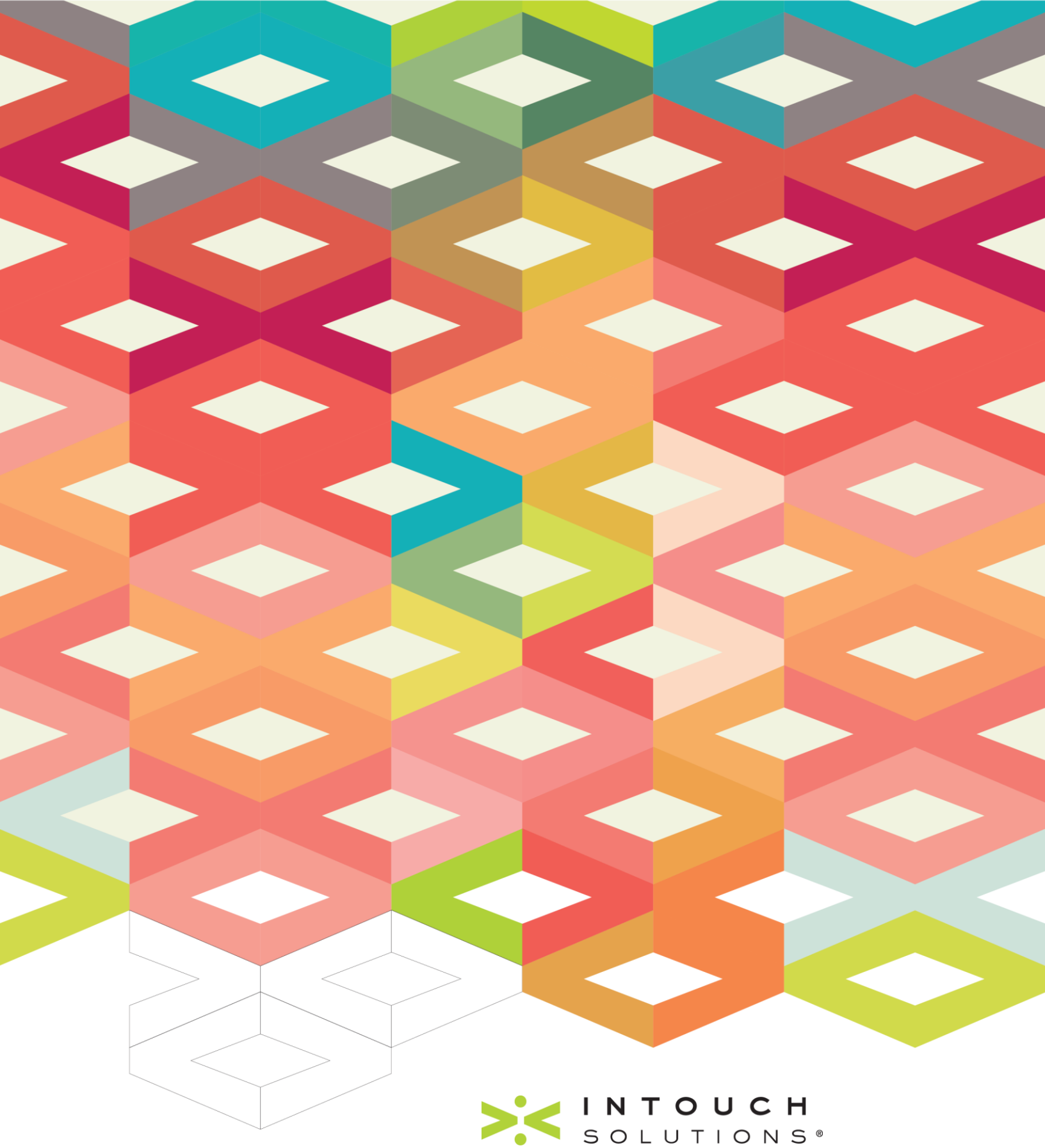


INTOUCH SOLUTIONS®

proprietary

POV: FDA SAYS LIMITED CHARACTERS IN SOCIAL MEDIA MEAN LIMITED OPTIONS FOR PHARMA

JUNE 2014

FDA RELEASES DRAFT GUIDANCE ON USING CHARACTER-LIMITED SOCIAL MEDIA FOR RISK/BENEFIT INFORMATION

EXECUTIVE SUMMARY

On June 17, the U.S. Food and Drug Administration released new draft guidance on the topic of how pharmaceutical and related companies can promote products using digital platforms in which character spaces are limited (e.g., Twitter, paid search advertising).

The crux of the FDA's stance — though they take 15 pages to state and restate it — is summed up in one sentence:

> "If a firm concludes that adequate benefit and risk information, as well as other required information, cannot all be communicated within the same character-space-limited communication, then the firm should reconsider using that platform for the intended promotional message."

