Senator Targets Self-Referrals In Imaging Battle

To combat the rising costs of medical imaging, Sen. Chuck Grassley (R-Iowa) has introduced legislation aimed at creating more transparency in the physician’s office.

Offered as an amendment to the Ethics in Patient Referrals Act, the Medicare Imaging Disclosure Sunshine Act of 2008 “will provide another necessary tool to address the significant increase in Medicare spending for in-office imaging services by providing more transparency and shedding some light on physician referrals to facilities and medical imaging equipment they own,” Grassley said in introducing S. 3343 last month.

The amendment requires physicians, at the time of referral, to inform patients in writing that they may get the necessary imaging services elsewhere and to provide them with a written list of imaging suppliers in their area. It does not expressly require disclosure of the physician’s interest in any facilities.

Lawmakers Crack Down On FDA’s Environmental Policy

A House subcommittee is accusing the FDA of not following National Environmental Policy Act (NEPA) requirements and calls on the agency to reform its rulemaking concerning dental mercury.

In a July 28 letter to FDA Commissioner Andrew von Eschenbach, the Domestic Policy Subcommittee addresses the agency’s “total disregard” of NEPA requirements to prepare an environmental impact statement (EIS) or environmental assessment (EA) when creating new federal rules, specifically those regulating dental devices containing mercury.

The letter, signed by Rep. Dennis Kucinich (D-Ohio) as committee chairman, reminds the FDA of its duty under NEPA to

(See Grassley, Page 3)
prepare an EIS or an EA as part of the rule-making process in reclassifying dental mercury, classifying encapsulated amalgam alloy and dental mercury or issuing special controls for amalgam alloy.

According to the letter, NEPA’s purpose is “to require federal agencies to take a ‘hard look’ at the environmental consequences of their actions” when making decisions.

The FDA said it inadvertently erred in the 1980s when it did not separately classify encapsulated amalgam alloy and dental mercury as Class II devices. When it reopened the case in 2002, the agency maintained that its proposed regulation of mercury-related dental devices was excluded from NEPA and did not require an EA because the devices were “of a type that does not individually or cumulatively have a significant impact on the human environment,” according to the letter.

As part of a settlement in a lawsuit filed by Moms Against Mercury, the FDA agreed to classify dental amalgam by July 28, 2009. After reviewing any comments submitted during the required comment period, the FDA will issue a final rule classifying the product and possibly requiring revised labeling (D&DL, June 16).

“While the proposed classification and reclassification of mercury-related dental devices may arguably maintain some sort of regulatory status quo, it would certainly not maintain an environmental status quo,” Kucinich says in the letter. “I urge the FDA to now take the requisite ‘hard look’ at the environmental impacts of these devices, and conduct a thorough analysis of this important issue.”

Studies by the Environmental Protection Agency claim mercury, a neurotoxin that can impair the development of fetuses and children and damage the central nervous system of adults, has become a global burden — with dental uses generating 34 tons of it per year.

“Despite these direct, cumulative, long-term, and far-reaching adverse effects on the environment, the FDA has regulated these devices for over twenty years without ever preparing an environmental review to inform its rulemaking,” Kucinich says.

The FDA did not return calls for comment. The letter is available at www.fdanews.com/ext/files/NEPA.pdf. — Renee Frojo

Registry for Breast Cancer Thermal Ablation Trials Considered

The FDA is asking industry whether it makes sense to set up a registry for feasibility studies of local treatment of small breast cancers using different thermal ablation devices and therapies.

The registry could help design such studies with standardized protocols specifying uniform methods of evaluating tissue biopsy pathology, the selection of tumors amenable to ablation, image guidance for ablation, post-ablation imaging and assessment, and tissue pathology of ablated specimens.

The registry would collect information on studies involving cryoablation, focused ultrasound, interstitial laser, microwave and radio-frequency ablation.

