

STATEMENT OF DIANE JOHNSON
SENIOR DIRECTOR, NORTH AMERICAN REGULATORY AFFAIRS POLICY AND INTELLIGENCE
JOHNSON & JOHNSON

FOR PRESENTATION BEFORE THE
HOUSE ENERGY AND COMMERCE COMMITTEE
SUBCOMMITTEE ON COMMERCE, MANUFACTURING, AND TRADE
HEARING TITLED “DISRUPTER SERIES: HEALTH CARE APPS”
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Before I begin my testimony, I would first like to thank Chairman Burgess for his key leadership on this issue and others. He has been a longstanding advocate for patients, and we appreciate his tireless efforts.

Subcommittee Chairman Burgess, Ranking Member Schakowsky, and Distinguished Members of the House Energy and Commerce Committee Subcommittee on Commerce, Manufacturing, and Trade:

Thank you for the opportunity to come before you today to detail critical applications within development at the Johnson & Johnson Family of Companies that will enhance the physician and patient interaction while delivering additional patient tools in innovative ways. In addition, my testimony will focus on how Congress can help support those ongoing activities.

As part of the Johnson & Johnson credo, we believe our first responsibility is to the doctors, nurses and patients, mothers and fathers and all others who use our products. The commitment to safety is part of our DNA, factoring into our decisions and development of our products and services.

With that credo in mind, the Johnson & Johnson Family of Companies has developed a number of apps to help individuals monitor their health or the health of their family and support the doctor-patient relationship by extending clinical care outside of the in-person consultation. I will describe a few key apps created by the Johnson & Johnson operating companies as well as in cooperation with partnering organizations, but there are many more. The goal of this suite of apps is to empower patients, reduce costs of care, and enhance patient outcomes.

OneTouch Reveal (“diabetes”) – One Touch Reveal Allows a patient to check blood sugar results on a mobile phone or tablet. This app provides a 14, 30, or 90 day overview and a 365 day logbook—with colorful visuals and simple navigation. In addition, it allows a patient to share results with his or her physician — as progress reports (PDF) or as data tables (CSV). It provides the patient with the ability to share ongoing information with his or her physician, allowing for enhanced care management for people with diabetes.

Care4Today™ Mobile Health Manager 2.0 (medication management) -- The Care4Today™ Mobile Health Manager 2.0 is a free mobile app and website with new features, including Care4Family™ and Care4Charity™, designed to support and motivate people to stay on schedule with their medications and report their adherence to a treatment plan as prescribed by their physician. By assisting with medication compliance issues, the application helps ensure that the physician is aware of possible drug interactions or problems with medication adherence.

The PATIENT ATHLETE™ Program (surgery patients) -- The PATIENT ATHLETE™ Program is designed to help patients preparing for surgery to take their experience beyond merely reducing the pain. The program encourages patients to align their personal purpose with their daily behaviors to emerge stronger, healthier and ready for the next chapter of life. Key components include:

- Self-guided, video-based training program led by a Performance Coach who had bilateral knee replacements and used these same concepts to enhance his own experience,
- Utilizes science-based tools and techniques from the Johnson & Johnson Human Performance Institute®,
- Eight core lessons (two per week) to complete over the four week period prior to surgery,
- Ideas for immediate application with simple action steps, and
- Eleven refresher lessons to complete post-surgery for sustained focus and encouragement.

Johnson & Johnson 7 Minute Wellness for Expecting and New Moms™ App (new mothers) -- The Johnson & Johnson 7 Minute Wellness for Expecting and New Moms™ App is a science-based wellness resource designed to help new moms manage and expand their energy during pregnancy and after giving birth.

Digital Health Scorecard (health management) -- The Digital Health Scorecard helps one determine one's personal "health score" and better understand the likelihood of developing common chronic diseases such as diabetes, heart or respiratory diseases or cancer.

