Weekly Roundup: FDA Regulations, Science Funding and Newborn Screening

by Sharon Goswami and Dan Vorhaus

With so many developments at the intersection of genomics and the law, there is often a variety of interesting stories that, for one reason or another, don’t find their way into a full-length posting on the Genomics Law Report. In this post we recap several recent key developments and, at bottom, round up all of the recent tweets from @genomicslawyer.

Continuing Uncertainty Over FDA’s 510(k) Overhaul. As we have discussed previously, in addition to overhauling the approval process for direct-to-consumer (DTC) and laboratory developed tests (LDTs), the FDA is also in the midst of a comprehensive review of its 510(k) clearance process for medical devices.

The FDA’s Centers for Devices and Radiological Health (CDRH) released proposed changes to the 510(k) program this past summer and further revised its recommendations in January after substantial industry feedback. The goal of the recommendations is to streamline the 510(k) review and clearance process while ensuring certain higher-risk devices, particularly those currently approved as substantially equivalent to existing devices, receive appropriate scrutiny.

Even with the ongoing overhaul, the FDA’s 510(k) review process drew renewed attention from two separate Congressional committees last week. On Wednesday the Senate held a hearing entitled “A Delicate Balance: FDA and the Reform of the Medical Device Approval Process.” The House followed a day later with “Pathway to FDA Medical Device Approval: Is there a Better Way?”

The Senate hearing was held before the Special Committee on Aging, in part to address concerns raised in a new GAO report which alleges that the FDA is putting patients at risk by approving high-risk medical devices under the 510(k) medical device pathway without sufficient pre-market review. The House hearing focused on “the FDA’s inconsistent application of reasonable standards for safety and effectiveness in approving medical devices, and the impact it has on American job creators.”

Overlaid on all of the FDA-proposed 510(k) changes and Congressional hearings is the forthcoming independent review of the 510(k) program by the Institute of Medicine (IOM). The IOM, whose report is due this summer, has already been criticized for failing to incorporate representatives from the medical device community into its review process. Last week, Senator John Kerry (D-MA) added his voice to the list of IOM critics, delivering an open letter to FDA head Margaret Hamburg expressing concerns with several proposed 510(k) changes and urging greater industry representation in the IOM review process.

FDA Looking Ahead to Companion Diagnostics, WGS and EHRs. Also in FDA regulatory news, long-awaited companion diagnostics guidance is in the “sign-off” stage at CDRH. The announcement was made by Elizabeth Mansfield, Director of Personalized Medicine in the CDRH’s Office of In Vitro Diagnostics (OIVD) and reported by Pharmacogenomics Reporter. FDA officials also note that similar guidance for co-developed diagnostics will likely take much longer.

Mansfield also responded to criticism that the FDA does not appear well-prepared for forthcoming regulatory challenges, including the likely rapid expansion of diagnostic tests based on whole-genome sequencing (WGS). This is a topic we have addressed several times (see, e.g., here and here), and Mansfield noted that “the FDA has formed an inter-agency, inter-departmental working group to try to discuss some of its forthcoming challenges, including whole-genome sequencing technologies.” She added that the FDA is “on top of it as we can be.”

Finally, another looming question for the FDA as it seeks to clarify its regulation of new medical technologies: will the FDA deal with the increasing prominence of electronic health records (EHRs) by regulating EHRs as medical devices? Speaking at a recent EHR conference, CDRH Director Jeffrey Shuren “acknowledged that the potential of FDA regulation [of EHRs] raises serious clinical issues and is a ‘political hot potato.’” As of right now we’re not regulating EHRs, and it may turn out that we won’t,” he said. According to Healthcare Informatics, the FDA is likely to issue new rules for software regulation, including medical apps for mobile platforms, in either late 2011 or in 2012.

As we have written previously, the FDA will face substantial challenges over the next several years as it attempts to apply its limited regulatory resources to an expanding array of healthcare products and services, all while walking the fine line between protecting public safety and safeguarding scientific and medical innovation.

Science Funding Updates. Although many federal employees anticipated a furlough earlier this month, Congress reached an eleventh hour agreement to cut $36 billion from discretionary spending and avoid a government shutdown.

We have updated the figures from our earlier roundup to show how this latest budget compromise affects federal science funding.