Small studies have demonstrated almost 100 percent ablation accuracy, but “unfortunately, the lack of uniformity among different feasibility study protocols has resulted in various study results that cannot be easily compared,” the agency says.

Creating a registry could help develop best practices for imaging and pathologic assessment. A registry also might help identify the conditions under which imaging would be a good surrogate for pathology and distinguish the genotypes of patients who respond well to therapy from those who do not, the FDA says.

The FDA’s request for comments, which are due Oct. 24, can be found at www.fda.gov/OHRMS/DOCKETS/98fr/FR Doc E8-11899.htm. — Martin Gidron
The bill, which would go into effect Jan. 1, 2010, applies to MRIs, CTs, positron emission tomography and other radiology services the HHS secretary deems appropriate. The bill was referred to the Senate Finance Committee.

In citing the need for such an amendment, Grassley mentioned the Government Accountability Office’s (GAO) June report on Medicare that found Part B spending for imaging services more than doubled in six years, growing from nearly $7 billion in 2000 to more than $14 billion in 2006.

The GAO linked that growth, in part, to physician offices providing imaging services (D&DL, July 28). “During this time, the percentage of Medicare spending on imaging services provided in physician offices grew from 58 percent (about $4 billion) in 2000 to 64 percent (about $9 billion) in 2006,” Grassley said.

The war on imaging costs is playing out on other fronts too. Last week, America’s Health Insurance Plans (AHIP) released a white paper, “Ensuring Quality through Appropriate Use of Diagnostic Imaging.” The insurance group says private payers, such as WellPoint and Magellan, increasingly are rejecting imaging procedures recommended by physicians. Instead, they are turning to radiology benefit managers (RBMs) to reject scans they deem unnecessary.

Neither Grassley’s efforts nor the insurance companies’ action are enough to halt the growth, Jean Mitchell, professor of public policy at Georgetown University, argues.

Mitchell criticized Grassley’s bill for not having any teeth. “Disclosure itself is not going to do anything but make things more transparent. But whether it’s going to reduce utilization? I don’t think so,” she told D&DL.

And RBMs will only help control the increases in utilization, especially those that involve privileging, she added.

If Congress were to end self-referral all together, manufacturers of lower-end imaging equipment would feel an impact, Mitchell said, estimating that demand for imaging would fall by around 30 percent. But, she added, the demand for high-end equipment would increase because the need for radiologists would rise.

“One way or another, they need to deal with utilization. And if this is accomplished by reimbursement cuts, it will reduce the demand for imaging equipment as well,” Mitchell said. “[It is] much better to address [the] self-referral issue directly.”

Grassley’s office did not return calls for comment.

S. 3343 is available at thomas.loc.gov/cgi-bin/query/z?c110:s.3343:. The AHIP white paper can be accessed at www.ahip.org/content/default.aspx?docid=24057. — Renee Frojo, Mari Serebrov

NICE Denies Cordis Appeal on Drug-Eluting Stents

A UK National Institute for Health and Clinical Excellence (NICE) panel has denied an appeal from Cordis, a unit of Johnson & Johnson (J&J) Medical Ltd., regarding reimbursement for drug-eluting stents used to treat coronary artery disease.

NICE issued a guidance in February recommending drug-eluting stents as a “possible treatment” for coronary artery disease patients — if two conditions are met:

- The artery to be treated is less than 3 mm in diameter or the affected section of the artery is longer than 15 mm — conditions that indicate a patient is at high risk of requiring further interventions if a conventional bare-metal stent is used; and
- The additional cost of a drug-eluting stent over a bare-metal stent is no more than $600 (D&DL, Feb. 4).

Cordis appealed the guidance, arguing that NICE was seeking to fix or control the price of

(See NICE, Page 4)
Justice Investigating Biliary Stent Sales, Marketing Practices

The Justice Department has subpoenaed Abbott Laboratories, seeking information about its biliary stent product sales and marketing activities, the company says in a recent SEC filing.

