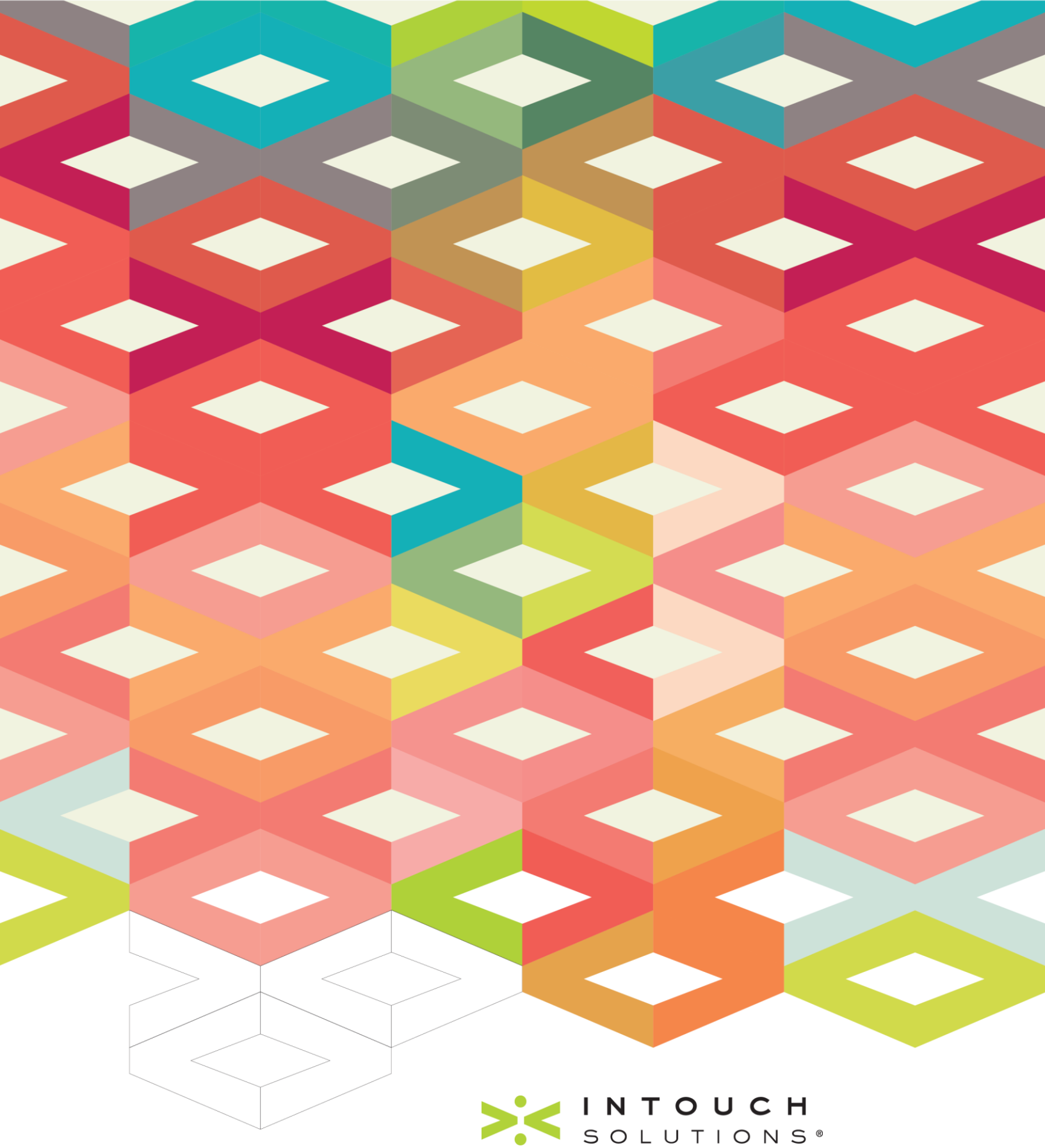

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POV: FDA WILL NOT REVIEW LOW-RISK WELLNESS APPS OR WEARABLES

JANUARY 2015

FDA WILL NOT REVIEW LOW-RISK WELLNESS APPS OR WEARABLES

EXECUTIVE SUMMARY

The FDA's Center for Devices and Radiological Health (CDRH) released guidance Jan. 20 for low-risk general wellness products, which stated that they do not intend to examine products within those parameters (low-risk and general wellness) to determine if they are medical devices. Such products are allowed to make claims about sustaining or improving general health and may even make disease claims, but only in conditions where it's obvious that a healthy lifestyle improves the condition.

