Pharmaceutical Track-and-Trace Legislation Passes Senate, Advances to President Obama

Drugmakers have 13 months to revamp how they track drugs after the Senate voted Nov. 18 to send to President Barack Obama’s desk a measure that would establish a nationwide track-and-trace requirement for prescription drugs.

H.R. 3204, the Drug Quality and Security Act, was approved by a voice vote without amendments following House passage in late September. The bill also included provisions to increase regulatory oversight of compounding pharmacies.

Once signed into law, H.R. 3204 will immediately preempt all state laws concerning track-and-trace, including California’s strict e-Pedigree measure set to go into effect in 2015 (WDL, Oct. 7).

The legislation sets a number of important deadlines for manufacturers.

(See Track-and-Trace, Page 4)

Congress Denies FDA’s Call for Mandatory Oversight of Compounding Pharmacies

Congress rejected the FDA’s call for mandatory oversight of compounding pharmacies, passing legislation Nov. 18 that instead allows compounders to volunteer for agency oversight.

Under the Drug Quality and Security Act (H.R. 3204), which has passed both houses of Congress and which President Obama is expected to sign, compounders would be allowed to stay under state supervision or voluntarily register as an “outsourcing facility.”

An “outsourcing facility” that agrees to FDA scrutiny would have to:

● Be subject to risk-based inspections;
● Pay user fees, including a $15,000 establishment fee and a reinspection fee for each reinspection in a fiscal year; and
● Report adverse events.

(See Compounding, Page 4)
Roche Escapes EMA Rebuke on Drug Safety

The European Medicines Agency (EMA) has concluded a review of adverse event reporting deficiencies at Roche, concluding the company’s failure last year to report adverse events for 19 drugs did not cause any additional risks to consumers.

However, the EMA’s first-of-its-kind infringement case against Roche may still produce a stiff fine for the compliance failings, potentially totaling as much as five percent of the Swiss pharma giant’s EU revenue from 2012. The agency’s ongoing legal assessment is expected to be finalized by April 2014, the EMA told WDL Nov. 19.

Ever since Roche was alleged to have infringed on its EU pharmacovigilance obligations in October 2012, the drugmaker has moved to improve the collection, processing, evaluation and reporting of adverse event data, Roche said Nov. 19. Roche’s corrective and preventive action plan was approved by EU officials, spokesman Luke Willats noted.

The incident began in June 2012, when the EMA called on Roche to immediately report any possible adverse events from marketed drugs or those in clinical trials to EU authorities. The alleged deficiencies were identified in May of that year during a pharmacovigilance inspection of Roche subsidiary Genentech by UK regulators.

During the inspection, the company identified about 80,000 case reports from a patient support program that had not been evaluated for adverse events or reported to the EU. The investigation did not reveal any evidence of a safety risk for patients, although the case reports included 15,161 deaths, the MHRA said at the time.

The drugs impacted by the probe include many of Roche’s best-selling products, such as Tamiflu (oseltamivir), Avastin (bevacizumab) and Herceptin (trastuzumab). — Robert King

FDA CALENDAR

Upcoming meetings through Dec. 9:

- Nov. 25: The FDA will hold a public meeting on meta-analyses of randomized controlled clinical trials for the evaluation of risk to support regulatory decisions. Silver Spring, Md.
- Dec. 9: The Gastrointestinal Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee will hold a joint meeting to discuss two BLAs for Entyvio (vedolizumab injection) submitted by Millennium Pharmaceuticals. The first BLA seeks approval of the drug for the treatment of adults with ulcerative colitis. The second proposes an indication for the treatment of certain adults with moderately to severely active Crohn’s disease. Silver Spring, Md.

Comment deadlines through Dec. 2:


Comings & Goings

Theresa Michele has been appointed director of the Division of Nonprescription Clinical Evaluation in CDER’s Office of Drug Evaluation IV. She had been serving in the position in an acting capacity.

Aradigm appointed Juergen Froehlich its chief medical officer. He joins Aradigm from Vertex Pharmaceuticals, where he was head of regulatory affairs. Froehlich also has industry experience in preclinical, clinical and regulatory activities at Boehringer Ingelheim, Genentech, Quintiles, Bristol-Myers Squibb and Ipsen.
FDA Clarifies Next-Generation Heart Drug Expectations

The FDA says developers of next-generation heart drugs, known as PCSK9 inhibitors, will need to present data showing only their effectiveness at lowering cholesterol, blood pressure and inflammation, not reducing heart attack or stroke.

