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DRAFT REUSE PLAN WOULD LET FDA REVIEW CURRENTLY EXEMPT DEVICES

Draft device reprocessing legislation obtained by *FDA Week* would impose more stringent requirements for certain class I devices, along with some devices that currently are exempt from FDA review. The plan, which was hammered out by lawmakers and industry, would use sterility criteria for determining what devices need additional data.

[The draft legislation is available on *InsideHealthPolicy.com*; see page 5 for details.]

FDA has 18 months to publish a list of devices that will no longer be exempted from 510 (k) review. Once

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Third-party expanded reviews of devices off bargaining table
DEVICE USER FEE MARK-UP DELAYED TO WORK ON THIRD-PARTY INSPECTIONS

A key House committee this week postponed its mark-up of medical device user fee/reform legislation because Democrats were concerned the third-party-inspection provision could lead to a gradual decline in FDA's inspector cadre as private companies take over, according to congressional and consumer advocate sources. Republican and Democratic staffers for the House Energy and Commerce Committee are ironing out the wrinkles in the "maintenance of effort" clause, which ensures that FDA does not have to lay off employees when the

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McCLELLAN MAY BE FIRST FDA COMMISSIONER WITH ECONOMICS DOCTORATE

If confirmed by the Senate as FDA Commissioner, Mark McClellan — a member of the White House Council for Economic Advisors and a senior health advisor for the administration — would be the first FDA commissioner to hold a doctorate in economics, according to sources.

Rumors have been circulating since earlier this summer that the White House would tap McClellan for the top FDA slot. Back in July a biotechnology industry representative said during a two-day investor meeting in New York sponsored by the Biotechnology Industry Organization (BIO) that McClellan would be named imminently.

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DOJ says appeals ruling would diminish FDA's power to regulate drugs
DOJ, CTFA, GMA, PhRMA ASK CA SUPREME COURT TO REVIEW PROP. 65 RULING

The Department of Justice (DOJ), the California Medical Association and trade associations representing the food, cosmetic, brand-name and over-the-counter (OTC) drug industries are urging the California Supreme Court to review an appeals court finding that FDA's required labeling for OTC smoking-cessation products does not preempt warnings required under California state law Proposition 65. DOJ argues that if the appeals decision were allowed to stand, then it would diminish the agency's power to regulate drugs.

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Despite lack of industry consensus
HOUSE COMMITTEE DEM, GOP NEGOTIATORS AGREE ON DEVICE USER FEE PLAN

Key House Republicans and Democrats have agreed on the user-fee portion of medical device reform legislation even though a group representing small device manufacturers is still not on board, according to a congressional source. The two-tiered user fee plan defines small companies as those with annual revenue less than $10 million and allows FDA to collect user fees during the first three years even if Congress underfunds FDA's device center, congressional and industry sources say. The Medical Device Manufacturers Association (MDMA) still has

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major concerns with the language.

Despite the user-fee agreement, the House Energy and Commerce Committee this week postponed its mark-up of the device user-fee/reform legislation to address a technical issue with the third-party inspection provision and to consider device safety amendments (see related stories). Congressional staffers involved in the negotiations also have agreed to the device reprocessing portion of the legislative package.

[The device reprocessing language is available on *InsideHealthPolicy.com*; see page 5 for details.]

A spokesperson for the device industry's largest trade group, the Advanced Medical Technology Association (AdvaMed), says the group has agreed to the plan. The spokesperson declined to comment further on the legislation, saying he was not aware of details other than what he has read in the press.

An MDMA source says the group did not agree to the language floated during the last negotiating session. The source adds that the group thought there would be additional negotiations before the mark-up was scheduled.

A congressional source says the limitations clause, or trigger, allows FDA to collect user fees until the third year of the program, even if Congress does not meet the appropriations goals – $15 million the first year adjusted for inflation in following years.

Industry would pay $25 million the first year, adjusted for inflation in following years. FDA would increase the amount of fees retrospectively if the agency received fewer applications than expected to meet the $25 million commitment, according to an industry source.