The agency notified the company in June that it is investigating whether Abbott violated civil or criminal laws in connection with Medicare or Medicaid reimbursement paid to third parties. Justice is focusing specifically on the Federal False Claims Act, the Food and Drug Cosmetic Act and the Anti-Kickback Statute, according to the filing.

Abbott had no comment other than to say it was cooperating with the investigation.

The FDA met with Abbott, Boston Scientific, Johnson & Johnson and other companies in March 2007 to discuss curbing off-label promotion of biliary stents. The FDA said it was aware that the devices were being promoted and used to open arteries in the vascular system — a use that has not been approved (*D&DL*, March 26, 2007).

In its annual report issued in February, Boston Scientific said it was informed last December that Justice was conducting a civil investigation “of allegations that we and other suppliers improperly promoted biliary stents for off-label uses.”

Boston Scientific spokesman Paul Donovan told *D&DL* last week that the company is continuing to cooperate with the investigation.

Carol Goodrich, spokeswoman for Cordis, a unit of Johnson & Johnson, declined to comment on the issue.

Biliary stents are inserted into bile ducts to treat obstructions. According to Abbott’s website, the company markets six biliary stents and stent systems. — Elizabeth Collins

---

NICE, from Page 3

the stents or to establish procurement policy for the UK’s National Health Service (NHS). It cited evidence that drug-eluting stents are cost-effective at price premiums up to roughly $800–$900 over the cost of bare-metal stents, saying this should be reflected in the guidance.

The appeals panel released its decision late last month. At about the same time, NICE re-released its final guidance, confirming the criteria it set forth in the February guidance.

“We’re disappointed that NICE’s appeal panel did not uphold our appeal, and we’re in the process of evaluating our options regarding the appeal panel’s ruling,” Christopher Allman, J&J spokesman, told *D&DL*. According to NICE, J&J could challenge the decision by applying to the High Court for permission to apply for judicial review.

NICE’s final guidance on drug-eluting stents reverses its position in a 2007 draft guidance. It had recommended against all reimbursement for the devices in the UK, and analysts were concerned that its action might set a precedent for other European countries (*D&DL*, Sept. 3, 2007).

At the time, an independent committee concluded drug-eluting stents were not cost-effective. However, the committee solicited comments on the draft and considered evidence of their effectiveness. NICE Chief Executive Andrew Dillon said the final guidance was “the result of careful consideration of the evidence, as well as comments received during consultation and further economic modeling.”

Daniel Beach, Medtronic spokesman, told *D&DL* the new guidance “is excellent news” for patients in the UK who otherwise would not have received drug-eluting stents.


— Elizabeth Collins
Report: New Reactors Needed For Medical Isotopes

To minimize disruptions in medical imaging, the Atomic Energy of Canada Limited’s (AECL) National Research Universal (NRU) nuclear reactor needs to be replaced, according to a group of specialists convened by Health Canada.

Their report, released by the Canadian health minister last week, recommends exploring opportunities to bring new nuclear reactors online to produce medical isotopes, which are used with positron emission tomography and single photon emission CT machines. They also are used in cardiac stress tests.

The NRU reactor, which is more than 50 years old, produces roughly half of the global medical isotope supply. When it was shut down for almost a month last year due to a maintenance issue, the impact was significant.

As a result of that outage, AECL and the Canadian Nuclear Safety Commission (CNSC) contracted with Talisman International to conduct an independent review of the reactor. They announced last week that they had accepted 15 recommendations detailed in that review, all of which are aimed at preventing similar situations in the future.

One of the recommendations is that CNSC and AECL develop a formal process to quickly determine whether, and under what conditions, continued operation of the NRU reactor may be justified “during off-normal conditions.”

“To address the review team’s findings and recommendations, CNSC has put a corrective action plan in place with aggressive timelines,” Michael Binder, CNSC president, said.