> "Will the [FDA] ever regulate your FitBit, Apple iWatch or calorie-tracking mobile apps? Almost certainly not, the regulator confirmed … in a new draft policy document covering all 'low-risk' general wellness devices."
>
> – RAPS.org

This guidance does not appear to change FDA's position on other health-related items of any sort (technological or not); those that target general health do not fall in their purview.

BACKGROUND/OVERVIEW

This guidance is being released as the market conversation regarding wearables and their corresponding apps grows. Health is a particular area of focus for apps, wearables and "The Internet of Things" devices with increasing capabilities.

Thus, it's important to be clear on what CDRH defined as low-risk and general wellness.

+ **General wellness includes:**
  - Claims that relate to the **promotion** or **improvement** of overall conditions of health
    - Weight and eating; fitness, energy, mobility and coordination (including enhancing cardiac function); sleep, relaxation, stress management and mental acuity; self-esteem; sexual function; or the flow of qi
  - Claims that associate a healthy lifestyle with helping to reduce the risk or impact of **certain chronic diseases or conditions**, where that **positive role is well-understood and generally accepted** and for which the product is intended to promote, track and/or encourage choices that:
    - May help to **reduce the risk** of the disease or condition
    - May help **living well with** the disease or condition
+ **Low-risk refers to:**
  - A product that is **noninvasive**, does not pose a **safety risk**, and does not raise questions of **usability** or **biocompatibility**

Examples of products that ***would*** **be classified as low-risk, general wellness** and are covered by this guidance (e.g., FDA does not intend to review them) include:

+ A music app for stress management
+ An activity tracker for cardiovascular health
+ A food tracker app for weight management that offers alerts for unhealthy activity
+ A heart rate monitor

Examples of **disease-related general wellness claims** covered by this guidance (e.g., FDA does not intend to review them) include:

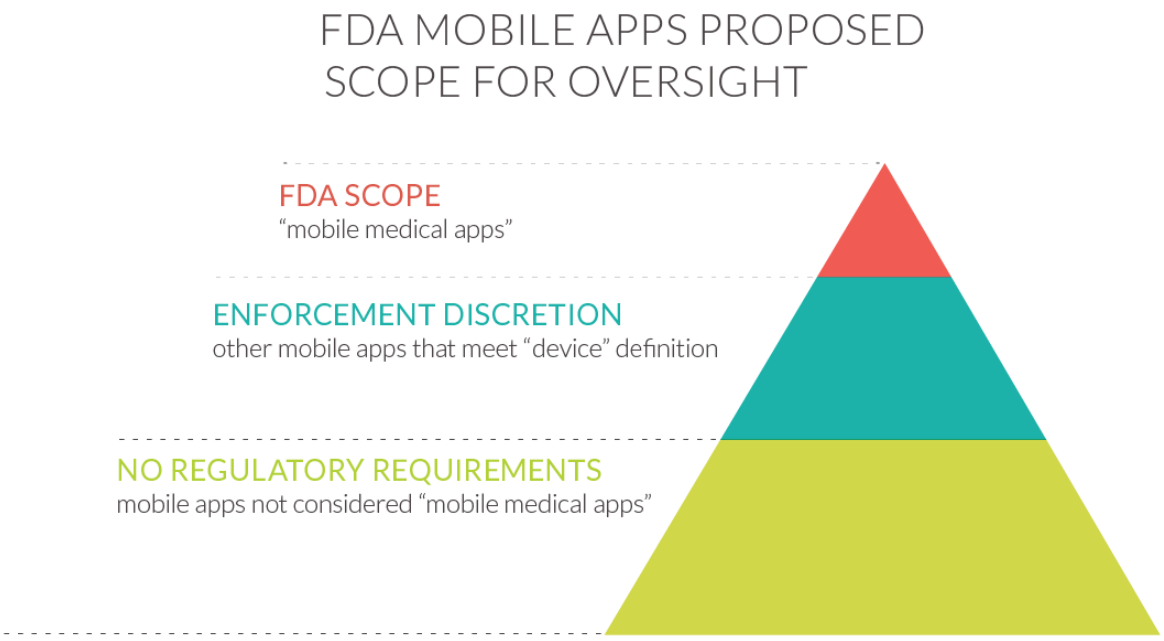
+ Product X promotes physical activity, which, as part of a healthy lifestyle, may help reduce the risk of high blood pressure.
+ Software Product Y tracks your caloric intake and helps you manage a healthy eating plan to maintain a healthy weight and balanced diet. Healthy weight and balanced diet may help living well with high blood pressure and type 2 diabetes.
+ Product Z tracks activity sleep patterns and promotes healthy sleep habits, which, as part of a healthy lifestyle, may help reduce the risk for developing type 2 diabetes.