It is unlikely that Congress will appropriate $15 million for fiscal year 2003 because of this year's likely lame duck appropriations session, according to congressional and industry sources. It is possible that Congress will hit the target for FY 04, but lawmakers need an extra year to make up the difference from the FY 03 shortfall, the congressional source says.

If Congress does not meet the appropriations goal by the third year of the program, the source says, user fees would be renegotiated with industry. If Congress fails in the fourth year, the user-fee program would be canceled.

However, some industry sources who have seen recent draft legislation say the plan would not sunset the program. They say staffers may still be tweaking the user-fee provision.

The limitations clause had been a bone of contention since the beginning of negotiations. MDMA threatened early on to oppose any bill allowing FDA to collect user fees without ensuring that Congress gives the agency appropriate funding.

FDA and AdvaMed, the device industry's largest trade group, struck a deal last May allowing the agency to collect fees irrespective of congressional appropriations. The agreement also would not require FDA to meet performance goals during the first two years. FDA negotiators have said they would accept language stating that FDA is not required to meet "all" of the goals, instead of current language stating that FDA is not required to meet "any" of the goals, according to an industry source. This could allow FDA to say that it has agreed to meet some of the goals during the first two years. However, FDA negotiators would not commit to what goals or what percentage of the goals it would meet, the source says.

[The original AdvaMed/FDA agreement is available on *InsideHealthPolicy.com*; see page 5 for details.]

FDA negotiators say the agency cannot meet the performance goals without full funding from both industry and Congress, according an industry source, so it is unlikely the agency will meet its goals in the first two years.

Sources say the aggregate funding goal of $40 million in the first year for device review activities has not changed.

An industry source points out that the user fees will have to be adjusted if the program is not authorized soon. The plan is based on the program starting in October, and a late start would mean that funding would fall short.

HOST OF SAFETY PROVISIONS CONSIDERED IN DEVICE REFORM/USER-FEE BILL

House lawmakers working on device reform/user-fee legislation are including provisions to increase the safety of devices in children and to require that consumer and patient groups be included during negotiations of the program's reauthorization, according to congressional and consumer advocate sources. Report language accompanying the bill directs FDA to use a substantial portion of industry's fees toward postmarket surveillance. Additionally, Reps. Roy Blunt (R-MO) and Gene Green (D-TX) are pushing an amendment that would strengthen the informed consent process for device implants.

It is unclear what percentage of the user fees Congress intends for FDA to use on postmarket safety activities.

The legislation would require that companies follow through on postmarket studies. The FDA Modernization Act already includes such a provision for drugs and biologics, but it does not mention medical devices. Some have charged that this provision is ineffective because there is no punishment for firms that do not fulfill their post marketing commitments.

At the last minute Blunt and Green requested that the provision be included in the legislation, which some say was part of the reason the mark-up of the legislation by the House Energy and Commerce Committee was cancelled

on Wednesday. Staffers met yesterday (Sept. 26) to negotiate the provision, according to a congressional source. Another congressional source says the legislative package does not depend on the Blunt-Green amendment. The mark-up is expected to be rescheduled for next week.

The Blunt-Green amendment is based on the lawmakers' breast implant bill, H.R. 1961. The lawmakers would like to extend the ideas in that bill to all implanted devices. The amendment would establish for implanted devices a program similar to the Medguide system that FDA uses for prescription drugs, according to congressional and consumer sources. FDA would be responsible for listing the risks and benefits of the device in plain English in a consumer guide, and physicians would be required to inform patients of these risks and benefits at the initial consultation. A consumer advocate says there have been cases of patients being handed consent forms to sign after being prepped for surgery, and in some cases the patient already is under the effects of drugs on the way to the operating room.

The amendment also calls for postmarket surveillance, but a congressional source says a sticking point is figuring out how to pay for it.

Some House lawmakers also would like the bill to require that pediatric experts be included on advisory committees reviewing devices that reasonably could be expected to be used in children. This provision also would require the Institute of Medicine to study the long-term safety of implanted devices.

Frist asked Kennedy to delay introducing bill

KENNEDY WILL SOON INTRODUCE BILL ON MEDICAL ERROR REPORTING

Senate health committee chairman Edward Kennedy (D-MA) was set to introduce medical error reporting legislation earlier this week when GOP committee members convinced him to hold off in order to pursue a bipartisan agreement. Kennedy's draft bill closely mirrors the legislation that was passed out of the House Ways and Means Committee last week, according to congressional sources.

