July 3, 2014

Leslie Kux, Assistant Commissioner for Policy
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

<u>Re: FDASIA Health IT Report Docket No. FDA–2014–N–0339</u>

Dear Ms. Kux:

The Wireless-Life Sciences Alliance ("WLSA") thanks you for the opportunity to comment on the Food and Drug Administration Safety and Innovation Act (FDASIA) Health IT Report: Proposed Risk Based Regulatory Framework (the "FDASIA Report" or "Report"). We value the significant commitment of time and resources expended by the Food and Drug Administration ("FDA" or "Agency"), the Office of The National Coordinator ("ONC"), the Federal Communications Commission ("FCC"), other agencies, and industry and citizen volunteers on these matters. These comments are submitted by the WLSA and do not necessarily represent the opinion of WLSA members, some of whom may submit comments in their own name.

WLSA compliments the FDA, ONC and FCC on their thoughtful approach to considering improvements to existing approaches for regulation of medical devices and health IT. We have had positive interactions with staff, especially at the FDA, about these matters. Our prior comments to the FCC and FDA on related matters, specifically the Draft Guidance on Mobile Medical Applications and the FCC/FDA Joint Meeting on Life Saving Wireless Medical Technology, are attached as addenda to this letter.

The Wireless-Life Sciences Alliance

The WLSA, which formed in 2005, is a special purpose association of companies and organizations that are focused on all aspects of connected health. Our community is international, multi-disciplinary and inclusive of regulated and non-regulated industry, research and nonprofit organizations. WLSA's mission is to improve access to affordable high quality healthcare, globally, by promoting innovation in connected health devices, services, and applications, and accelerating their adoption by consumers and institutions.

We believe it is self-evident and universally acknowledged that current approaches to healthcare are severely dysfunctional and cannot scale to meet the healthcare demands of the U.S. or other countries. We are confident that the convergence of technology, life sciences knowledge, and

consumer engagement, if supported by regulatory institutions, will deliver significant improvements to public health.

The matters addressed by the FDASIA Report are of the highest importance to the United States. The public's health, the safety and wellbeing of patients, the economic competitiveness of the United States in the global economy, and ultimately the character of our society as open, inclusive and innovative, or the opposite, depend on properly addressing the issues described in the Report. WLSA recommends the creation of an alternative that is dynamic and that leverages connected health technology and the fast increasing participation of consumers in their own health. The WLSA proposal is not a complete substitute for the FDASIA recommendations and we recommend that it be implemented as a voluntary alternative to traditional health IT and device regulation.

WLSA also recommends that improvements be made to the current model for the regulation of health IT and medical devices. Other organizations have focused on this topic. We commend the work of the Mobile Regulatory Coalition ("MRC"), with which WLSA collaborates. The MRC's analysis and recommendations have much value and we urge that FDA, ONC and FCC utilize them in considering their next steps. Specifically, WLSA shares MRC's sense of urgency regarding the need for guidance on the key topics of accessories and wellness, and believes that the suggested three-part model for regulated and unregulated health IT will not maximize achievement of the twin policy goals of protecting patients and improving public health.

Open Outcomes Based Regulation

The WLSA proposal, which we refer to as Open Outcomes Based Regulation ("OOBR"), leverages the power of connected health technologies and has the benefit of establishing a framework that can be applied to improve the regulation of drugs as well as health IT and medical devices. It is sufficiently flexible to deal with the fact that the boundaries between hardware, software, and drugs are changing rapidly. The future of consumer health and health care services belongs to combination products that are utilized within the unregulated consumer sector and regulated health care systems. The formerly bright line between unregulated consumer health and regulated health care is being erased by the activities of both consumers and traditional health care players (providers, payors).

OOBR may be considered as a modernization of the established regulatory concept of post-approval studies with the objective of using current technology and knowledge platforms to expand its use and make the process as open, continuous, and timely as possible. This can be a voluntary system that will be improved over time due to ongoing improvements in technology, regulatory principles, and consumer/industry acceptance. The goal is to establish a dynamic regulatory system that speeds the entry of promising medical products and services to market while it frequently reevaluates the risks associated with the devices and adjusts the approved uses accordingly. The open nature ("transparency") of the system will improve levels of self-enforcement by manufacturers and rely as much as possible on the marketplace to determine the value and efficacy of devices.