That’s good news for at least five companies developing the new cholesterol treatments. Industry feared FDA would set the bar higher, and demand tougher trials for emerging PCSK9 inhibitors.

FDA spokeswoman Lisa Kubaska on Nov. 15 provided WDL with the agency’s expectations around the development of PCSK9 inhibitors, which reduce levels of “bad” cholesterol, or LDL.

“Decisions will be based on the compound’s effects on the entire lipoprotein lipid panel, particularly LDL-cholesterol, its effects on other markers of potential cardiovascular risk, such as hsCRP, and blood pressure, and any evidence of off-target toxicity,” she said. “The compound’s overall safety profile will also be factored into this decision,” she added.

“Looking ahead, the results of the ongoing trial IMPROVE-IT will provide important insight into the incremental effect on risk for major adverse cardiovascular events of adding a non-statin, LDL-cholesterol lowering drug to subjects receiving background statin therapy.”

That closely watched study compares a combination of Merck’s LDL-lowering drug Zetia (ezetimibe) and Merck’s Zocor (simvastatin) to simvastatin alone for preventing heart attacks, strokes and deaths. The results are expected to be released in late 2014.

The FDA’s clarification follows on the heels of new heart disease and stroke prevention guidelines released last week by the American Heart Association (AHA). The AHA now recommends expanded prescribing of cholesterol-lowering statin drugs after previously cautioning they should be used only in certain at-risk patients. The 2002 federal cholesterol guideline only considered a person’s risk for heart disease, leaving out the risk for stroke.

That call gave new urgency to developers of PCSK9 inhibitors to speed their candidates to market. Roche, Sanofi and Regeneron currently lead the pack with their late-stage PCSK9 inhibitors. Pfizer, Bristol-Myers Squibb, Merck and Alnylam Pharmaceuticals also have candidates in various stages of early development.
— Johnathan Rickman

FDA Offers Flexible Enforcement Of Product Name Placement

A drug’s active ingredient name does not need to appear every time its brand name is repeated in an advertisement, the FDA says, clarifying the most common advertising issue that drugmakers question the agency about.

The agency made the clarification in newly revised draft guidance on product name placement issued Nov. 18.

For print promotions, the active ingredient name must be named at least once per page (or spread) where the proprietary name appears.

For radio and telemarketing, the active ingredient name must be announced in conjunction with the most prominent use of the proprietary name, usually the first instance.

For text in television ads, the active ingredient name must be named in conjunction with the most prominent placement of the brand name.

And for electronic and web displays, the active ingredient must appear at least once per web page or screen where the proprietary name most prominently appears on that web page or screen.

The guidance also provides recommendations for ads involving two or more active ingredients.

— Johnathan Rickman
Track-and-Trace, from Page 1

By Jan. 1, 2015, all finished-dose forms of prescription drugs must include a lot-level transaction history that documents each step a product takes from manufacturer to final sale. Manufacturers face the same deadline for establishing a system to quarantine, investigate and validate via the history record a product suspected of being counterfeit, adulterated or stolen.

The bill also states that four years after enactment, drugmakers must affix product identifiers to each package and case of a product that includes a numerical identifier, lot number and expiration date. When a manufacturer receives a returned product that it intends to redistribute, that manufacturer must verify the product identifier on each package beginning four years after enactment.

Ten years after enactment, manufacturers must develop an electronic traceability system that identifies products down to the sales-unit level.

The bill also directs HHS to seek public and industry input and issue guidance that:

● Defines the circumstances in which a manufacturer can infer that drugs in a large container are what they purport to be. HHS must hold a public meeting on the issue and then issue a guidance 18 months after that meeting;

● Explains how drugmakers and other supply chain stakeholders can get a waiver from any of the law’s requirements. The guidance is to be issued no later than two years from the date of enactment;

● Helps drugmakers establish mechanisms to identify a suspect product and what to do after it is identified as such. This guidance must be published no later than 180 days after enactment; and

● Provides detail on how to grandfather products that were already distributed in the supply chain when the bill became effective. This guidance is to be issued no later than two years from the date of enactment.