Kennedy and GOP senators in the Senate health committee have been unable to reach an agreement on the scope of liability protection that would be given to health care providers reporting medical errors. Another contentious issue both sides cannot agree on is whether federal law would preempt state laws. Kennedy, sources say, would like a bill that clarifies that no state laws will be preempted.

The Ways and Means bill was revised by chairman Bill Thomas (R-CA) prior to mark-up, last week (Sept. 18) to appease committee Democrats. The bill passed the committee with bipartisan support (see *FDA Week*, Sept. 20, p3).

While Kennedy's bill would amend the Public Health Service Act, the Ways and Means bill is written to modify the Social Security Act. Also, Kennedy's bill would provide numerous grant programs for hospitals, pharmacies and state health agencies, a congressional source says.

Meanwhile, the House Energy and Commerce Committee this week passed its own version of medical error reporting legislation (see related story).

[The House Ways and Means Committee and Energy and Commerce Committee bills are available on *InsideHealthPolicy.com*; see page 5 for details.]

Earlier this year Sens. Bill Frist (R-TN) and James Jeffords (I-VT) were trying to get Kennedy to support their own bill on medical error reporting. Their bill on patient safety would create incentives for voluntary reporting systems that are non-punitive and that promote learning, according to the bill summary. The bill would recognize the Agency for Healthcare Research and Quality (AHRQ) as the leader in patient safety for funding research and for dissemination of information gathered about improving patient safety (see *FDA Week*, May 31, p13).

At the time, Kennedy refused to support the Frist-Jeffords bill on the grounds that it would provide broad legal protections to health care providers reporting medical errors to patient safety organizations.

HOUSE ENERGY AND COMMERCE PANEL PASSES TAUZIN'S MEDICAL ERROR BILL

The House Energy and Commerce Committee this week overwhelmingly passed chairman Billy Tauzin's (R-LA) bill on medical error reporting, which among other things calls for bar-coding of drugs and biologics.

The bill would also place a lower limit on the level of civil monetary penalties that could be slapped on providers for retributive action against reporters of medical errors in comparison to a similar medical errors bill passed by the Ways and Means Committee last week (see *FDA Week*, Sept. 25, p3).

The two committees share jurisdiction over the issue and are seen as engaging in a turf battle with their competing bills.

[Both bills are available on *InsideHealthPolicy.com*; see page 5 for details.]

Tauzin's bill, according to some congressional sources, offers a clearer, better definition of how the Health Insurance Portability and Accountability Act (HIPAA) applies to the new national patient safety database that the

legislation would create. Sources from both committees claim, in turn, that their bill offers the "clearer" version.

Tauzin's bill, like the bill passed by the Ways and Means Committee last week and the bill introduced by Sens. Bill Frist (R-TN) and James Jeffords (I-VT) in May, aims to create patient safety organizations that would collect and analyze reports of medical errors from health care providers and come up with recommendations to avoid such errors in the future. Sen. Edward Kennedy (D-MA) is also working on a bill to reduce medical errors (see related story)

The House Ways and Means Committee passed its version of the medical error reporting bill last Wednesday (Sept. 18), which Democrats on the panel said took care of most of their concerns with the subcommittee-passed version of the bill. The bill amended by Ways and Means Committee chair Bill Thomas (R-CA) included revisions to appease committee Democrats.

Rep. Pete Stark (D-CA), ranking member of the Ways and Means health subcommittee, warned last week that the bill being marked up by the committee reflects a "tenuous and delicately crafted compromise." He stressed that members would have "to pull together" to keep the agreement that had been worked out "from being eroded by other committees who share jurisdiction" (see *FDA Week*, Sept. 20, p3).

Reps. John Dingell (D-MI) and Sherrod Brown (D-OH) are cosponsors of Tauzin's bill, and there will be more Democratic cosponsors, according to congressional sources. The bill had not been introduced at the time of the mark-up and the committee passed it by voice vote. At press time, congressional sources said GOP staffers were still in the process of signing on more Democrats, and the bill had not yet been introduced.

