in conjunction with ASQ – New England Biomedical Discussion Group & RAPS

FDA UPDATE
Capitol Hill 2013

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2013 Themes

- Taxes
- Mobile Health Technology
- FDA Efficiency, Transparency, Effectiveness
Legislation Highlights 2013

Introduced

- H.R.3303 - The Sensible Oversight for Technology which Advances Regulatory Efficiency ("SOFTWARE") Act
- H.R.2363 -- Health Care Innovation and Marketplace Technologies Act

Passed

- Pandemic and All-Hazards Preparedness Act Reauthorization of 2013
Legislation Highlights 2013

**Died (Stalled?)**
- Bills to Repeal the Medical Device Excise Tax

**Updates, Hearings, Reports**
- FDASIA
- MDUFA III
- Mobile Apps
H.R.3303
The Sensible Oversight For Technology Which Advances Regulatory Efficiency Act
The SOFTWARE Act

H.R. 3303

The Sensible Oversight for Technology which Advances Regulatory Efficiency ("SOFTWARE") Act

(Rep. Marsh Blackburn (R-TN07) introduced Oct. 22, 2013)

- Intended “to provide regulatory clarity regarding mobile medical applications, clinical decision support, electronic health records, and other health care related software.”

- Creates a regulatory scheme and new definitions for 3 new categories—"medical software," "clinical software," and "health software" -- a carve out from FDCA device definition

- “Medical software” would be subject to the same regulatory requirements as medical devices

- New definitions for "clinical software" and "health software" would exempt them from regulation.
The term “medical software”

would mean software that is –

“(1)(A) intended to be marketed to directly change the structure or any function of the body of man or other animals; or

(B) intended to be marketed for use by consumers and makes recommendations for clinical action that –

   (i) includes the use of a drug, device, or procedure to cure or treat a disease or other condition without requiring the involvement of a health care provider; and

   (ii) if followed, would change the structure or any function of the body of man or other animals;

(2) not software whose primary purpose is integral to the functioning of a drug or device; and

(3) not a component of a device.”
The term “clinical software”

would mean –

“. . . clinical decision support software” or other software (including any associated hardware and process dependencies) . . . that—

(A) captures, analyzes, changes, or presents patient or population clinical data or information and may recommend courses of clinical action, but does not directly change the structure or any function of the body of man or other animals; and

(B) is intended to be marketed for use only by a health care provider in a health care setting.”
The term “health software” would mean -

“...software (including any associated hardware and process dependencies) that is not medical software or clinical software and—

(A) that captures, analyzes, changes, or presents patient or population clinical data or information;

(B) that supports administrative or operational aspects of health care and is not used in the direct delivery of patient care; or

(C) whose primary purpose is to act as a platform for a secondary software, to run or act as a mechanism for connectivity, or to store data.”
“SEC. 524C. CLINICAL SOFTWARE AND HEALTH SOFTWARE.

Clinical software and health software shall not be subject to regulation under this Act.”

H.R. 3303
The Sensible Oversight for Technology which Advances Regulatory Efficiency ("SOFTWARE") Act
http://blackburn.house.gov/
@MarshaBlackburn
H.R. 1913
Application Privacy, Protection, and Security Act
H.R. 1913 -- The APPS Act of 2013
(introduced by Rep. Hank Johnson (D-GA07) 05/19/2013)

- Directs mobile device app developers, before the app collects personal data about the user, to notify user and obtain user's consent for collection, use, storage, and sharing of such personal data.
- Excludes “de-identified data”
- Requires violations to be treated as unfair or deceptive acts or practices under Federal Trade Commission Act.

http://thomas.loc.gov/cgi-bin/query/z?c113:H.R.1913
H.R.2363
Health Care Innovation and Marketplace Technologies Act
H.R. 2363 The Health Care Innovation and Marketplace Technologies Act

(Rep. Mike Honda (D-CA07) introduced 06/13/2013)

- Would allow medical care providers to deduct from gross income amount paid or incurred for qualified health information technology placed in service during taxable year.

- Would require DHHS to award grants for “development of an effective product, process, or structure that enhances the use, particularly by patients, of health information technology.”

- Would establish FDA Office of Wireless Health Technology

- Would require Health Information Technology Research Center to provide support for mobile health software app technology.
Passed

Pandemic and All-Hazards Preparedness Act Reauthorization of 2013
Public Law No. 113-5 (03/13/2013)

Title III: Enhancing Medical Countermeasure Review

Under Sec. 301, requirements for FDA’s “special protocol assessments” (SPAs) amended –

– to include agreements on the design and size of animal and any associated clinical trials which, in combination, are intended to form the primary basis of an effectiveness claim for a countermeasure or epidemic or pandemic product when human efficacy studies are not ethical or feasible.
Under Title III, Sec. 302

DHHS/FDA may authorize use of unapproved medical products or unapproved use of approved product when circumstances justify use (TBD by FDA).