The agency is also tasked with creating standards for the interoperable and secure electronic exchange of data along the supply chain. The standards must be available 18 months after a public meeting on the electronic system.

HHS must hold at least five public meetings in all to solicit feedback on how to implement the law, and at least one pilot project that evaluates unit-level traceability and the use of the product identifier.


Compounding, from Page 1

FDA Commissioner Margaret Hamburg last year asked Congress to give the agency a clear, mandatory oversight role over high-volume compounders and those dealing with the most complex drugs (WDL, Nov. 19, 2012). The FDA was disappointed with the compromise legislation, but glad for some authority over compounders.

“While this bill does not provide FDA with the additional authorities it sought, it provides a regulatory framework for certain compounders who register with the FDA,” the agency told WDL.

Congress hopes that hospital and consumer pressure will prompt compounders to register with the agency. Hospitals need to insist on compounded drugs from FDA-regulated facilities, enticing compounders to register, Allan Coukell, senior director of drugs and medical devices for Pew Charitable Trusts, says (WDL, Sept. 30).

“I think that all the other stakeholders in the supply chain and clinicians working with compounding pharmacies will make sure [the compounders] are regulated,” Michael Werner, a lawyer with Holland & Knight, who works on pharmaceutical cases, told WDL.

The International Academy of Compounding Pharmacists, which opposed any additional regulations for compounders, says it still believes states are the appropriate regulators for compounding pharmacies. Spokesman David Ball says the association will work with the FDA and its members to prepare for the new law. — Robert King
Pharma Investing in Biotech To Dampen Patent Cliff Fall

Orphan drug incentives, new technology and anxiety over expiring patents have dramatically spurred investment into biotech products, with the number of large molecule, biologic drugs in development tripling over the past decade.

The latest Impact Report by the Tufts Center for the Study of Drug Development (CSDD) says biotech products in development have risen from 355 in 2001 to 907 in 2012. Authors of the report emphasize large drugmakers have dramatically changed their drug development focus from small molecules to biotech.

CSDD Director Kenneth Kaitin opines the reason for this has been as much about new technologies that have allowed drugmakers to develop large molecules as it has been about countering the patent cliff that many companies have been suffering from over the past few years.

Tracy Cooley, a spokesperson for the industry group BIO, says another key factor is the return on investment drugmakers have seen over the past few decades. “The revenue generated by biotech therapies is a major reason why large pharmaceutical companies are interested in the growing promise of the industry to treat and cure disease,” she told WDL.

Examining the 10 best-selling products in 2001, biologics accounted for 7 percent of sales. Today, that has ballooned to 71 percent, the Tufts report states. Drugmakers have also invested 10 times as much in biotech research, from $10.5 billion to $103 billion, over the same period.

In 1989, only 13 biological medicines were on the market; by 2012, that number grew to 210. Many of those, such as Johnson & Johnson’s Remicade (infliximab), have become blockbusters.

FDA incentive programs intended to promote development of therapies that treat serious or lifethreatening illnesses is also driving the shift in R&D toward biologics.

Oncologic drugs constitute the largest focus of biologic clinical development, according to Tufts. And among biotech products in development, monoclonal antibodies are dominating pipelines.

Monoclonal antibodies saw an increase of 351 percent over the past decade accounting for 37

(See Biotech, Page 10)

Sanofi Blood Cancer Drug Nixed on Safety Concerns

Sanofi has decided to stop pursuing regulatory filing for its blood cancer drug fedratinib after new safety concerns arose from several clinical trials.

Fedratinib is a JAK2 kinase inhibitor intended to treat three types of myeloproliferative neoplasms including myelofibrosis, polycythemia and thrombocythemia. Its JAKARTA trial to treat myelofibrosis was the furthest along in the pipeline and the company trumpeted in May that the study had met its primary endpoint (reduction of spleen volume) in both dose groups.

The drugmaker has pulled the plug on clinical trials and halted further development, however, due to concerns the drug puts patients at increased risk of developing the brain disorder Wernicke’s encephalopathy.

The drug’s discontinuation is only the latest safety-related setback for the French drugmaker.