AECL President and CEO Hugh MacDiarmid said he personally would oversee implementation of the changes.

AECL issued a statement in May announcing the immediate discontinuation of the MAPLE project, which included building two new nuclear reactors and a processing facility. In that statement, AECL said the decision would not affect the medical isotope supply as the NRU’s operating site license is authorized through October 2011. It pledged to work with the CNSC and MDS, an Ontario-based company that processes medical isotopes, to ensure continued isotope production beyond 2011 (D&DL, July 21).


Expert: Knowing FDA Import Policy Eases Border Process

If a device manufacturer encounters problems at the U.S. border, it can reduce the likelihood of a full-blown product detention by understanding the FDA’s import policy and knowing how to work with U.S. customs personnel, a former FDA attorney says.

“There is often more than one way to skin a cat,” Benjamin England, founder of Benjamin L. England & Associates, said at an FDAnews audioconference.

Firms attempting to import healthcare products into the U.S. may have entry denied because they fail to provide data the FDA has no legal authority to demand. “It happens far more often than people realize,” England said.

The FDA’s refusal authority stems from 21 USC 381, which gives it the right to refuse products that appear on examination of samples “or otherwise” to be un­sanitary, adulterated, misbranded, or forbidden or restricted for sale in the country of origin.

The appearance standard can be a fairly low level of evidence, England said, as Congress gave the FDA discretion to determine what

(See Import Hold, Page 7)
Harmonization Task Force Finalizes STED Guidance

Designed to create a technical snapshot of a device at a given stage in its life cycle, a new guidance is a key piece of the Global Harmonization Task Force’s (GHTF) effort to develop a global regulatory model.

Recently released by GHTF’s Study Group 1, the final guidance instructs manufacturers on preparing summary technical documentation (STED) to demonstrate that a device conforms to the essential principles of safety and performance. It explains how to cull the most relevant information from the full documentation of a device so the manufacturer can effectively satisfy the demands of regulators in markets that require evidence of manufacturing and production processes.

How extensive the STED is depends on the complexity and classification of the device — whether it involves a new technology, represents a new use for an existing device, is new to the manufacturer, incorporates new or potentially hazardous materials or is associated with a high incidence of adverse events or public health risks, the guidance says.

The technical documentation needs to include summary information on certain topics, detailed information on other specified topics and an essential principles (EP) checklist. “The information provided may include, for example, abstracts, high level summaries, or existing controlled documents, as appropriate, sufficient to communicate key relevant information and allow a reviewer to understand the subject,” the guidance says.

In general, the STED should contain:

- Device description and product specification, including variants and accessories;
- Labeling;
- Design and manufacturing information;
- EP checklist;
- Risk analysis and control summary;
- Product verification and validation;
- Format of the STED; and
- Declaration of conformity.

“The use of the STED should reduce costs for the manufacturer and reviewer, remove barriers to trade and facilitate timely international access to medical devices,” the GHTF says. Harmonizing documentation requirements across jurisdictions will reduce compliance costs and hasten patient access to new technologies and treatments, it adds.

The guidance describes differences in the use of the STED in premarket and postmarket phases and its role in notifying authorities of proposed changes to a device.

“Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)” can be accessed at www.ghtf.org/documents/sg1/sg1final-n11.pdf. — Meg Bryant
Import Hold, from Page 5

amounts to an appearance of a violation. The “or otherwise” clause is even more nebulous and hard to pin down, he added. It can be based on examination of prior shipments, adverse events associated with the product in the U.S. or foreign markets, or the prior compliance history of the product, foreign manufacturer, exporter, importer or geographic region or country of origin.

Having a product subjected to FDA import screening can result in several possible actions: a request for documentation, request for sampling and examination notice, detention recommendation or “may proceed” notice.

According to England, FDA-regulated imports increased by about 272 percent to roughly 8 million commercial lines of entry from 1991–2000. By 2007, the agency had jurisdiction over 17 million lines of entry, he said, noting that the number has been doubling every five years and is not expected to stabilize.