Tauzin's bill is written into the Public Health Service Act, while the Ways and Means bill would modify the Social Security Act. Both bills aim to create incentives for health care providers to report medical errors to Patient Safety Organizations (PSO) in an effort to collect information that would better patient safety. Both bills state that these PSOs would have to be certified by the HHS secretary.

The Ways and Means bill would ask the General Accounting Office (GAO) to conduct an evaluation of the system, and as part of the evaluation to conduct a survey looking at whether healthcare providers have adopted error reduction methods.

Tauzin's bill, on the other hand, would require that the HHS secretary prepare a draft report within 18 months after the national patient safety database is operational on the strategies for reducing medical errors and increasing patient safety, and on the appropriate use of these strategies.

Tauzin's bill also includes protection for the reporter of medical errors against retribution by the health care provider. The bill clarifies that no adverse employment action may be taken against the reporter and provides a civil monetary penalty of not more than $20,000 for each violation by the provider.

The Ways and Means bill provides civil monetary penalties of up to $50,000 per violation by health care providers, while at the same time providing an appeals process for providers.

The revised Ways and Means bill clarifies that patient safety data is not considered protected information in criminal procedures, according to a bill summary (see *FDA Week*, Sept. 13, p1).

Tauzin's bill clarifies that the patient safety work product "shall not be – subject to a civil or administrative subpoena or order; subject to discovery in connection with a civil or administrative proceeding." It says the information given to a PSO is therefore confidential. The bill does not mention confidentiality under criminal proceedings.

Tauzin's measure also contains a provision on required use of product identification technology. It would amend the Food, Drug and Cosmetic Act to require that a drug or a biologic products packaging should include a unique product identifier. In its press release, a prominent hospital group, Premier, says the bill includes Premier-advocated language stipulating the required use of bar code or "product identification" technology at all levels of packaging. The statement says that Premier has championed industry adoption of the Universal Product Number (UPN) bar code and the requisite scanning technology for a long time.

[Premier's statement is available on *InsideHealthPolicy.com*; see page 5 for details.]

The bill also calls for two grant programs not included in the Ways and Means bill. The grant programs are meant to encourage the use of electronic prescriptions by physicians and to help hospitals incorporate information technology in their daily work to reduce medical errors.

A separate amendment offered by Rep. Eliot Engel (D-NY) calls on the HHS secretary to ensure that when standards are developed for interoperability of information technology systems, their efficacy and usability should be tested in various clinical settings. For instance, it lists an urban academic medical center, a rural hospital and a community health center as examples.

New FDA Rules and Guidances

Guidance for Industry: Establishing Pregnancy Exposure Registries:

The guidance provides sponsors with guidance on how to establish pregnancy exposure registries to monitor the outcomes of pregnancies exposed to specific medical products.

Substitute pulls mandatory gluten declaration

SENATE PANEL PASSES WATERED-DOWN FOOD ALLERGEN LABELING BILL

This week the Senate health committee passed without objection a watered-down version of a bill that would require food processors to label the eight most common types of food allergens in plain English. The substitute version, unlike the underlying bill, would give food firms two options for labeling these allergens and would not require the declaration of gluten.

A congressional source says committee chairman Edward Kennedy (D-MA) hopes to see the Food Allergen Consumer Protection Act passed this year. Rep. Nita Lowey (D-NY), the cosponsor of the House companion bill to the original Senate bill, is expected to introduce legislation that would match the substitute bill passed by the Senate committee, according to the congressional source.

If the legislation were to pass, it would bring about the first changes to food labels since the Nutrition Labeling and Education Act was enacted in 1990, according to a press release issued by the Center for Science in the Public Interest (CSPI).

There are several differences between the original legislation, which was introduced by Kennedy, and the substitute passed out of committee, according to sources. The new version would give sponsors of products containing one of the eight food allergens two options on how they could label the ingredient. The eight allergens include peanut and tree nuts, egg, milk, Crustacean shellfish and fish, wheat and soy. The labels could either state that the ingredient contains one of the allergens, or could put the plain English name in parentheses.