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<th>Current FY ‘10</th>
<th>continuing Resolution FY ’11</th>
<th>White House Request for FY ’12</th>
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<tbody>
<tr>
<td>NIH</td>
<td>$31.2 billion</td>
<td>0.8% cut in funding to $30.7 billion</td>
<td>2.4% increase to $31.8 billion</td>
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<tr>
<td>NSF</td>
<td>$6.9 billion</td>
<td>6.7% cut in funding to $6.4 billion</td>
<td>13% increase to $7.8 billion</td>
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Even with these changes, the budget compromise for FY 2011 (pdf) is not quite complete. The CR does not mention spending for CAN (the
Cures Acceleration Network), part of NIH Director Francis Collins's hotly debated National Center for Advancing Translational Science (NCATS).

Keep in mind, too, that FY 2011 ends in September. A renewed debate later this year over science funding levels in the FY 2012 budget is a strong possibility.

**Uncertainty in Newborn Screening.** An area of ongoing controversy and uncertainty is the legal status of newborn screening programs, with recent litigation in Minnesota and Texas focusing attention on the issue (see prior GLR coverage).

A recent study published in Pediatrics (pdf) evaluated state laws and policies on newborn screening, including the retention of dried blood samples (DBS), which are often retained for both quality control and unrelated scientific and public health research. The study authors found that states vary widely in the treatment of newborn blood samples following initial screening. A total of 18 states appear not to have addressed DBS retention or use at all, while the remaining states “have wide variability in their policies regarding the retention and use of DBS.”

The study, which was also covered by the Genetics & Public Policy Center, is another reminder that many states lack clear legal and regulatory guidance across a range of increasingly important healthcare activities, including newborn screening. Legal harmonization will be important to support efforts seeking to improve the effectiveness and breadth of newborn screening, such as the national newborn screening clearinghouse under development by Genetic Alliance.

