RETURN OF THE "ONE CLICK RULE" – THE 21ST CENTURY CURES ACT[1]

What would you say if I told you that the "one click rule" is now in a Bill making its way through the political process in Washington and if passed would compel the FDA to accept it as an adequate way to handle safety information in space-limited channels? We at Klick Health say "yes please."

On Tuesday, January 27 the House of Representatives' Energy & Commerce Committee started promoting a bill that has been in development for a while: The 21st Century Cures Bill, drafted by the Health Subcommittee, currently in "discussion document" phase. This document is a giant bill that has five major sections:

- Title I: Putting Patients First by Incorporating their Perspectives into the Regulatory Process and Addressing Unmet Needs
- Title II: Building the Foundation for 21st Century Medicine, Including Helping Young Scientists
- Title III: Modernizing Clinical Trials
- Title IV: Accelerating the Discovery, Development, and Delivery Cycle and Continuing 21st Century Innovation at NIH, FDA, CDC, and CMS
- Title V: Modernizing Medical Product Regulation

There are two parts that healthcare marketers care about in this bill. They relate to:

- **Social Media:** the bill seeks to make social media a level playing field between drug manufacturers and the patients they serve, especially on the "space limited" channels.
- **Mobile Medical Apps:** the bill wants to clearly define what the FDA does and does not regulate in software, which for healthcare marketers mainly means mobile medical apps.

Social Media and the "One Click Rule"

The Bill under discussion instructs the FDA to accept linked safety information as adequate for digital communications in space-limited channels. There really is no wiggle room here for the FDA, if this Bill passes then the regulator has 12 months to review regulations and issue guidance telling companies they can use space-limited channels for branded conversations and that a link to important safety information (ISI) is adequate for regulatory purposes. This will cause the FDA to completely rewrite their existing guidance[2] on these channels.

[1] Credit where credit is due, we first heard about this bill from an excellent overview provided by RAPS: http://www.raps.org/Regulatory-Focus/21st-Century-Cures-Act/

[2] Digital Rx: http://www.klick.com/health/news/blog/sem-media/fda-draft-guidance-on-isi-in-space-limited-channels/

For those who only believe what they can see for themselves, next is the verbatim text from the Bill itself.

Verbatim Text

The verbatim from the Bill:[3]

> *(1) review each regulation and guidance that applies to the dissemination by means of the Internet (including social media platforms and character-limited applications) of information about medical products; and*
>
> *(2) propose revisions to such regulations and guidance (in the form of proposed amended regulations and draft guidance, respectively) that—*
>
> > *(A) facilitate meaningful use, by the sponsors of medical products, of the Internet, including Internet applications and social media, for dissemination of truthful, nonmisleading information about medical products;*
> >
> > *(B) recognize that such sponsors may use the Internet—*
> >
> > > *(i) to disseminate, in character-limited applications, truthful, introductory information about medical products,* ***including the name of such products and their approved uses****; and*
> > >
> > > *(ii) to provide additional information about the* ***safety and effectiveness*** *of the medical products using* ***information that is hyperlinked*** *to such introductory information; and*
> >
> > *(C) for regulatory purposes, treat hyperlinked information described in subparagraph (B)(ii) as if the information appeared in introductory information described in subparagraph (B)(i).*

If this Bill is passed into law, the FDA will be directed to accept the one-click rule in "character-limited applications." It is not too much of a stretch to assume this will apply not only to social media such as Twitter but to search engine ads as well. The Bill gives the FDA only 12 months to review regulations and guidance and propose changes. It is unclear how long it would take to make the regulations official although healthcare marketers are typically willing to act on guidance immediately if it makes sense.

Of course, that is only "if" the Bill passes with the current wording.

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[3] Text taken from full text PDF of the Bill: *"*A BILL To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes*"* pages 92-93

Mobile Medical Apps

The other directive of interest in this Bill is surrounding the definition of a Mobile Medical App. The section which includes this information is titled "*Sensible Oversight for Technology Which Advances Regulatory Efficiency*." The wording here implies that perhaps the current regulatory environment isn't "sensible."

The FDA guidance documents claimed that they were bestowing the app categories with "regulatory discretion" whereas the Bill looks to draw a clear line between what the FDA does, and does not, regulate and remove the possibility of the FDA interfering with any categories outside its purview. However, whereas the space-limited social media section was clear and unambiguous, it seems that the Health subcommittee ran into the same definition issues that have plagued the FDA when it tries to provide Mobile Medical App guidance.[4,5]

What the Bill wants to do is create four categories:

- Medical Software: regulated by the FDA
- Health Software: not regulated by the FDA under the Act, and specifies how the Act will be changed to ensure that
- Accessory or Component: which could fit into one of the two above categories, depending on the master device

Medical Software

The Bill instructs the FDA, within 24 months, to set up an entirely separate process for certifying "medical software." This process will be documented by "standards, policies, and procedures" for:

- Classifying medical software
- Standards for development and validation
- Review processes for new development and modifications
- Manufacturing and quality systems for the software
- Labeling requirements
- Postmarketing requirements including adverse event reporting

This looks like it would replace the current policy of using the 510(k) certification process[6] for tools such as mobile medical apps that are deemed to be "medical software."

[4] Digital Rx: FDA releases final guidance on mobile medical apps
[5] Digital Rx: FDA updates app lists for mobile medical apps
[6] In fact the Bill says that this process will replace three certifications: 513, 510(k), and 515

The Bill further instructs the FDA to include specific types of participants in 6-month workshops before making draft regulations binding:

- Patients
- FDA staff
- Experienced software developers
- Healthcare software experts

Health Software

This software is defined specifically as not medical software or a component [of a medical device] but is still intended to be used for healthcare purposes. The authors of the Bill are struggling with the definition here as the Bill includes the aside:

> *How do we ensure that products that have features that should be regulated as medical software or medical devices or components thereof are not exempted from regulation as such products?*

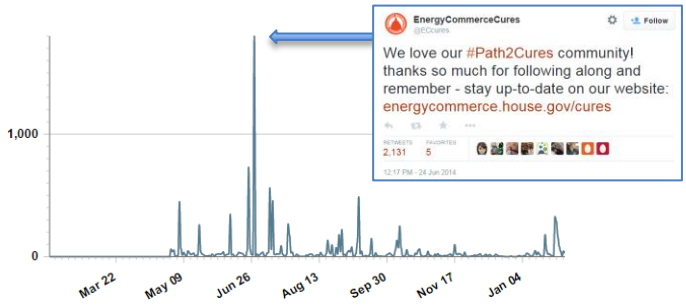
Essentially, they want the same outcome as the current FDA guidance: control the software that has the potential to harm patients but to ignore software that does not. This piece of the Bill will almost certainly be subjected to more discussion as issues such as the presentation of data vs. the suggestion of a diagnosis are hashed out.

History of this Conversation

This Bill has been in development for a while, and has had multiple inputs. The Committee's Facebook page[7] listed the efforts so far:

[7] Facebook: https://www.facebook.com/energyandcommerce

Looking at the history of the hashtags shows a topic that spikes around Committee events:



The current Congress has nearly two years left in its mandate, and the bipartisan Committee makes a point of talking about how both sides are working together, so there is no particular reason to think this Bill will die. But, like all politics, it's anyone's guess as to how it proceeds.

Questions?

If you have any questions about these developments, reach out to your account representative or contact:

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