The substitute deletes language in the original bill that specified the standardized font, color contrast, and upper-and-lower case that firms would have to use, according to the CSPI press release. The substitute strikes the requirement that labels include a telephone number consumers could call for information on ingredients, the congressional source says.

Under the substitute, firms would no longer be required to declare gluten, the congressional source explains.

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- FDA Study Finds Improvement In Safe Food Handling By Consumers
- FDA Releases Guidance On Establishing Pregnancy Exposure Registries To Monitor The Outcomes Of Pregnancies Exposed To Specific Medical Products
- CDC Releases Smallpox Vaccination Guidelines To Help State And Local Officials Vaccinate One Million People Within 10-Day Timeframe
- GPhA Calls On PhRMA To Immediately Halt Ad Campaign On Hatch-Waxman Reforms
- Sens. Kennedy, Clinton Question HHS Policy Moves On Advisory Committees
- PhRMA Fires Back At GPhA, Defends Its Ad On GAAP
- President Bush Announces His Intent To Nominate Mark McClellan As FDA Commissioner
- HHS Secretary Thompson Praises White House's Decision To Choose Mark McClellan As FDA Commissioner
- Draft Device-Reprocessing Bill Language Agreed To By House Negotiators And Industry
- Tauzin Applauds House For Passing Medical Liability Reform
- PhRMA Asks FDA To Clarify Stand On Transshipment Of Experimental Drugs
- DOJ, Industry Trade Associations, OTC Drugmakers Ask California Supreme Court To Hear Proposition 65 Case
- Dowhal Lawyers Want California Supreme Court To Refuse To Hear Proposition 65 Case
- Tauzin's Bill On Medical Error Reporting Sails Out Of House Energy And Commerce Committee
- Hospital Group Pleased That Its Language On Bar Coding For Drugs And Biologics Is Included In Marked-Up House Energy And Commerce Committee's Bill On Medical Errors

Instead, the bill stipulates that FDA must promulgate a regulation on qualifications a firm would have to meet in order to label a food "gluten-free." Also, the Institute of Medicine and FDA must do reports on celiac disease and gluten labeling.

The substitute drops the earlier version's call for civil monetary penalties. The substitute also pulls language that would have required FDA to promulgate good manufacturing practices (GMPs) regulations on how to reduce cross-contamination. Under the substitute, FDA must study and issue a report on cross contact and on labeling that says a food "may contain" allergens.

The new version significantly extends the amount of time firms have to comply with the legislation.

A source from CSPI, who helped craft the initial bill, says that while the group prefers the earlier bill it strongly supports the legislation passed by the committee and want to see it passed this year. Although provisions were dropped from the bill, there was nothing added to the bill that the group opposes. According to the source, in the process of negotiating Congress often adds something objectionable, but this was not the case here.

A source from the Grocery Manufacturers of America (GMA) says that while the substitute drops many of the provisions the group opposed, GMA still believes the legislation is unnecessary in light of industry's voluntary efforts. GMA recently completed a survey of its members that shows that 100 percent of those surveyed have at least started to put into place voluntary allergen guidelines developed by industry and a food allergen group called Food Allergy and Anaphylaxis.

The bill went through several iterations as Kennedy negotiated with Republican members of the committee, according to a congressional source. In August, *FDA Week* reported that Kennedy was floating a substitute in an effort to garner Republican support. Republicans had indicated that although the substitute offered at that time was a move in the right direction, it did not go far enough.

Negotiations continued and Sens. Judd Gregg (R-NH), Bill Frist (R-TN), Pat Roberts (R-KS) Hillary Clinton (D-NY) and Jack Reed (D-RI) reached agreement on the substitute that was subsequently passed by the committee.

DEVICE USER FEE MARK-UP PUSHED TO NEXT WEEK . . . begins on page one

agency's funding does not match salary increases.

Sources say the House Energy and Commerce Committee likely will reschedule the mark-up for sometime next week. The mark-up was originally scheduled for this Wednesday (Sept. 25).

An earlier plan to expand third-party reviews of devices has been dropped from the bill, according to a patient advocate. FDA already allows private companies to review certain 510(k) devices, but does not allow third-party reviews of premarket applications (PMAs).