The Report correctly calls for a system that supports an "environment of learning and continual improvement" and recommends the establishment of a Health IT Safety Center to establish this

principle for health IT. OOBR is consistent with this this proposal and may be perceived as extending the concept of continuous learning to combinations of technologies that will be used together in the emerging world of connected health. WLSA does not believe that the approach we propose will have any material difference in the near term regarding the (absence of) regulation of either "administrative health IT" or "health management health IT" as recommended by the Report. OOBR recognizes that the unregulated aspects of health IT are integral parts of the systems in which medical devices and drugs are used and thus have an influence on the safety and efficacy of regulated products. This is based on a perspective that is patient and consumer-centric, aligning with the shifting focus of our health care system and the increasing pace of health and health care innovation.

Perspective on the Regulation of Medical Devices and Health IT:

Why the US Needs a New Approach to Regulation

The core concepts on which WLSA's recommendations are based are as follows:

- The status quo for public health and the health care system is not acceptable. Millions of our citizens do not have affordable access to needed care. Key indicators of public health are much worse than in other OECD countries and are getting worse, despite the fact that per capita US health care spending is 2 - 3x that of comparable countries.
- Government has three overlapping responsibilities in regulating health IT, medical devices and drugs:
  - Protecting the public health by reasonably assuring their safety, efficacy, and security;
  - Promoting public health by promoting useful innovation and ensuring that there is timely access to new technologies and knowledge; and
  - Helping the public get the accurate, science-based information they need to manage their own health.
- The pace of change in technology, medical knowledge, and health behavior is increasing while regulatory processes remain slow and isolated from post-approval results.
- The concept of "risk," which is central to the Report's recommendations, is two-faceted and dynamic:
  - The two facets:
    - The risk to a patient from the use of a product (including services and integrated solutions); and
    - The public health risk from lack of access to a product.
  - The five dynamic factors in determining risk that change constantly over time:
    - Technology improves;
    - Knowledge improves;
    - Average user competence generally improves;
    - Support systems may improve or decline; and,
    - External factors change for better and worse, both rapidly and slowly (e.g. environmental conditions, diet, epidemics).
  - For purposes of regulation of a specific product, the two types of risk should both be considered and risk should be regularly evaluated over time in light of the five dynamic factors.

- In light of these factors, long delay or failure to act may be equally or more harmful than approval. Moreover, the true risks and efficacy of products are best discovered in real world use.
- No traditionally structured regulatory approval process will be efficient or effective in maximizing the twin goals of protecting patients and promoting health.
- The tools of connected health offer the resources to create a dynamic system in which safety and efficacy can be easily monitored and are more transparent in near real time, thus leveraging the power of markets to support regulatory goals.

Outline of Open Outcomes Based Regulation

The principles of OOBR are based on a system for continuously improving risk and efficacy estimates that incorporates the investigational and computational power of the research community in addition to agency resources. Essentially, the system would include these steps:

- A product is approved by an agency or is self-certified based on defined categories, sometimes including pre-market clinical research;
- Initial market authorization may be limited, based on estimates of the likelihood and degree of unanticipated risks;
- Once the product is in the market, data about its safety and efficacy are collected in a de-identified database that is available to approved researchers under defined rules for access and publication;
- As appropriate, the marketing approval and labeling of the product are revised in accordance with the data.
- In addition, customers and users will have access to analysis that equips them to make informed purchasing decisions.

We envision this approach to start as a voluntary program and alternative to traditional regulation of Class I, II and III products. It would be applicable to products that by their nature or based on evidence do not pose a material risk of significant unavoidable harm to users taking into account the restrictions on use, the anticipated learning curve based on the analysis of data gathered through use of the product, and the harm (if any) associated with its not being available. In order to effectuate this continuous learning process, manufacturers would agree to the continuous/regular sharing of data on product utilization, efficacy and outcomes. This responsibility may be shared with clinical organizations that utilize or prescribe the product. Liability issues require specific study, but in general we support an approach that takes into account the willingness of a clinical provider to accept legal responsibility for the safety and efficacy of a product.