Examples of **products or claims that *would not* be low-risk or general wellness** and therefore would be reviewed by FDA (e.g., not covered by this guidance):

+ Claims that a product could **diagnose, treat** or **restore** function, such as:
  - A product to diagnose or treat obesity or eating disorders
  - A product to treat anxiety
  - A computer game to diagnose or treat autism
+ Products that could be **invasive**, pose **safety risks**, or raise questions of **usability** or **biocompatibility**, such as:
  - Tanning lamps
  - Implants to improve self-image or sexual function
  - Laser skin rejuvenation

IMPACT ON PHARMA

With this guidance, the FDA is further refining the pinnacle of the triangle they outlined in their mobile medical apps Proposed Scope for Oversight graphic:



As their algorithm defines, the FDA seeks to focus its oversight on:

- Products that go beyond promoting general health to attempting to actively diagnose, treat or improve specific conditions
- Products whose technology could present inherent risks to safety

Pharma apps for traditional wellness topics — often addressed by standard trackers — are likely to be unaffected by this guidance.

The positive examples provided by the FDA are careful to connect the dots between habits and lifestyle, and disease and condition. Items that are green-lit are those that very clearly address the former in hopes of benefitting the latter. Marketers must, however, begin to consider the increasing integration of apps, products and data. If a wellness app is — or could be — used in combination with a diagnostic or treatment tool, the app may fall outside these guidelines.

RECOMMENDATIONS

With the publication of this draft guidance, there may be implications for companies that develop apps, wearables, and/or games in the healthcare industry, as well as those that may have a part in the integration of these devices and products. Below are recommendations for companies that may be affected.

IMMEDIATE AND NEAR-TERM

+ Review existing and planned apps, products, games, tools, trackers and programs - using the diagram on page eight - to determine if this draft guidance applies. In some cases, this guidance may assuage prior concerns from regulatory reviewers.
+ Err on the side of conservatism with this guidance and confirm the assumptions of brand specialists and KOL physicians when in doubt. What is well understood or generally accepted by a portion of the medical community may not meet that definition for the general public.

LONGER-TERM

Consider whether this guidance may open an avenue for more unbranded apps. We know that patients seek tools to understand and manage their health — and that branded content capabilities can be strictly limited. As such, we may see patient-journey tools taking the shape of wellness apps, providing a variety of "beyond the pill" services not related to any specific treatment or disease.

Consider a general healthy living app that gives patients a variety of optional functions, enabling them to set notifications, track and pair the app with a wearable. An engaging, highly customizable UX would help patients measure, schedule and analyze data of their choosing, from meals to moods, pain to activity, and medication timing to moments with family.

This strategy can be effective for a variety of reasons:

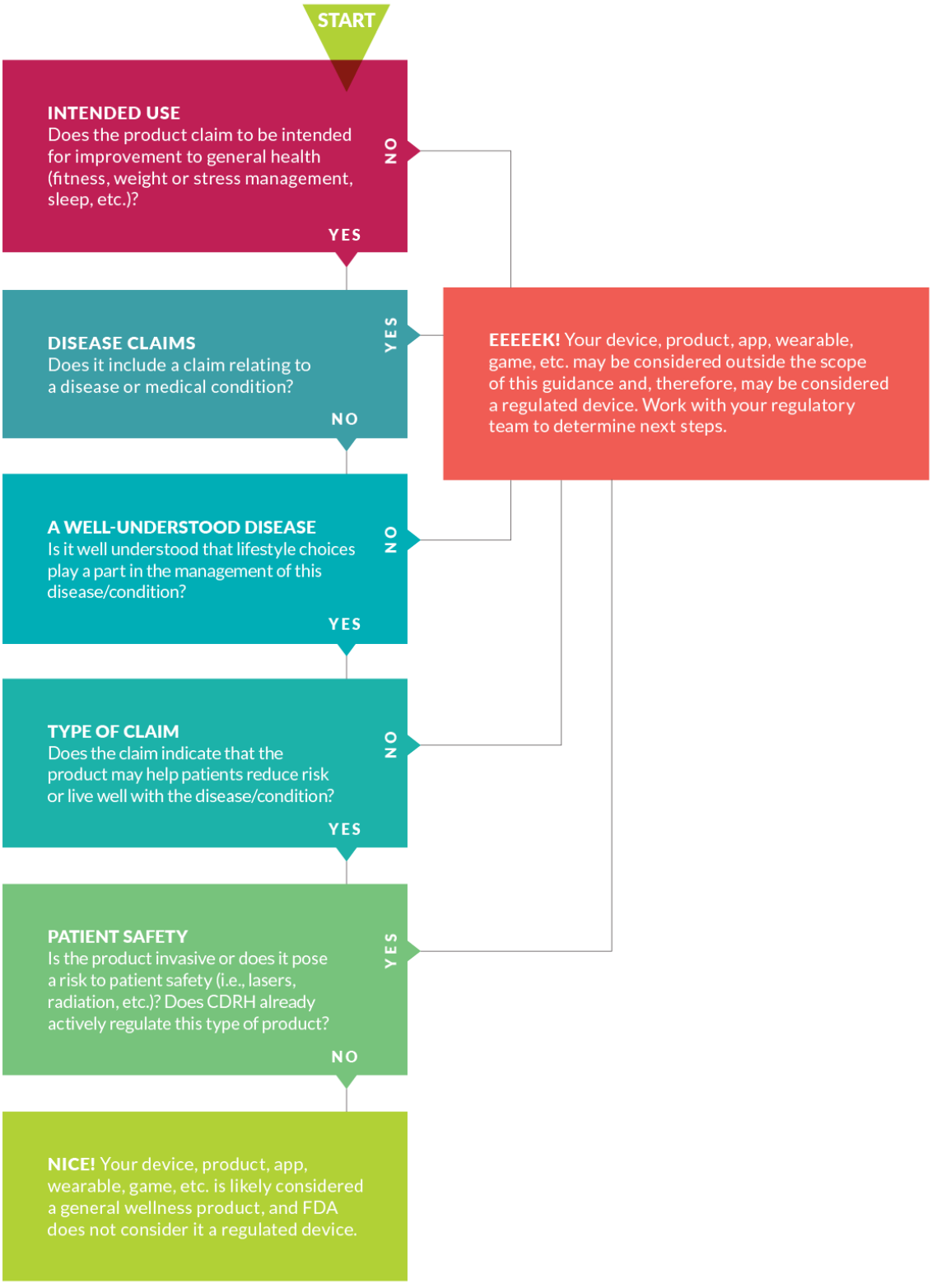
+ High-quality, general wellness tools can serve as powerful vehicles to build relationships with consumers.
+ Patient tools can serve as helpers to HCPs seeking adjunct programs that drive better outcomes for their patients. We continue to move toward a world where physicians regularly prescribe apps and online programs as part of their overall treatment.
+ Apps can be developed as modules, tested in the general wellness category, and adjusted and improved for branded use after real-world testing.
+ Anonymized, aggregated data from the general wellness apps can provide valuable information toward better understanding the patient population.
+ Simultaneously, the data can be used to provide useful information and conclusions for the general wellness users (i.e., "Your mood averages two points higher in weeks when you exercise!")

This approach could propel a strategy combining social responsibility, corporate communications and individual brand goals.

As consumers, patients, caregivers and HCPs continue to seek assistance from technology's increasing capabilities, pharma's relationship with each of these groups will take shape alongside FDA oversight.

For more information and additional viewpoints, see:

+ FDA Says It's Not Interested in Regulating Most Mobile Apps or Wearable Devices
+ FDA Says It Will Not Regulate Low-Risk Mobile Health Apps as Medical Devices



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