Under the latest draft, FDA would have to inspect manufacturing facilities during the premarket approval process of a device, leaving the possibility of inspections by private companies for follow-up inspections only, according to a consumer advocate. The source says FDA would maintain a list of companies it approves for inspections, and device manufacturers would choose from this list and negotiate a price with the third-party. The source says this plan creates a conflict of interest and would prefer that FDA choose the company and name the price.

Both parties agree in concept to the maintenance-of-effort clause, according to a congressional source. The source says staffers must work out technical aspects such as the growth factor, but declined to give details. The concern is that when a budget remains flat and FDA gives salary increases or promotes employees, other employees could be laid off for lack of funding. This would mean that private companies would be doing a larger share of device plant inspections.

Sources say the mark-up also was postponed in part because staffers are considering new safety measures for devices used in children, and Rep. Roy Blunt (R-MO) intervened at the last minute to push for a device implant

SUBSCRIPTIONS:
703-416-8500 or
800-424-9068
custsvc@iwpnews.com

NEWS OFFICE:
703-416-8572
Fax: 703-416-8543
fdaweek@iwpnews.com

Health Group Publisher: Donna Haseley
Managing Editor: Jamie Wolszon
Associate Editors: John Wilkerson, Veena Menon
Production Manager: Lori Nicholson
Production Specialist: Daniel Arrieta

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safety provision – which is based on his interest in increasing safety of breast implants, sources say (see related story).

The maintenance-of-effort measure must be worked out before marking up the bill, the congressional source says. But the additional device safety amendments likely will not block the progress of the bill if staffers cannot agree on them.

It remains to be seen if Sen. Edward Kennedy (D-MA) will accept any form of third-party inspections. The chairman of the Senate Health Committee has said that he opposes allowing private companies to perform what he believes is a core function of the government.

However, Kennedy has been talking to industry representatives about aspects of the device reform/user-fee legislation, according to the senator's spokesperson. The spokesperson said third-party issues have yet to be worked out but declined to discuss the matter further.

The device reform negotiations have dealt with three main areas: user fees, third-party inspections and device reprocessing. Staffers have quit working on the user-fee provision, according to a congressional source, but some industry sources say there is interest in changing the definition of a small business.

Asking Thompson to rethink decision

SENS. BLAST PLAN TO DISBAND SUBJECT PROTECTION, GENETIC TEST PANELS

Two senior Democratic senators are taking HHS secretary Tommy Thompson to task over the abolishment and planned reconstitution of "key" scientific advisory committees covering human subject protection and genetic testing, and the "wholesale replacement" of members in some others. The senators are asking Thompson to "reconsider" his decision and provide Congress with a report on future plans for these advisory committees.

In a letter to Thompson, Sens. Edward Kennedy (D-MA) and Hillary Clinton (D-NY) are questioning the department's decision to dismiss the National Human Research Protections Advisory Committee (NHRPAC) and the Secretary's Advisory Committee on Genetic Testing (SACGT).

[The letter is available on *InsideHealthPolicy.com*; see page 5 for details.]

NHRPAC was advising FDA and HHS on issues regarding protection of human subjects in clinical trials. The letter states, "It is unimaginable…that the public could be well served by the dismissal of [NHRPAC] after the tragic deaths of patients involved in clinical trials."

Referring to the dismissal of SACGT, the letter states, "the public deserves assurances that the genetic tests now becoming available are safe."

The senators expressed their concern over the possibility that the changes are being made because of ideological conflicts the advisory panels have with the administration and that committee members are being replaced by people with close ties to the industry that the committees were engaged in studying.

Earlier this month *The Washington Post* reported that the Bush administration has begun restructuring HHS' scientific advisory committees. The article said that the administration was doing away with committees that were coming to conclusions not in tandem with the president's views and in other cases replacing the committee members with "handpicked choices."

Citing the HHS spokesperson's statement in the *Post* article, the senators say in their letter that while they are pleased that HHS aims to maintain unbiased advisory committees, the department's actions have been contrary to this goal.