**Roundup of tweets from the intersection of genomics, personalized medicine and the law:**

- RT @MishaAngrist: MT @matthewherper: DNA Sequencing Story Wins Pulitzer Prize [http://bit.ly/IR5Vu3] Pulitizer awarded before X Prize...
- Biotech missing big opportunity by focusing on major mktks & “thought leaders,” ignoring Smalltown, USA [http://bit.ly/97Brw]
- Hope lessons of #sagecon will flow to this conf next month: [http://bit.ly/opPub3] HT @BiotechPatent
- Favorite Latham line: “failure to find meaningful inherited genetic predispositions likely to become most profound crisis science has faced”
- Do-it-yourself DNA testing: A risk or a right? [http://bit.ly/1atmsg] Pro/con in LA Times, incl. view from @MishaAngrist HT @Sagebio
- Yes. RT @bigs: @drjonboyg @dgmacarthur @matthewherper What if we think of (data) consent as process rather than event?
- Beta site for “That’s My Data” [http://bit.ly/9dD5QI] @sharonferry @GeneticAlliance Looking forward to more.
- RT @wilbanks: $1M USD pledged by @sagebio to fund open legal tools for citizen engagement in health. Informed consent, etc. #sagecon
- RT @jasonbobe: Wonderful proposal by @sharonferry: “That’s my data”: develop tools, help ppl liberate data from academia/industry #sagecon
- For data only, I take the under. MT @iGenomics: Lee Hood: $1000 genome in 3 years. 5-8 yrs to be cheap enough to get info into health record.
- RT @FierceBiotech: RT @celiacdisease: I love this from NIH chief Collins: Data is not the plural of anecdotes #ahcj11
- RT @finchtalk: #sagecon for the FDA, the tidal wave of data, comes to them on paper, delivered by trucks.
- Vicki Seyfert-Margolis of FDA speaking at #sagecon. @MishaAngrist @ldtimmerman @finchtalk @sharonferry have commentary.
- Find it interesting @CompleteGenomic ($GNOM) considers WGS a "two-horse race" w/ $ILMN: [http://bit.ly/eODk70] Even if true, it lasts.
- More from the "if genetic information is not perfect, it is unethical to provide it" camp: [http://ind.pn/1DFqmQN] HT @MishaAngrist
- RT @InSequence: Complete Genomics Shipped 600 Genomes in Q1: Plans to Expand to Asia in 2013: [http://bit.ly/9E3dO]
- Boston Globe recalls the life of Henry Louis Gates, Sr., incl. his involvement with @PGorg: [http://bo.st/v723FF]
- Already reading this, at least definitionally. RT @genome_gov: key will be if GINA’s principles incorporated into other legislation #ELSI11
- RT @westr: RT @dinekeis2 "Direct-to-consumer testing: if consumers are not anxious, why are policymakers?" [http://bit.ly/9pYpE] #ELSI
- RT @InSequence: 454 GS Junior Drives 1 Percent Growth in Roche’s Sequencing, Array Business in Q1: [http://bit.ly/e7nsuP]
- RT @dgmacarthur: Ooh, @genomera is looking for a new product designer. Smart tweeps interested in startups and DIY genomics, talk to @bigs.
- RT @wilbanks: #sagecon great example why data governance more complex than open/not open. data governance > definitions and declarations.
- Damn! I’m clearly in the wrong Cambridge! MT @dgmacarthur: celebrating DNA Day w/ @genomesunzipped crew @ The Eagle (Watson & Crick’s pub).
- RT @FierceBiotech: Biotech VC dollars rise, but deal numbers fall. [http://bit.ly/37v46]
- Idea similar to what @PGorg does, but PGP relies on information altruists. One thing clear: we must try multiple models of informed consent
- On new models for genomic research, at #AAAS event yesterday Latanya Sweeney made very similar argument: informed consent as contract.
- Great #DNADay lineup, opportunity, Gong on right now RT @mikesgene: Let’s Talk DNA: [http://bit.ly/exlZa]
• RT @bmahersciwriter: Collins: grant success rate will drop below 20% in the next year. For the first time in history #ahcj11
• Post from @23andMe officially announcing new Alzheimer's/APOE reporting: http://bit.ly/I0W4hW
• RT @mwbanks: Watch out for tons of g Soniaegon tweets today. Filter if you don't like om bio, watch online @ http://bit.ly/iFdlkJ if you do.
• RT @dgmacarthur: To access new APOE results at @23andMe you need to pass this (entirely appropriate) lock screen: http://twtpic.com/411jd
• RT @dgmacarthur: Some very quick thoughts (with screenshots) on @23andMe's new APOE Alzheimer's risk prediction: http://bit.ly/1qYuy5
• The future of personalized medicine: gene patents, DNA testing & FDA regulation http://smrli/dP3SAP my Q&A w/ @boonspoon on @SmartPlanet
• Off to MA for "Privacy. Autonomy & Personal Genetic Info in the Digital Age" w/ @geochurch, @zitrin et all: http://bit.ly/2ipfi
• Thx to @drjono for live tweets. Recommend going back and reading them here: http://bit.ly/eCFEBW_ENVII
• The #ELSI11 panel on WGS w/ Duke's Bob Cook-Deegan & @MishaAngrist, @23andMe's Joanna Mountain & NHGRI's Jeff Schloss seemed great.