Determination for authorization must be based on:

1. A (general) threat (rather than a specific threat as under current law),
2. A significant potential for a public health emergency,
3. The health and security of U.S. citizens abroad, and
4. The identification of a material threat sufficient to affect national security.
Under Title III, Sec. 304

Requires the Secretary to establish a procedure by which a sponsor or applicant developing a countermeasure for which human efficacy studies are not ethical or practicable, and that has an approved investigational new drug application or investigational device exemption, may request and receive:

(1) a meeting to discuss proposed animal model development activities, and

(2) a meeting before initiating pivotal animal studies. Requires such meetings to include discussion of animal models for pediatric populations, as appropriate.
Medical Device
Excise Tax
Government shutdown/debt ceiling negotiations

• Repeal of the medical device tax was included in proposed measures to fund the government.

• When repeal negotiations stalled, one proposed package to fund government /raise debt ceiling included a 2-year delay of the tax.

• October 16, 2013, the President signed a compromise measure that neither repealed or delayed the medical device tax.

• Medical device tax remains

• October 31 was the quarterly deadline to file the Form 720 — the Quarterly Federal Excise Tax Return.
FDASIA
MDUFA III REPORTS
MEDICAL MOBILE APPS
TESTIMONY
"Examining Federal Regulation of Mobile Medical Apps and Other Health Software"

Subcommittee on Health, Committee on Energy and Commerce, U.S. House of Representatives

November 19, 2013
Testimony Jeffrey Shuren, M.D., J.D.
Director, CDRH

before the Subcommittee on Health,
Committee on Energy and Commerce, U.S.
House of Representatives

November 19, 2013

Examining Federal Regulation of Mobile Medical Apps and Other Health Software
Opening Statement of the Honorable Joe Pitts, Chairman of Subcommittee on Health:

“While guidance is a valuable tool for the FDA, there is a significant limitation: certainty. What stands today could change tomorrow. * * *

* * * we need to give FDA new tools that create regulatory certainty not just today but also tomorrow. That certainty can start with properly defining what these technologies are for the purposes of regulation. * * * “
“[We need to] give the FDA a new tool – a 21st century definition – to regulate a 21st century technology.

The SOFTWARE Act is a starting place and an opportunity to begin a dialogue with thought leaders like the FDA. Rep. Blackburn and five of her colleagues – Democrats and Republicans – have put forward one way to modernize the FDA. . . .”
Testimony of J. Leonard Lichtenfeld, MD, MACP, Deputy Chief Medical Officer, American Cancer Society

“We need a risk-based oversight paradigm for this software that does not impose a heavy regulatory hand that might stifle innovation, but we must never allow the pursuit of innovation to displace patient safety and privacy as our primary considerations. Wherever software is involved directly in patient health, oversight is not only appropriate, but necessary.”
“. . . all software is not the same; there should not be a one size fits all regulatory approach for healthcare technology. Using the current medical device regulatory framework to determine if and how to regulate the diversity of potential healthcare IT software would be the proverbial case of trying to fit a square peg in a round hole.”

IBM supports the SOFTWARE Act.
FDASIA Implementation Update to Subcommittee on Health, Committee on Energy and Commerce November 15, 2013
Testimony of Jeffrey E. Shuren, M.D., J.D.
Director, CDRH

Subcommittee on Health, House Committee
on Energy and Commerce

November 15, 2013

Reviewing FDA's Implementation of The Food and Drug Administration Safety and Innovation Act (FDASIA)
FDASIA includes the Medical Device User Fee Amendments of 2012 (MDUFA III)

- MDUFA III took effect October 1, 2012; sunsets October 1, 2017
- User fees will total approximately $595 million (plus adjustments for inflation) over 5 years.
- FDA new hires -- more than 200 full-time-equivalent (FTE) workers between October 2012 and 2017. **90 FTEs hired.**
- FDA performance goals
CDRH two-phase assessment to objectively assess FDA’s premarket review processes including--

- Performing technical analyses,
- Management, and
- Program evaluation.

Currently in process.

“High-priority findings” expected before December 31, 2013
FDASIA, § 618, requires FDA, in consultation with the National Coordinator for Health IT and the Chairman of FCC, to prepare a report by January 2014 containing —

“a proposed strategy and recommendations on an appropriate, risk-based regulatory framework pertaining to health IT, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication.”
Thank You.

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