Commerce Committee
U.S. House of Representatives
2368 Rayburn House Office Building
Washington, D.C. 20515

Re: Biocom's Comments in Response to the Energy & Commerce Committee's 21st Century Cures White Paper: A Call to Action – Digital Health

Dear Chairman Upton and Congresswoman DeGette:

Biocom represents the Southern California life science industry, which includes biopharmaceutical, medical device, and diagnostic companies, universities and research institutions, as well as service providers and patient groups. With more than 600 members dedicated to developing life-enhancing and life-saving drugs, medical devices, and biologics for patients in need, Biocom leads advocacy efforts to positively influence the region's life science community in the development and delivery of innovative products.

In our mission of providing feedback and communication between legislators and industry, we write in response to the Committee's White Paper on Digital Health. Biocom supports the 21st Century Cures initiative and applauds the Committee's efforts to improve our nation's innovation ecosystem. In particular, we commend you on taking a specific interest in the digital health industry, which has undergone tremendous growth these past decades and holds promise for revolutionizing the delivery of care as we know it. We thank you for the opportunity to provide comments.

How can the increased utilization of digital health technologies change the health care landscape and improve patient care?

Health care is at the cusp of a sector-wide transformation due in large part to the development of digital health technologies, from genomic testing to mobile applications to remote patient monitoring. Advances in digital health will improve the efficiency of health care delivery and enable better health care resource utilization, such as pre-crisis intervention, which will lead to cost containment and improved patient outcomes across a wide spectrum of disease conditions.

Digital health technologies often reduce the need to physically visit a doctor's office or hospital, allowing patients to communicate with their physicians and receive and transmit health care information instantly in a home setting, thus containing costs, preventing the deterioration of conditions, reducing the frequency of visits to medical institutions, and ensuring the continuity of care. Digital health also empowers patients to be active participants in their health care decision-making process.

For example, receiving wellness information, monitoring symptoms, and having access to genomic data on digital or mobile health devices have enhanced communication between patients, practitioners and care-givers, and clearly demonstrated how digital health can improve patient monitoring and medication adherence, and facilitate the integration of genomics in patient care.

In addition, advances in digital health technologies have the potential to simplify and modernize the collection of clinical trial data. Mobile sensors and wearable devices can help monitor patients' physiological data and streamline the collection of information to be used by study investigators. In addition, the use of Electronic Health Records (EHRs) can be leveraged to facilitate data collection. For example, instead of requiring investigators to complete traditional case report forms, clinical trial data could be obtained directly from EHRs, which are routinely completed by treating physicians as part of patients' care. This approach would enable the study to be conducted more efficiently, alongside the delivery of care.

What are some of the barriers preventing these technologies from being used on a larger scale?

Lack of a clear regulatory framework

Innovators continue to face hurdles dealing with the lack of a well-defined framework for the regulation of digital health technologies. As an example, unclear regulations about the direct delivery of genomic data to patients have slowed down the entire genomic space. Disparate regulations across states, and between state and national programs are also burdensome and problematic.

The lack of payment coverage is indisputably one of the major barriers to the development of digital health technologies. Reimbursement restrictions deter providers from utilizing advanced information communications technologies in their practices, which in turn limit patient access to these life-enhancing technologies and discourage investors from further financing innovative solutions.

Another challenge has been the lack of references to remote patient monitoring technologies and patient generated health data (PGHD) as criteria in the Centers for Medicare and Medicaid Services Electronic Health Records (EHR) incentive payment program, popularly referred to as the "Meaningful Use" rules. To date, meaningful use has focused on Certified EHRs, EHR modules, and EHR systems, but has yet to fully encourage the involvement of patients and families in their care. Remote patient monitoring technologies such as telemedicine, telehealth and mobile health are increasingly playing a vital role capturing PGHD.

Lack of understanding and readiness

All new technologies come with a period of adjustment from the public before they understand, trust, and recognize the benefits of using them. Health information technologies are no exception and important caveats in the adoption of digital health technologies by patients and healthcare providers exist. Indeed, there is a very high attrition rate to digital health usage. Specifically, less than 30 percent of individuals who proactively seek self-care using digital health technologies, such as pedometers, weight scales, blood pressure and calorie monitors, continue to use these technologies after 6 months[1]. Without proper support systems and education, patients are likely to eventually discontinue the use of these technologies, while physicians may not be appropriately informed and equipped to direct patients to these innovative products and counsel them adequately.