WLSA recognizes that the implementation of Open Outcomes Based Regulation would require a substantial effort, including participation by government agencies, research funders, manufacturers, and health care organizations. By leveraging the power of big data, the research community and the market, OOBR offers a pathway to move promising products to market more quickly, modify the permitted uses of these products more quickly and enable the health care community to more quickly identify the most efficacious use of approved products.

There is an example of another major sector in the US economy that operates on a similar basis. Automobiles are primarily brought to market through a self-certification process. Adverse events (accidents, mechanical failures) are analyzed by private parties, regulatory agencies, and researchers. Products are continuously improved and marketed for different intended uses. As a result, automobiles have continuously become safer, more efficient, more comfortable, and cheaper over the last few decades. The US auto industry has become competitive in the world market and users have modified their behavior (seat belts, impaired driving) to improve safety. WLSA recommends that, over time, US regulation of all aspects of health care move toward this model which is based on standard setting, self-certification, adverse event analysis and shared liability.

Conclusion

In conclusion, we reiterate our support for the constructive approach adopted by the agencies and pledge our support. The U.S. is a global leader in the life sciences and it can retain its role as the global leader in mobile and wireless health with the support of the agencies. Wireless health has significant policy benefits for the U.S. and the entire world:

- Improve access to services.
- Lower the cost of healthcare.
- Improve the quality of healthcare.
- Make healthcare services transparent and thus measurable and accountable.
- Improve public health.

Respectfully Submitted,

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Addendum. Comments to FDA on Mobile Medical Applications Draft Guidance

October 18, 2011

Mr. Bakul Patel
Policy Advisor
Center for Devices and Radiological Health
Food and Drug Administration
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> **Re: Comments to FDA's Draft Guidance on Mobile Medical Applications:**
> **Docket No. FDA-2011-D-0530**

Dear Bakul:

The Wireless-Life Sciences Alliance ("WLSA") thanks you for the opportunity to respond to the Notice of Availability ("NOA") published by the U.S. Food & Drug Administration ("FDA" or "Agency") in the Federal Register on July 21, 2011.   In the NOA, the Agency requested comments on *Draft Guidance for Industry and Food and Drug Administration Staff: Mobile Medical Applications* ("Draft Guidance") and on two specific issues: regulation of accessories and clinical decision support ("CDS") software. This letter is intended to (1) establish our support for the thoughtfulness with which Agency staff are approaching the issues and (2) recommend certain policy considerations, human perspectives and specific recommendations for future action.

We do not intend to duplicate the detailed work of the mHealth Regulatory Coalition ("MRC") that is presenting a detailed and well-reasoned analysis and recommendations.

The Wireless-Life Sciences Alliance

The WLSA, which formed in 2005, is a special purpose association of companies and organizations that are focused on all aspects of wireless connected health, which includes "mobile health" and "mHealth." WLSA's mission is to improve access to affordable high quality healthcare, globally, by accelerating innovation in wireless connected health devices, services and applications. We believe it is self-evident and universally acknowledged that current approaches to healthcare are severely dysfunctional and cannot scale to meet the healthcare demands of the U.S. or other countries. We are confident that the convergence of technology, life sciences knowledge and consumer engagement can deliver significant improvements to public health, which otherwise will begin or continue to degrade.

Perspective on the Regulation of Mobile Medical Applications

WLSA compliments the FDA on its thoughtful approach to the regulation of mobile medical applications. In all of our interactions with Agency staff over the past two years we have found them to be aware of the importance of the mobile health ecosystem and interested in seeing it succeed. We were encouraged by the joint FDA and FCC announcement in 2010 and joint session. WLSA provided comments for the record following that hearing (copy attached).

As much as we appreciate the thoughtfulness of the proposed guidance, and the careful and thoughtful comments and suggestions of the MRC, we believe that a fundamental preliminary step to regulation must first be taken. Without first considering the impact of delaying the introduction of useful mobile health products and applications on public health, any regulatory approach is likely to unduly delay significant potential improvements in the health status of U.S. citizens and residents.

The Agency has two equal and overarching roles, which must be balanced:

> "The FDA is responsible for **protecting the public health by assuring the safety, efficacy, and security** of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation, and by regulating the manufacture, marketing, and distribution of tobacco products.