The FDA physically examines only about 0.7 percent of foreign products arriving at U.S. borders, a figure England said is somewhat deceptive because the agency employs a risk-based approach determined by the type of product. “I can tell you the FDA inspects zero percent of plastic forks,” he said. Many refusals are made without the product being inspected.

Most of the import program is based on guidance. Many of the procedures the FDA follows are unpublished, making it hard for firms to find out about them. “There are no clear stated procedures regarding a myriad of issues importers and exporters encounter with FDA,” England said. Since there are variations in the ways different FDA district offices process imports, it is “like having a dozen FDAs to deal with,” he added.

England offered advice on eight critical stages of border entry:

- Review stage. “Find out what they [the FDA] like to see and give it to them. ... The goal is to convert a conditional customs release to an unconditional release.”
- Correspondence stage. Firms must be ready with copies of supplier filings, batch certifications, notification and affirmation of compliance codes and “have all proof of accurate identifiers available.”
- Sample/exam stage. Firms need to hold the product until a release is given. The “FDA will sample the largest lot number in the shipment and extend the results to other lots. ... That’s the ‘or otherwise.’”
- Detention stage. “Remember a detention is not a final action. The FDA is often wrong.” Firms should provide the requested data as soon as possible. If it is in FDA databases, the fact that a company cannot get it is not an actual violation of the law.
- Reconditioning stage. Simple reconditioning or relabeling may suffice to bring a detained product into compliance.
- Refusal stage. This is usually final, so firms should immediately appeal to the supervisor of the individual who made the decision.
- Redelivery stage. Usually exportation or destruction of refused goods is required within 90 days of refusal. However, by seeking a rescission of the refusal, firms may be able to stop the clock.
- Liquidated damages stage. Firms that fail to redeliver refused goods face liquidated damages at three times the invoice value. This is the time to present an argument against the FDA to customs officials.

Even if the FDA releases a product, customs can demand redelivery for 30 days, England said. This usually occurs when the agency can show that information it relied upon to issue the release was somehow flawed.

At each stage, firms can benefit from face-to-face encounters with compliance officers and their supervisors. “Meet with them when things are going well, too. Don’t be a stranger,” England said, noting that discussing a firm’s internal compliance or how it verifies data and qualifies vendors may prove useful in obtaining releases later. — Meg Bryant
Ontario to Expand Diabetes Initiative

Ontario’s Ministry of Health and Long-Term Care will invest $741 million in a healthcare initiative that includes improving access to insulin pumps for adults with Type 1 diabetes.

The Ontario government launched a program two years ago to provide insulin pump therapy for diabetics younger than 18 who met certain clinical criteria. The government says it is extending that program to fund insulin pumps and supplies for adults with Type 1 diabetes who meet the criteria, beginning in September.

Roughly 1,700 children are helped by Ministry-funded insulin pump therapy; the inclusion of adults will add approximately 1,300 patients to the program.

Animas, a unit of Johnson & Johnson, has provided insulin pumps for the pediatric program and will provide Animus 2020 insulin pumps under the new program for adults, Melissa Katz, Animas spokeswoman, told D&DL.

Katz and Medtronic spokesman Chuck Grothaus praised the government of Ontario for its leadership in increasing access to the devices.

Expansion of the program to include adults “is very positive news for those who can benefit from insulin pump technology,” Grothaus said.

In the next 18–24 months, Ontario’s Insulin Pump and Supplies for Adults Expert Panel plans to review medical literature and consider further expanding the program to adults with Type 2 diabetes.