Sanofi’s multiple sclerosis drug candidate Lemtrada (alemtuzumab) last week raised serious safety concerns with FDA advisers (WDL, Nov. 18). The company also recently moved to withdraw its NDA for its Type 2 diabetes drug lixisenatide, and shutter several pipeline projects for cancer and multiple sclerosis drugs in the past year over safety concerns (WDL, Sept. 16).

The news also follows recent comments by Sanofi management that the company has weathered the patent cliff and is on a path to building itself back up with higher sales and a strong pipeline. — Ferdous Al-Faruque
Industry Groups Slam Short Deadline for GMP Requirements

Drugmakers are pushing back on proposed EU GMP requirements that would expand safeguards against product cross-contamination, saying the proposed six-month timeline for implementation is unworkable.

The proposal calls for cross-contamination toxicological risk assessments for any new product introduced into a facility. If all existing facilities must implement the changes, manufacturers will need more time to complete assessments and, if necessary, perform new validation and changes to equipment and facilities, the International Society for Pharmaceutical Engineering said in comments on the regulation.

The European Federation of Pharmaceutical Industries and Associations echoed the comment. It recommends the new requirements apply only to certain products, such as high-potency anticancer drugs and DNA-reactive compounds. It believes drugmakers can use quantitative risk management to assess risks in other new drugs introduced into a facility.

The proposed GMP changes, rolled out by the European Commission in January, also call for changes to supplier qualification. In line with a similar push by the FDA, the revisions urge drugmakers to discuss quality requirements with suppliers and document agreed-to controls in a quality accord.

The EU also recommends manufacturers treat high-risk excipient makers the same as active pharmaceutical ingredient suppliers, meaning they audit the supplier to ensure quality.

The International Pharmaceutical Excipients Council is actually lobbying for tougher auditing requirements for excipient suppliers under the supplier qualification rule. The proposal would mandate audits for high-risk excipient suppliers. The group is calling for audits of all excipient suppliers.

To read the comments, visit http://ec.europa.eu/health/human-use/quality/developments/index_en.htm#pc20133. — Robert King

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Judge Says Biosimilars Law Prohibits Premature Patent Suit

A California judge has ruled that Sandoz must file an application with the FDA for approval of a biosimilar referencing Amgen’s biologic arthritis drug Enbrel before it can challenge the brand drug’s patents.

The ruling in the closely-watched case could discourage biosimilar makers from making preemptive strikes against innovative products, a common tactic generic drug manufacturers employ against branded drugs.

Sandoz is currently conducting clinical trials on its own etanercept product and plans to file an application to license it as a biosimilar upon completion of those trials, the drugmaker told the U.S. District Court for the Northern District of California.

Sandoz had argued that federal law provides for declaratory judgment actions to be filed by either party once the biosimilar manufacturer gives the reference drug sponsor “notice of commercial marketing,” which Sandoz has done.

The court was not persuaded, noting that a notice of commercial marketing is only required by law for licensed products.

Sandoz cannot, as a matter of law, have provided a “notice of commercial marketing” because its etanercept product is not licensed under the Biologics Price Competition and Innovation Act of 2009, Chesney wrote in an order granting Amgen’s motion to dismiss the case. — Melissa Winn

FDA Raps US WorldMeds for Unsupported Treatment Claims

US WorldMeds, a specialty drugmaker, has been issued a warning letter from the FDA, noting false claims and omitted risk information for the company’s drug Revonto.

The Louisville, Ky.-based company’s “About Revonto” web page touted the malignant hyperthermia (MH) treatment for its ease of reconstitution, allowing operating room teams to be better equipped to manage an MH crisis.

However, the drugmaker doesn’t cite any evidence to support that claim, the letter posted Nov. 13 says.

While Revonto (dantrolene sodium) for injection supports a reconstitution time of about 20 seconds, no evidence shows “this directly correlates with an improvement in overall MH crisis management compared to other MH treatments,” it adds.

The web page also omits risks such as possible respiratory depression and skeletal muscle weakness. While the company provides links to the full prescribing information, it doesn’t make up for the misleading impression, the FDA said. Risk information is also relegated to the very bottom of the web page and in a single-spaced format, it also notes.

US WorldMeds did not respond to requests for comment.