> "The FDA is also responsible for **advancing the public health by helping to speed innovations** that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods, and to reduce tobacco use to improve health."
> (http://www.fda.gov/AboutFDA/CentersOffices/default.htm - emphasis added.)

In the area of mobile health, these responsibilities are highly interdependent – the Agency must establish the optimal balance between the **protection** of public health and its **promotion** in order to maximize the achievement of both goals. Striking the right balance is a pre-condition to the appropriate regulation of mobile health applications and other wireless health products. In doing this we believe that the severity of the public health problems we face, the acuity of our need for new approaches to promoting health, and the mismatch between traditional approaches to regulation and the manner in which innovation in relevant fields occurs, call for an emphasis on safety, intended use and marketing claims, and less near term demand for proof of efficacy.

Classes of new products and applications offer affordable access to health knowledge and healthcare for the individuals who have little or no access and support today. Our society's current approach to public health is failing by many measures and for millions of individuals, especially our uninsured and disadvantaged citizens. Even among insured and wealthy populations, increased morbidity associated with aging and the increase of chronic disease will overwhelm our society's ability to provide support and services. Market experimentation with applications that pose little or no immediate risk can be harnessed by the FDA to carry out its goal of advancing public health through the encouragement of innovation.

Many if not most mobile health products and applications are categorically different from poisonous elixirs or thalidomide, which established the necessity of regulation. Furthermore, unlike traditional therapeutics and medical devices, mobile medical applications have the

inherent capability of self-reporting. They can provide data about outcomes based on their use in the real world, a more relevant source of information than that created in randomized clinical trials. In addition, many mobile medical applications are creating new and useful information (e.g. monitoring individuals in their residence) for caregivers, improving access of individuals to information and tools that increases their ability to self-manage, and creating massive new sources of data that scientists will use to create new approaches to improving health.

We urge the Agency to first assess the potential of the mobile health sector to offer affordable access to healthcare and to reverse the negative trends in cost, access and outcomes. This does not require that dangerous products and applications be permitted to enter the market without supervision. It does require recognition that the status quo in public health is not satisfactory. It is deteriorating and we must embrace new approaches if we are to reverse this trend. The tools of innovation are available and are being focused on these problems. The Agency's challenge is to adapt its processes to speed the time to market of these innovations and deliver to healthcare that which we enjoy in other sectors of commerce - the rapid creation of complex products, services and applications that improve in quality and decrease in cost over time.

WLSA encourages the Agency to adopt the following principles in determining the appropriate manner of regulation of mobile medical applications and indeed the broader wireless connected health sector:

1. Traditional medical device development and regulation is a slow process. Technology and behavior innovations are very fast. In order to promote public health and reverse adverse trends in health and healthcare, the power of innovation and scale established by the technology industry must be harnessed for public health. The FDA should accelerate its collaborative initiatives to define processes for speedier approaches to identifying risks, including alternatives to the use of Randomized Clinical Trials in select situations.

2. In order to improve public health, we must increase both personal knowledge of the factors that lead to chronic disease and personal responsibility for its avoidance and management. The key approach to implementing this principle is to couple the power of engagement that has been created by the consumer sector with the life sciences sector of providers, researchers and funders. Given the fickleness and inherent difficulty of quantifying and predicting human behavior, substantial leeway should be given to applications that promote consumer knowledge and attempt to improve healthy lifestyles. In general, the market will quickly determine the efficacy of these initiatives. Failure in the market eliminates future risk.

3. The public is harmed by the absence of mobile medical applications. Hence, as with therapeutics, there must be acceptable risks for imperfect products. The absence of access to a "perfect" device is more deleterious in some situations than affordable access to imperfect devices and services. In determining acceptable risk, consider the timing and severity of potential adverse consequences. If the consequences are immediate and severe (e.g. automated calibration of an insulin pump wirelessly connected to a glucose meter), great care must be taken. As the severity of potential harm declines and as the timing of its occurrence recedes into the future, after market reporting and subsequent product improvement will continually reduce the risk of adverse effects.