In addition to insulin pumps, the new program will include:

● Expansion of chronic kidney disease services, including dialysis and home renal replacement therapies;
● A $75 million initiative to increase Ontario’s capacity for bariatric surgery; and
● An online registry with information for patients and access to patient records for healthcare providers. — Elizabeth Collins

Doing Business in the EU: A Life Sciences Summit
Complying with Pharma and Device Regulations
Sept. 22–23, 2008 • Hilton Arlington, Arlington, VA
Presented by FDAnews in conjunction with Squire, Sanders & Dempsey, L.L.P.

Every drug and device manufacturer who wants to operate in the European Union (EU) — or is looking to expand — needs to understand the EU regulatory environment to avoid unnecessary scrutiny, product delays or financial penalties that could sink their companies.

Discover what you need to do to navigate the nuances of the EU market with guidance from those who have been there and succeeded. At Doing Business in the EU: A Life Sciences Summit, industry experts from both the EU and the U.S. will reveal what they’ve learned from years of working in the trenches every day. No other conference will give you the knowledge you need to prepare for challenging EU legal, regulatory and compliance requirements — get your game plan here.

Register online at: www.eusummit08.com
Or call toll free: (888) 838-5578 (inside the U.S.) or +1 (703) 538-7600
Website Promotion Draws Warning Letter

Carematix’s website promotion of its recently cleared wellness system attracted a warning letter and an FDA request that it immediately cease such marketing efforts.

The company’s website claimed the “Carematix Wellness System is intended for use in diagnosing asthma ‘using a peak expiratory flow meter,’ diagnosing chronic obstructive pulmonary disease using a spirometer, and monitoring forced expiratory flow in clinical trials,” the warning letter says.

But when the FDA cleared the system’s 510(k) in January, it did not clear it for spirometry or peak flow measurement. The agency says promoting the device for use with a peak flow meter or spirometer to measure peak expiratory flow rate (PEFR) or forced expiratory volume (FEV) “is a significant change in intended use that requires submission of a new 510(k).”

The FDA asks the company to “immediately cease marketing the Carematix wellness system for use in conjunction with a spirometer or peak flow meter to measure PEFR and FEV, or for use in the diagnosis or treatment of any diseases or conditions related to such measurements.”

As a result of a March inspection, the letter also cites several good manufacturing practice violations, including 50 corrective and preventive action (CAPA) reports filed between last August and February that remain open even though the action plan due date for some of the reports had passed.

One CAPA report indicated there are no records of review performed for Carematix’s suppliers.

The company also was cited for failure to investigate or close 24 complaints submitted last year. The FDA says each complaint required investigation, but Carematix had failed to investigate or close any of them by the March inspection.

In its response, Carematix said it has closed every complaint and proposed rewriting its CAPA procedure and retraining employees.

Since the company had not completed these actions or provided documentation of their completion, the FDA deemed its response inadequate.

The July 3 warning letter was posted recently to the FDA's website and is available at www.fda.gov/foi/warning_letters/s6858c.pdf.