This POV document lays out a summary and analysis of the draft guidance, as well as implications and recommendations for pharma companies who are currently or are planning to engage in character-limited platforms. The full draft guidance can be found on the **FDA's website**.

INTRODUCTION

The FDA continues to provide clarity around social media use with its recently published **Internet/Social Media Platforms with Character Space Limitations** draft guidance. Indeed, 2014 looks to be the year that FDA will deliver the social media guidance the industry has been hoping for for years (see **LINK**). Five draft guidelines were anticipated — on accountability, space limitations, correcting third-party information, using links, and AE reporting — and this latest document is the third in that series.

This draft guidance outlines the proper use of digital platforms with natively restricted communication parameters — primarily, Twitter and paid search links to Google and Yahoo. First, the FDA recommends firms "carefully consider the complexity of the indication and risk profiles for each of their products to determine whether a character-space-limitation platform is a viable promotional tool for a particular product." This cautionary, almost skeptical tone is characteristic of the entire document.

Again, FDA's stance — summed up in one sentence — is:

> *"If a firm concludes that adequate benefit and risk information, as well as other required information, cannot all be communicated within the same character-space-limited communication, then the firm should reconsider using that platform for the intended promotional message."*

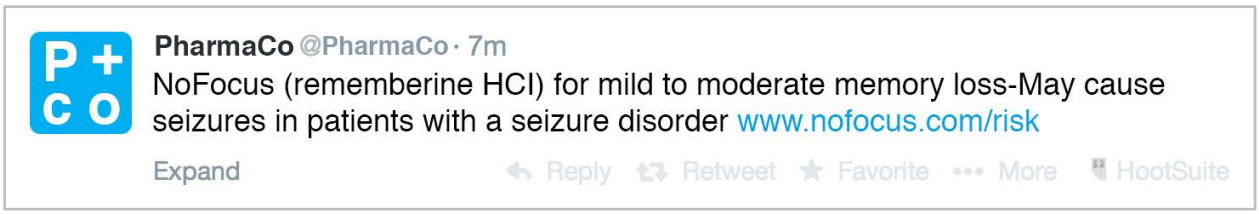
While this could be construed as a deterrent, Thomas Abrams, director of the office of prescription drug promotion at the FDA, added on the **FDA's blog,** "FDA sees social media as an important resource for industry and is committed to developing additional guidance for drug and device manufacturers that outline the agency's current thinking. We do all of this work with the best interest of patients in mind."

The draft guidance does use several examples to demonstrate that compliant use of character-limited platforms, while indeed difficult, is not impossible.

TWITTER AND OTHER MICROBLOGGING PLATFORMS

Intouch views Twitter as a valuable and viable platform with increasing usage among patients, physicians and brands alike. However, this guidance made it clear that any information within a branded tweet must incorporate a voluminous combination of information.

For some products, even a summary of the indication won't fit in a 140-character tweet — and that space needs to hold not only the indication, but also the brand name, generic, material facts, serious risks and a link. Below is the FDA's hypothetical example of a compliant branded tweet:



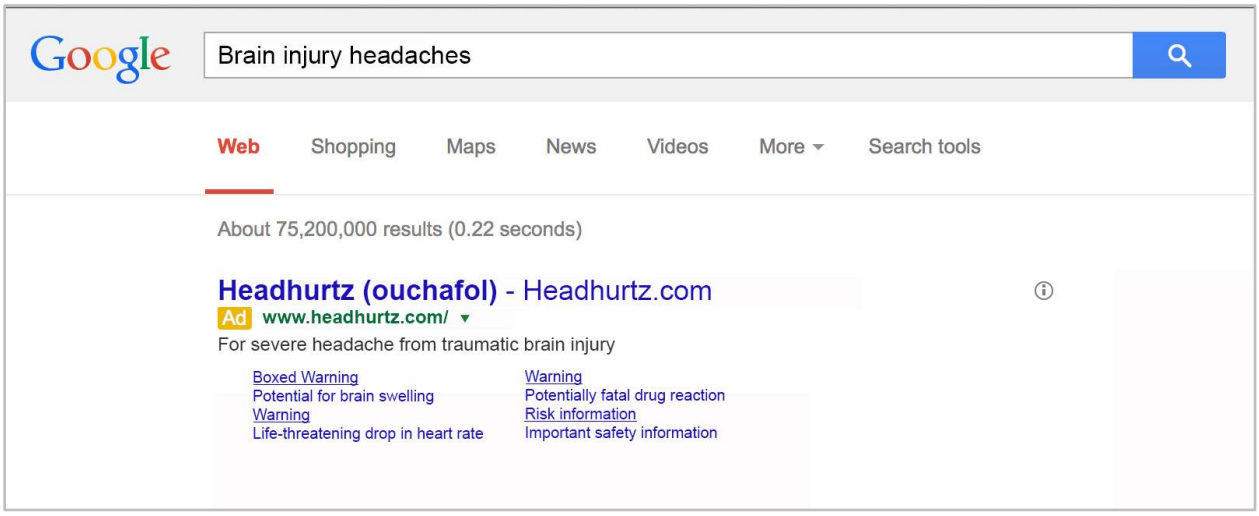
As a result of this direction, the "one-click rule" theory (i.e., hoping that linking to fair balance would suffice) is thoroughly discredited. This is not surprising and is in line with recommendations made by Intouch Solutions numerous times in the past (LINK).