4. A key tactic in striking the correct balance between a specific device risk and the population risks posed by an unsatisfactory status quo is to focus on the marketing (intended use) claims. The Draft Guidance is correctly taking this approach. For example, inexpensive home monitoring platforms may have imperfect connectivity compared with institution-based systems, but even a partial solution improves the chance of a favorable outcome for the otherwise unmonitored individual. Similarly, applications that consolidate and analyze information from disparate sources will help clinicians, caregivers and patients to lower the costs of care and improve outcomes, but they will initially have imperfections and we can reasonably expect their improvement over time. These imperfect applications should be acceptable so long as they are associated with accurate marketing claims.

5. The post-market "transparency" associated with mobile medical applications should be leveraged by the Agency. This will enable potentially useful products and applications to more quickly be brought to markets and more quickly improved or withdrawn based on real world use. This approach offers the advantages of both reducing the costs and uncertainty of development prior to market and reducing the after-market risk that adverse effects will not be identified.

Comments on the Draft Guidance

The following suggestions are more specific comments and suggestions based on our own analysis as well as input from WLSA members and other organizations and individuals who participated in our Town Hall session on July 14, 2011. Some of our suggestions are intended to be common sense approaches to moving forward. Others offer potential new approaches to the regulation and encouragement of a sector that is moving faster, and has greater capacity for good, than many previous subjects of FDA regulation.

1. Clarify the activities within which wireless carriers will have freedom from regulation in order to encourage their support for the regulated and non-regulated devices and applications.

2. We recommend that the Agency build on its current proactive and collaborative approach to address the challenges and opportunities posed by wireless and mobile health.

    a. The early establishment of approved approaches for important challenges such as using mobile applications to collect, analyze, and display data that is derived from multiple devices and sources would be of substantial benefit to industry and the public.

    b. Applications that only collect and display data should not be regulated.

    c. Device companies should be regulated only on their own devices and applications, not third party applications that pull data from their device. Manufacturers should be encouraged to make their data available to third parties, as the public will benefit from competition to build better solutions that consolidate data from multiple sources.

3. The mobile and wireless health sector includes many individuals and companies that have no prior experience with healthcare and thus are uninformed about FDA regulatory

requirements. The success of the sector also requires the increased participation of investors. We need the engagement of these newcomers but they are daunted by the complexity of the regulatory structure and uncertainty about the scope of future regulation. To encourage broad (creative) participation in the sector, we encourage the Agency to take certain practical steps:

    a. Create and maintain list of companies and products within the examples of regulated and non-regulated mobile health devices, applications and solutions.

    b. Help innovators find predicate devices and applications for their mobile health solutions. This can include the explicit description of the rationale applied the regulation of devices and applications that are approved by the Agency.

    c. Clarify "intended use" with concrete examples. Restrictions on marketing claims are well understood by those in the healthcare field but intended use is a new and often confusing concept for the consumer device and mobile applications developers who are new to the wireless and mobile health field Provide clearly defined examples of when a product or application crosses the line from a (non-regulated) wellness to (regulated) clinical solution.

4. Mobile computers should not be treated differently from desktop computers when used for the same purposes.

5. In order to encourage the acceleration of data sharing and increase both consumer and clinical access to data and knowledge, do not regulate compendia, databases and clinical decision support tools unless there is no alternative to the avoidance of a significant risk of patient harm.

6. Consider adopting approaches that will lead to a more efficient review process:

    a. Self-certification of compliance for certain classes of manufacturers and device categories, based on efficient post-market reporting.

    b. Identification of software and hardware components that are pre-approved for use in both regulated and non-regulated devices.

    c. Simplification of manufacturer's compliance for casual or small developers.

    d. In order to encourage market experimentation, establishment of a threshold for the regulation of certain classes of devices and applications tied to number of end users. Based on registration and post-market reporting, this would enable the Agency to focus more of its attention on viable commercial offerings.

Conclusion

In conclusion, we reiterate our support for the constructive approach adopted by the agencies and pledge our support. The U.S. is a global leader in the life sciences and it can retain its role as the global leader in mobile and wireless health with the support of the agencies. Wireless health has significant policy benefits for the U.S. and the entire world:

- Improve access to services.
- Lower the cost of healthcare.
- Improve the quality of healthcare.
- Make healthcare services transparent and thus measurable and accountable.
- Improve health!

Respectfully Submitted,

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Enclosure.