This marked the third enforcement action in a week concerning misleading statements — an unusual spate of enforcement letters following a relatively calm summer.

To read the letter, visit www.fdanews.com/ext/resources/files/11/11-14-13-UntitledLetter.pdf. — Robert King
Generic Drugmakers Will Benefit From China’s Low-Cost Drug List

Chinese authorities are gearing up to keep the cost of certain drugs sold in the country down via publication of a “low-cost” drug list expected to expand access to generics.

The cost-control initiative is expected to take hold just as the country is set to become the world’s second-largest drug market after the U.S. by 2017, according to a new study by IMS Health. China will represent 34 percent of total growth in global pharma spending over the next five years.

China’s National Development and Reform Commission will release the list of drugs that must be sold at low-cost prices, according to Xinhua, the state news organization for China. No timeline was given stating when the list will be released, but sources close to Xinhua say the standard sticker price for low-cost western drugs will be mandated at just under fifty cents a day, or 3 yuan. Chinese patented drugs will be closer to $1, or 5 yuan, according to the news group.

The list, including criteria and cost principles, is expected to be adjusted every two to four years.

The Chinese government earlier this year launched a review of drug pricing and manufacturing costs for nearly 60 domestic and international drug companies, including GlaxoSmithKline, Boehringer Ingelheim, Fresenius Kabi and Sandoz.

The review, by the National Development and Reform Commission (NDRC), is focused on data from 2010 through 2012, including corporate audit reports, sales agreements and shipping records. Importers have also been asked to provide information about border control costs such as customs clearance, quarantine fees and storage fees.

The mandate for lower drug prices is also expected to prompt a round of mergers and acquisitions in the country, industry insiders told Xinhua.

The price cap is “essentially price insurance for pharmaceutical companies,” allowing a number of low-cost drug manufacturers to either re-enter the market or ramp-up production, Shi Lichen, a general manager of healthcare at PKU Management Consulting Group, told Xinhua. Smaller companies already producing generic drugs in the country will become “hot acquisition targets.”

The boon for generic drugmakers could be especially high if China’s drug spending continues to grow at its current rapid clip. China’s drug spending levels are expected to increase 34 percent and account for 15 percent of total global drug spending by 2017, the IMS Health report states.

Meanwhile, the country continues to crack down on pharma fraud and improve drug quality, an effort that most recently has targeted internet pharmacies operating in the country.
— Melissa Winn

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<td>10/18/2013</td>
<td>Acella Pharmaceuticals</td>
<td>EIR for Acella’s Alpharetta, Ga., facility.</td>
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<td>10/18/13</td>
<td>Viterion</td>
<td>Warning letters, seizures, injunctions, etc. for Cardiocom LLC over the past 12 months.</td>
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Gene/Cell Therapy Comment Period Extended

The wrangling over trial design guidance for gene/cell therapies will extend into next year as the FDA tries to satisfy industry concerns about how elements of the trials can be standardized.

Of particular concern to industry are issues of cell processing and potency development addressed in a draft guidance issued in July. The comment period on the draft was to close on Nov. 22, but the agency has extended the comment deadline until May 9, 2014.

The agency previously promised a two-day workshop to hash out the issues, but it had to be postponed due to the government shutdown. The FDA has now scheduled it for February 25-26, 2014 at the meeting of its Cellular, Tissue, and Gene Therapies Advisory Committee.

Drugmakers have taken issue with the FDA's thinking on preclinical assessments, and have asked for clarifications on issues such as expected duration to support long-term treatments; reproductive and developmental toxicity requirements; and elaborations on in-vivo studies.

SCOTUS Denies Teva Stay Request

The Supreme Court Nov. 13 dealt generic giant Teva a major blow as it denied the company’s request to stay a lower court’s ruling that will allow generic versions of the drugmaker’s blockbuster brand drug Copaxone (glatiramer acetate injection) to hit pharmacy shelves in May.

Without explanation, Chief Justice John Roberts rejected Teva’s plea to stay the ruling while the company prepares a petition for Supreme Court review.