• Solve this prob, become insta-billionaire: RT @dgmacarthur @pathogenомнектики reminder of email incompatible w/ getting 'real' work done
• RT @bioitworld: David Dooling (Wash U.): "Uncertainty makes some ppl want to cling to guns & religion. Others cling to their data."
• #BioIT11
• RT @ldtimmerman: RT @PearlF: & jobs won't be coming back RT @matthewherper: In past decade, drug cos have cut 300K jobs.
• http://ow.ly/dzuIT
• RT @GenomeWeb: Quest for Deal: Celera Clearus US Antitrust review: http://bit.ly/eYRSC
• MT @humanagenomeorg: OMIM (Online Mendelian Inheritance in Man®) available through new & improved site: http://www.omim.org/
• RT @dgmacarthur: I have a guest post on solving rare diseases with exome sequencing over at the Wellcome Trust blog: http://bit.ly/1Cypgu
• RT @dgmacarthur: Dan Koboldt has a typically thorough post on the new sample prep instrument from Ion Torrent: http://bit.ly/q1MJw
• Final SAGC00s (R.I.P.) report on Genetics Education and Training is now available: http://bit.ly/Iv6dD
• RT @Mjoseph: April 15, listen to Dr. Rodriguez, NHGRI, speak about new NIH Data Sharing Policy here: http://bit.ly/2QP1W
• The latest @IonTorrent upgrades (and ads) covered by @matthewherper: http://ow.ly/k7qZp PR here: http://bit.ly/4DjCj
• RT @dgmacarthur MT @djono for Malia Fullerton: Current human research protection emphasizes risk protection over respect #ELSI11
• GAO to appear at Congressional hearing, criticize FDA oversight: http://nyti.ms/e6Jlex via NYTimes #soundfamiliar?
• After revisiting '10 biotech IPOs, @LifeSciVc finds a glimmer of hope for the '11 class: http://bit.ly/IW0keL
• RT @awjourn: Biotech Execs Gather in NY to Banter about the City's Challenges and Opportunities http://tinyurl.com/3qr6xg
• Beyond drugs, devices & diagnostics there is "healthtech" (or the other 84% of healthcare): http://bit.ly/eLiLyA
• CollabRx Snags ASC0 Partnership: http://bit.ly/ePRWPs by @ldtimmerman
• RT @daphnezhohar: Pharma must innovate out of current predicament w/ new models according to @burrillreport: http://fb.me/WcJe0ka
• The @CompleteGenomic blog follows @ontorrent anti-$ILMN ad campaign as evid that WGS isn't just for big centers anymore.
• RT @dgmacarthur: I'll be keeping an eye on new corporate blog of @CompleteGenomic: http://bit.ly/e3J1Dz The authors are interesting guys.
• Overview of compromise FY11 budgets for science agencies: http://bit.ly/NC6E1 $260M haircut for NIH not good, but better than $1.5B
• As for GnuBio: RT @dgmacarthur: GnuBio a serious new player in seq? Maybe once they've sequenced more than 126 bases:
• http://bit.ly/PvYIs
• Update from @Ryan_McBride on cancer diagnostic firm On-Q-ity, next-gen sequencer GnuBio, others: http://bit.ly/30EzE
• Ditto (+ @DNAlawyer, @SmartPlanet & @san_bas as well) RT @drjono: Good to see @genomiclawyer and @MishaAngrist this evening.
• Registration open for "DNA Ethical Dilemmas" w/ @amy_harmon of NY Times: http://bit.ly/bqChOC I'm talking abt DTC & other topics on 5/19
• Eric Green: NHGRI needs to contemporize its ELSI research #ELSI11 http://bit.ly/1WZjna
• FDA considering whether to regulate EHRs as medical devices:
• The #ELSI11 panel on WGS w/ Duke's Bob Cook-Deegan & @MishaAngrist, @23andMe's Joanna Mountain & NHGRI's Jeff Schloss seemed great.
• Congress getting ready to hold another round of hearings on medical device regulation:
• One example of difficulty of applying device regs to info.
• #ELSI11 I'm talking about DTC & other topics on 5/19 by @bvbigelow cc @jcainhart http://ow.ly/4z8zI T
RT @wilbanks: startup idea in health? @Rock_Health is providing grants, office space, and time with mentors (like me!)
RT @dgmacarthur: DNA hacking - short piece on the potential risks and benefits: http://bit.ly/2tMftrm (via @sociallifeofdna)
WSJ, Senate seeking to overturn rule barring public disclosure of what MDs earn from Medicare: http://on.wsj.com/hiKeiAM HT @tgoetz
Another effect of gov't shutdown: SEC to skeletal staff, all IPO processing stops: http://nyti.ms/efPaQ0 cc @JCainHart
Sequencing ad wars: sign of things to come as prices fall, # of buyers rise? MT @dgmacarthur Ion Torrent's attack ad:
http://bit.ly/fi.mFU9
RT @dgmacarthur: How big pharma executives are killing their own companies: http://bit.ly/fiTo6 (via @tgoetz, @wilbanks)
Shutdown will leave NIH w/ 982 employees to oversee 281 bldgs valued @ $15B. Guess that's one form of small government
Wonderful high-level overview, incl. what happens at NIH, FDA: RT @NatureNews US shutdown: a scientist's guide
http://goo.gl/qbjRhUJz
Glad to see @BoraZ yesterday, even if only out my car window while driving between Chapel Hill and Durham. #15-501
RT @ASCOPost Fifth FDA Clearance Granted for MammaPrint Assay http://ow.ly/4v9mF