Addendum. Comments to FCC/FDA Joint Meeting on Wireless Medical Technology

The Wireless-Life Sciences Alliance (WLSA) is a special purpose nonprofit trade organization for innovators, globally relevant companies, scientists, physicians, and policy makers. We were founded in 2005 and are dedicated to creating value and improving health, globally, through the convergence of communications technologies, consumers, caregivers and all sectors of the life sciences and technology environment. WLSA partners and companies all over the world are using wireless health innovations to better manage chronic conditions, preempt disease and improve the lives of the elderly and under-served populations around the world. It is the WLSA mission to accelerate these developments.

We believe that WLSA was the first organization of its type to focus exclusively on the opportunities presented by utilizing wireless technology to lower the costs and improve the quality of healthcare services and to improve the quality of life for millions of Americans and billions of people around the world. Since 2006, we have been convening the best companies, innovators and thought leaders in this emerging space. Of the 21 companies demonstrating their products at the Joint Meeting, 17 were members of participants in our meetings. Five of the panelists at the hearing represented member companies. Our CEO and our Chairman have been exploring and writing about the opportunities and challenges of wireless health since early in this decade.

The WLSA supports the initiative of the FCC and FDA in joining together to work in this most important area. The Joint Statement issued on July 26th establishes an excellent framework for the agencies' efforts. We applaud paragraph number 5 for its vision of the future:

> "5. The FDA and the FCC agree to build upon this initiative launched today to proactively serve the national interest in finding innovative solutions to America's health care challenges."

We emphasize that in wireless health we have the potential to address three of the most important issues in healthcare:

- Its high **cost**.
- Variability in **quality**.
- Inadequate **access**.

The power of wireless health from a public policy perspective derives from its power to bring **accountability** to the opaque healthcare industry.

- Wirelessly enabled solutions for consumers/patients make them more **accountable** for their health (reference the importance of lifestyle in creating chronic disease and the importance of compliance to managing chronic disease).
- Wirelessly enable healthcare services for providers makes them more **accountable** for outcomes (reference CMS hospital readmission policy and the need for wearable vital signs monitors to implement it in a cost-effective way).
- Wireless connectivity for medical devices makes manufacturers more **accountable** for device functionality (reference Guidant recall of more than 100,000 defective implanted defibrillators – wireless monitoring could have identified the defects earlier).

While we do not now offer technical comments on the many topics in wireless health, we offer the following principles for your consideration.

- First Principle: In determining whether to permit a new device to be marketed, consider the **status quo risk** of NOT permitting the use of a wireless health device as measured by such considerations as:
    - The interests of people who could be helped (e.g. frail elderly able to remain independent of an institutional sentence).
    - The systemic benefits of expanding access to care by reallocating federal resources, such as savings from not paying for avoidable readmissions, toward coverage of the uninsured.
- Second Principle: Consider the **use case** and marketing claims prior to approval decisions and standards setting, taking into account such factors as place of use, acuity of services, availability of back-up services (including self-help) and considering the first principle. We note that some discussions during the hearing jumbled up use cases that require vastly different demands for quality of service. For example, compare the needs of an "aging-in-place" service and a wireless ICU monitor. Referencing the first principle, also compare the status quo – if the wireless platform enables the monitoring of a previously unmonitored situation, the expectations for quality of service should be dampened.
- Third Principle: Focus on establishing **quality of service expectations**, to be managed by marketing claims, rather than defining how they must be achieved. We do not want to freeze innovation and it is demonstrable with consumer electronics and mobile services that the quality of products and services will rapidly improve over time if technical standards are not frozen in regulation.
- Fourth Principle: Use **post-market surveillance and reporting** as a mechanism to manage the risks associated with new technology. Cell phone-based and wearable wireless monitoring platforms offer the ability to monitor and report on the use of devices and the efficacy and side effects of therapeutic products and

services. The agencies should take advantage of this inherent capability to accelerate the marketing of useful devices and services while monitoring their performance compared with marketing claims. This approach will help the healthcare industry to adopt the high tech approach of getting "fast innovation" to continuously improve technology.

In conclusion, we reiterate our support for the constructive approach adopted by the agencies and pledge our support. The U.S. is a global leader in the life sciences and it can retain its role as the global leader in wireless health with the support of the agencies. Wireless health has significant policy benefits for the U.S. and the entire world:

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Respectfully Submitted,

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