Teva will ask the high court to review a decision handed down in July by the U.S. Court of Appeals for the Federal Circuit. The appellate court reversed a decision by the U.S. District Court for the Southern District of New York and declared several Copaxone related patents expiring in May 2014 and one patent expiring in September 2015 to be invalid. The appellate court specifically ruled that asserted claims of these patents are invalid for being indefinite, Teva said at the time.

Any Supreme Court review of the case likely won’t happen until its next session, which begins in October 2014 and gives generic copycats of the multiple sclerosis drug at least six months’ worth of sales.

Horizon Acquires U.S. Rights to Vimovo

Illinois-based drugmaker Horizon Pharma has acquired the U.S. rights to AstraZeneca’s Vimovo delayed-release tablets in order to bolster the company’s primary care portfolio. Rights outside the U.S. will be retained by AstraZeneca.

Horizon anticipates the deal will “accelerate the company to profitable operations,” Timothy Walbert, Horizon’s chairman, president and CEO, said Nov. 19. The specialty drugmaker has incurred net operating losses and negative cash flows from operations since its inception in 2010.

Horizon will make a single up-front payment to AstraZeneca of $35 million and will make royalty payments of 10 percent on the drug’s sales going forward.

AstraZeneca will continue marketing Vimovo through the end of the year. Horizon expects to take over in early 2014 and projects revenue between $190 million and $205 million.

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<tr>
<th>Bill Name and Number</th>
<th>Bill Sponsor(s)</th>
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<td>The Drug Quality and Security Act (H.R. 3204)</td>
<td>Fred Upton (R-Mich.)</td>
<td>Senate Committee on Health, Education, Labor and Pensions</td>
<td>9/25/2013</td>
<td>Passed Senate by voice vote</td>
<td>To address high-risk drug compounding practices and secure the pharmaceutical supply chain.</td>
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Advisors Recommend BioMarin’s Vimizim, Despite Call for More Info

The FDA’s Endocrinologic and Metabolic Drugs Advisory Committee strongly urged approval of BioMarin’s orphan drug Vimizim to treat the rare disease Mucopolysaccharidosis Type IVA, overriding agency concerns of limited supportive data.

Eighteen of the panel’s 21 voting members said it should be approved to treat all patients with the rare disease, also referred to as MPS IVA. One voted against approval and two said it should only be used in limited populations, although no consensus was reached on a proposed subpopulation.

Vimizim (elosulfase alfa) is supported by a single randomized, double blind, open label Phase III trial that compared patients that were given either placebo, 2 mg of Vimizim once a week or 2 mg of elosulfase alfa once every two weeks. At issue was BioMarin’s limited efficacy data set.

The FDA questioned the validity of a six-minute walking test (6MWT) as an adequate primary endpoint assessment for approving Vimizim, especially as the drug failed to meet its secondary endpoint of a six-minute stair climbing test.

The only issue agency advisors seemed concerned with was why most patients receiving the drug appeared to plateau at around the same level on the walking test. By week 24, patients on the drug showed a mean change of 22.5 meters, or about a 15 percent, from baseline.

“The benefit of the 6MWT is an integrated test” that shows improvement in quality of life, Robert Fink, Wright State University, noted in the study’s defense. “It has shown its benefit in [chronic obstructive pulmonary disease] and cystic fibrosis,” he said.

The lone voter against approval, David Cook, Johns Hopkins, said he was uncomfortable supporting the drug candidate based on a 24 week trial. “I think [6MWT] is an important measure … but I don’t think it answers the true long-term benefit of the medication,” he added.

Noting the degenerative nature of Vimizim’s targeted disease, BioMarin Chief Medical Officer Henry Fuchs said the patients that plateaued on 6MWT still maintain a better quality of life.

Vimizim has a PDUFA date of Feb. 28, 2014.

— Nick Otto

Biotech, from Page 5

percent of all biotech products in 2012, up from 21 percent in 2001.

Large pharmaceutical companies in particular have invested heavily in monoclonal antibodies. The 21 largest drug companies report more than half of their 429 biotech products in development are monoclonal antibodies. Roche has 51 such drugs in development, Sanofi, 40; Eli Lilly, 36; AstraZeneca, 32; Bristol-Myers Squibb, 21; Johnson & Johnson, 19; and Merck, 17.

To access the report, visit http://csdd.tufts.edu/reports/impact_reports. — Ferdous Al-Faruque
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