HEALTHYDAY App (surveillance) -- HEALTHYDAY gathers data from the same trusted sources that doctors and hospitals use, cross-references information with local, crowd-sourced data to determine what illnesses are trending nearby. This helps inform a user to determine whether what they're feeling may be a cold, the flu, or pesky allergies. Then when you're feeling great, it lets you see what's going around locally and sends real-time alerts to help you know what to watch out for.

Given the wide variety of apps under development at the Johnson & Johnson Family of Companies, we see demographic and technology trends in healthcare shifting toward more consumer-driven decision making and self-care activities. With this demand for cutting-edge technologies and continuous innovation, we as manufacturers must remain diligent in ensuring that cybersecurity is an integral part of the process. We believe that patient safety (including the security of their data) is the most important consideration.

To that end, foundational in our approach to cybersecurity at Johnson & Johnson is the development of a formalized security framework for our products, which is based on both the National Institute of Standards and Technology (NIST) Cybersecurity Framework for Critical Infrastructure and the Food and Drug Administration (FDA) Guidance Documents. This framework enables us to more effectively drive integration of cybersecurity standards, guidelines and practices into all aspects of product innovation, including digital assets such as Mobile Medical Applications and Software as Medical Devices.

From a policy perspective we believe that in order to ensure the continuous innovation of these vitally important apps, smart regulation is critical. Currently, the FDA has shown great flexibility in establishing types of apps for which the Agency intends to exercise "enforcement discretion", that is FDA will not enforce the requirements of the Federal Food, Drug and Cosmetic Act, even if the app could be considered to fall within the definition of a medical "device". FDA released a guidance document that provides specific examples of apps for which FDA intends to exercise such enforcement discretion, while

also identifying the types of higher risk apps which it will continue to actively regulate. This guidance is extremely useful and J&J is supportive of their approach, but having the specific criteria that determines what is and is not regulated would provide more certainty, especially for small companies that may be less familiar with enforcement discretion. Both the SOFTWARE Act and the MEDTECH Act strive to achieve this goal, and we encourage Congress to finalize a flexible yet clear distinction between what should be regulated as a medical device, and what should not be regulated as such.

Johnson & Johnson worked extensively with the HELP committee and other stakeholders to craft the language in the SOFTWARE ACT that would provide this clarity. While additional work may be needed to reconcile the two bills the goal is similar and we would encourage Congress to complete this work and provide companies with the regulatory certainty that will foster innovation and encourage investment in this space. We would request that the following be considered during the deliberation: the medical device industry generally believes that the determination should be based on functionality (what the app does) not on the platform on which it runs (for example a smartphone, a computer, a server, or in the cloud) and that the determination should apply equally to all developers regardless of whether or not they are currently considered medical device manufacturers. These considerations are necessary in order to ensure that, at the end of the day, patient safety is the most important part of the decision making process.

With respect to the policy challenges, they are similar to those raised in the Wearable devices hearing that was held on March 3rd by this committee. Data security, data ownership, privacy law challenges – these all apply to mobile apps in much the same way as they do the wearables. The combination of wearable with apps could drive even more dramatic innovation. Johnson & Johnson believes that combined technologies such as electronic informed consent, remote patient monitoring through approved devices, tracking medication adherence, and wearables could revolutionize the way clinical trials are conducted by removing barriers associated with where a patient lives. This could help promote a key companion of patient empowerment, which is patient access.

As I hope you can ascertain from my comments, Johnson & Johnson strongly supports activities which help enhance the doctor-patient relationship, and improve patient empowerment and access to medical products. We look forward to continuing to work with our partners to develop additional interoperability while addressing any potential cybersecurity issues.

Given the myriad of activities which are underway, Congress has provided some incentives, especially in the area of cybersecurity. The current environment allows us to continue to innovate and drive key activities forward. Any additional legislation should support interoperability while understanding the resultant cybersecurity risks, maintain the level playing field for competition in the marketplace, support the continued dialogue and collaboration by not creating punitive barriers, and focus any additional restrictions in areas where there may be patient harm.

Again, thank you for the opportunity to discuss Johnson & Johnson's innovation in the medical apps space. I welcome your questions.