— Renee Frojo

<table>
<thead>
<tr>
<th>Company</th>
<th>Number</th>
<th>Product</th>
<th>Reason for Recall or Correction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class I</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Levitronix</td>
<td>867</td>
<td>CentriMag primary system; CentriMag back-up console</td>
<td>Stops pumping</td>
</tr>
<tr>
<td>Class II</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biomet</td>
<td>12</td>
<td>Vanguard DCM CR tibial bearings</td>
<td>Mislabeled packaging</td>
</tr>
<tr>
<td>Medline</td>
<td>6,453</td>
<td>EndurO2 oxygen concentrators</td>
<td>Component overheating</td>
</tr>
<tr>
<td>Abbott</td>
<td>882</td>
<td>AxSYM Ultrasensitive hTSH II Master Calibrators; microparticle enzyme immunoassay</td>
<td>High control value out of range</td>
</tr>
<tr>
<td>Stryker Howmedica Osteonics</td>
<td>106</td>
<td>Triathlon TS femoral trials</td>
<td>Sharp edges</td>
</tr>
<tr>
<td>Medtronic</td>
<td>844</td>
<td>Affinity NT hollow fiber oxygenator; extracorporeal circuit; Affinity pediatric; arterial filter; Affinity NT hollow fiber oxygenator; venous cannula; malleable single stage venous cannula; arterial cannula straight beveled tip; Select 3D &amp; Select CAP arterial cannulae; arterial cannula curved beveled tip; Bio-Medicus femoral cannula/Introducer; Bio-Medicus percutaneous cannula &amp; introducer set; catheter, cannula &amp; tubing for vascular cardiopulmonary bypass</td>
<td>Manufactured with contaminated heparin</td>
</tr>
<tr>
<td>Medtronic</td>
<td>59,500</td>
<td>Trillium Affinity NT, 511T, hollow fiber oxygenator with Trillium biopassive surface with plasma resistant fiber</td>
<td>Manufactured with contaminated heparin</td>
</tr>
<tr>
<td>Beckman Coulter</td>
<td>501</td>
<td>Cytomics FC 500 flow cytometry systems</td>
<td>Incorrect display</td>
</tr>
<tr>
<td>Class III</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hitachi</td>
<td>20</td>
<td>EUB-5500 Vision 5500 diagnostic ultrasound scanner</td>
<td>Miscalculation reading</td>
</tr>
</tbody>
</table>

The full enforcement report for July 30 can be seen at www.fda.gov/bbs/topics/ENFORCE/2008/ENF01066.html.
Older Eye Treatment More Effective?

A new drug therapy used to treat abnormal swelling in the eye — a condition called diabetic macular edema — proved less effective than traditional laser treatments in a study funded by the NIH’s National Eye Institute.

Between 40 percent and 45 percent of the 18 million Americans diagnosed with diabetes have vision problems, such as diabetic macular edema, which can cause blindness. The study demonstrates that laser therapy is not only more effective than corticosteroids in the long-term treatment of diabetic macular edema but also has fewer side effects, the NIH said.

In the study, nearly 700 patients with diabetic macular edema were randomly assigned to corticosteroid or traditional laser treatment. Of the corticosteroid-treated group, 51 percent required cataract surgery compared with 13 percent of those in the laser-treated group.

Additionally, 28 percent experienced substantial vision loss in the corticosteroid-treated group as compared with 19 percent in the laser-treated group. About one-third of the eyes treated with laser therapy showed substantial improvement in vision.

FDA Launches Fellowship Program

To attract more scientific talent to the FDA, the agency is launching a two-year fellowship program designed to train scientists and engineers on the scientific foundations of its regulatory actions.

The program will start in October, and the agency is considering applicants for 30–40 slots in the first entering class. Applicants must have a doctoral degree in medicine or another scientific field or at least a bachelor’s degree for engineering positions.

“The FDA Commissioner’s Fellowship Program is designed to attract these people to the FDA and provide them with in-depth knowledge of the science that underpins regulatory decisions as we meet the challenges of both globalization and rapid changes in science and technology,” Frank Torti, principal deputy commissioner and chief scientist, said.

RF Surgical Systems Raises $12 Million

RF Surgical Systems has raised $8.2 million with financing from Menlo Ventures and Stanford University. Combined with other private investments, the company has raised more than $12 million this year.

The company will use the new capital to expand its RF Surgical detection system into acute-care hospitals in the U.S.

The system, which has both FDA approval and CE Marking, scans a body to detect whether surgical sponges, gauze or towels remain in a patient, the company said.

FDA Clears Cardiac Probe

ImaCor has received 510(k) clearance from the FDA to market its ClariTEE probe, a miniaturized transesophageal echocardiography probe used for monitoring cardiac function.

Designed for use in intensive care units, the minimally invasive device allows physicians to see cardiac size and function and assess changes as pharmacologic interventions are made, ImaCor said.

The single-use device can remain in a patient for up to 72 hours, allowing assessments of the preload and left ventricular systolic function over time.