PAID SEARCH OR SPONSORED LINKS

Regarding search, note that, while paid search and microblogging were specifically mentioned, organic search was not. Since several examples were given for paid search and social, skipping organic search does not appear to be an oversight. This is likely because, although webmasters can influence how organic listings are displayed, search engine algorithms have ultimate authority on the presentation of results.

Some of the main takeaways for search are regarding the use and placement of descriptive information. The generic must be used in conjunction with the trade name in search listings, and scientific abbreviations (e.g., "HB" for hydrobromide) are permitted to help with character limits. They also provide clarity on which risks need to be listed in the search results, as well as the

necessity for a link to risk/benefit information that prominently lists the dosage form and quantitative ingredient information. Below is the FDA's example of a compliant sponsored link:



Over the next 90 days, while the FDA is accepting public comment on this draft, Intouch will be auditing meta data for clients' sites to confirm their compliance with the proposed guidelines.

QUESTIONS REMAIN

While this guidance is detailed and offers a variety of examples on how to handle character-limited platforms, there are still questions to be answered:

+ The guidance does not discuss unbranded advertising.
+ It also, as an example of how technology moves faster than bureaucracy, does it address responsive design (as it admits, frankly). After all, when the discussion began in 2009, responsive design didn't exist since mobile viewing was barely a consideration.
+ And while some abbreviations are permitted, as noted above, there is no comment on the use of other abbreviations or colloquialisms — such as using "pts" for "patients" or "Rx" for "prescription" or "RA" for "rheumatoid arthritis."

However, it's clear that while the FDA is attempting to address evolving digital communications, basic truths remain unchanged: "Regardless of the platform, truthful, accurate, non-misleading, and balanced product promotion best serves the public health."

With the right product profile and a carefully crafted message, compliant branded tweets and paid search ads are possible. For products with low-risk safety profiles, creative copywriting with a sharp attention to detail can make this happen. However, unbranded and reminder messaging is a far simpler solution for most products on a character-constrained platforms — and for some, particularly those with more complex risk profiles, Twitter still may not be the right place at all.

CONCLUSION: THINK BEFORE YOU JUMP

Despite all of this new information, our instinct is to take a step back. This FDA draft guidance is providing details on the "how" — the steps and requirements by which branded character-limited communication can done. What brands need to do, however, is first discuss the "why." What are the brand goals? Where is it in its lifecycle? What would be useful and helpful for patients?

The careful attention to risk/benefit balance outlined in the guidance document aligns with existing, successful methodologies like those in place at Intouch. Before leading a client through any social media opportunity, however, a thorough audit assesses whether the messaging of a brand is a fit for social media. If it is, a further analysis investigates which platforms provide the best alignment of patient needs and brand goals.

If character-limited platforms like Twitter are a valuable tool for the specific situation, the next evaluation determines whether benefit and risk information can:

+ Be accurate and non-misleading and reveal material facts within each individual character-space-limited communication (e.g., each tweet)
+ Be accompanied by risk information within each communication
+ Link in a compliant manner to details. Tools such as the Intouch-created **ssshare.it** URL shortener make this possible

Whether it's a discussion about specific platforms or about digital product communications overall, the conversation must always begin, and return, to the patient needs and brand goals. We need to have a precise understanding of the latest guidance and regulations and of the technical knowhow to comply with it — but foremost, we need to keep in mind the needs of the patients and the goals of the brand and how best our work can address those.

For more information and ideas about social media or this guidance, contact your Intouch Solutions representative.

The information contained in this document is for general guidance on matters of interest only. Intouch Solutions makes no representations as to the accuracy or any other aspect of information contained in linked websites. The information contained in this document is not, nor is it intended to be, legal advice.

© Intouch Solutions 2014
Author: Doug Weinbrenner

Kansas City
913.317.9700

Chicago
312.540.6900

New York
646.795.3600

www.intouchsol.com
email: info@intouchsol.com
blog: intouchsoul.com
twitter: @intouchsol