A significant factor in this attrition is a low sophistication of technology usage that is necessary to understand the requirements of mobile and digital health and to use these devices in a manner that harnesses continued and efficient use. For instance, populations such as the elderly and patients with chronic medical conditions are targeted groups for digital health use but often lack the understanding or readiness to fully benefit from these technologies. This poor working knowledge of digital devices, as well as a lack of educational policies facilitating the adoption of such technologies by both patients and physicians, are important barriers towards a larger-scale development of the digital health landscape.

Lack of data ownership protections

Biocom recognizes the challenge of protecting patients' information while allowing physicians and providers to access personal data to better coordinate care. With the rapid development of digital care, it has become increasingly difficult for patients to control who has access to their information, which is often captured by institutions and commercial entities without clear consent or understanding from individuals.

In addition, patients experience tremendous difficulties accessing their own personal data, which include lengthy processes and deterrent costs. As a result, there is no clear ownership of data in the health information space, including the data generated by these new digital health technologies.

What can be done to address these challenges?

Streamlining regulations

Defining a clear regulatory framework for digital health technologies is necessary to the development of breakthrough innovations. We believe that the regulation of digital health technologies should be platform agnostic and that products that qualify as medical devices

[1] Mattila E et al. Personal Health Technologies in Employee Health Promotion: Usage Activity, Usefulness and Health-Related Outcomes in a 1-Year Randomized Controlled Trial. JMIR Mhealth UHealth 2013:1:1-18.

should continue to be regulated as such, while products that represent a lower risk for patients could benefit from a less stringent set of regulations.

Regulating agencies, such as the Federal Communications Commission (FCC), the Food and Drug Administration (FDA), the Centers for Medicare and Medicaid Services (CMS), and the Office of the National Coordinator for Health Information Technology (ONC) should collaborate and coordinate policies more closely, when appropriate, to establish clear lines of jurisdiction and comprehensive guidances for industry, payers, and providers. We also recommend harmonizing regulations with well-established international standards.

In addition, we strongly urge Congress to work with CMS to devise and implement reimbursement policies that broaden coverage for new digital health technologies, allowing patients to access new health management and treatment solutions to their conditions and needs. It is also necessary to update overly restrictive and outdated Medicare reimbursement regulations that have inhibited the development of digital health technologies.

Lastly, the use of EHRs holds the potential to modernize both the collection of clinical trial data and the delivery of care. However, because it is unclear if regulators will accept data generated using these methods, clinical trial sponsors have been reluctant to fully incorporate these technologies into registrational studies. Congress should develop standards for the use of EHRs in clinical research and work with industry and academia to promote the development of these technologies. In addition, the ability to upload PGHD into certified EHRs should be included in future stages of meaningful use as criteria to incentivize eligible providers to embrace the use of remote monitoring technologies. Doing so would encourage patients to use these cost-saving technologies, especially the most chronically ill, who can be monitored in their homes and outside of healthcare institutions.

Educating the public about the use and benefits of digital health technologies

In order to alleviate the barriers towards efficient digital health adoption, we must focus our efforts on the education and dissemination of these technological advances to ensure that patients, physicians, providers, and care-givers are aware of the benefits of using digital health devices and technologies.

The incorporation of researchers, clinicians, patients, and policy makers in the implementation stages of digital health technology use is essential to efficiently navigating the technical challenges that hinder pragmatic digital health utilization. Physician coaching is of utmost importance to ensure that doctors are aware of the benefits of these technologies and properly trained to prescribe and use them, and appropriately counsel patients. The use of these technologies to encourage and manage wellness is not difficult if given the proper educational, regulatory, and reimbursement environments.

At the local level, communities are encouraged to tailor digital health solutions to their specific needs. At the national level, raising awareness of the industry and its individual and aggregated benefits is necessary. We commend the Energy & Commerce Committee on its efforts to better understand the industry and its needs.

Ensuring robust health data protections

With the rapid development of digital technologies, it has become increasingly important to ensure the safety and confidentiality of patient information. We encourage the Committee to look into ways to strengthen health data ownership by giving patients more control over the data generated by these new technologies.

Conclusion

Digital health technologies hold promise for revolutionizing our health care system through the expansion of preventive, personalized, and instant care, and the consequent containment of health care expenditures. Despite evident benefits, an unclear regulatory framework, a lack of awareness, and concerns with data ownership have made it more difficult for these technologies to develop to their full potential. Streamlining regulations and reimbursement policies, educating the public about the use and benefits of digital health technologies, and ensuring robust data protections are some of the steps that we support to alleviate these challenges. Patient outcomes could be easily and dramatically improved, at a minimal cost, with government support.

We appreciate the opportunity to provide feedback on behalf of our members and thank you for your time and diligence in examining our comments. We look forward to continuing working with you on this very important matter.

Sincerely,

Joe Panetta
President and CEO
Biocom