The letter urges Thompson to reconsider the decisions on the advisory committees and appoint members who "serve the public interest," and not a particular ideology.

PhRMA ASKS FDA TO CLARIFY STAND ON EXPERIMENTAL DRUG TRANSSHIPMENT

The Pharmaceutical Research and Manufacturers of America (PhRMA) is asking FDA to clarify its position on transshipment of investigational drugs. The drug industry group says that while FDA's new proposed rule on export requirements for unapproved new drug products states that transshipment is prohibited, the rule also says investigational drugs can be sent to principal investigators in a "listed" country for use by them in an "unlisted" country. This is equivalent to acceptance of transshipment, the trade group states, and the rule is inconsistent.

In Sept. 17 comments submitted to FDA, PhRMA calls for a clarification of the discrepancy of the agency's interpretation of the FDA Export Reform and Enhancement Act of 1996 (FEREA). The group says that the agency's proposed rule is inconsistent on whether transshipment is allowed. An industry source says that the law does not allow transshipment.

[The PhRMA comments are available on *InsideHealthPolicy.com*; see page 5 for details.]

A listed country is one that is listed in the Drug Export Amendments Act of 1986. Unapproved drugs and biological products may be exported to any one of 21 countries listed in the act. These countries have premarket

approval systems comparable to FDA's. Transshipment refers to the practice of shipping a product to a country from which it will later be shipped to another country.

PhRMA comments state that once an investigational drug has been exported from a listed country, the investigator has limited control over drug movement, storage and utilization. The group states that the investigator, sponsor and patient are exposed to significant risks through the transshipment process.

The group asks that the agency prohibit transshipment of drugs from listed countries to unlisted countries. Exports of drugs from the United States to unlisted countries should be allowed, the comments state and, "FDA should work diligently to assess the regulatory system in unlisted countries, and add them following approval to the listed countries."

McCLELLAN HAS HAD FORMAL POLICY TRAINING . . . begins on page one

McClellan received an MA, M.P.A. in regulatory policy from Harvard University in 1991. McClellan obtained his MD in 1992 from Harvard-Massachusetts Institute of Technology (MIT) Division of Health Science and Technology and his Ph.D. in economics from MIT in 1993.

Although there have been FDA commissioners with Ph.D.s, there has never been a commissioner with a Ph.D. in economics, according to a food and drug lawyer, an agency source and a drug consultant. For instance, points out the agency source, Donald Kennedy, who was FDA commissioner from 1977 to 1979, had a Ph.D. in biology.

The drug consultant says that Bush's choice of someone with a background in both medicine and economics signals that the administration wants the FDA commissioner to focus more on economic issues.

The Bush administration, according to the drug consultant, wants FDA to work more closely with the Centers for Medicare and Medicaid Services, and to provide companies some regulatory relief.

But an FDA source points out that the agency does not have jurisdiction over pricing issues. FDA approves drugs based on whether they are safe and effective, not on whether they will have a cost impact, according to the source.

However, with his background in economics McClellan might have an easier time persuading HHS and the Office of Management and Budget (OMB) of the validity of FDA's economic impact analyses for major rules. With every major rule, the agency must provide an economic impact analysis, which is generally scrutinized by HHS and OMB. With McClellan at the helm, there may be greater faith in FDA's economic impact analyses.

McClellan would also be the first FDA commissioner to have formal policy training, the food and drug lawyer adds, citing McClellan's advanced degree in regulatory policy. The lawyer adds that McClellan is unusual in that he will have been on the front lines of health policy decision-making by the government before coming to the agency.

Several trade associations representing a broad segment of FDA-regulated industries have endorsed the White House's choice. The Biotechnology Industry Organization (BIO) released a press release heralding the decision. "We are pleased that the Bush Administration has made a selection to fill this critical FDA position, and from Dr. McClellan's educational background and experience in medicine, health care and economic policy, he appears to be an exceptional candidate."

The food and device industries followed suit. The National Food Processors Association (NFPA) says that McClellan will round out an excellent leadership team at the agency. "With Dr. McClellan, the President, has provided outstanding leadership for an exceptionally strong management team at FDA. Under Dr. McClellan, FDA leadership will have complementary skills and capabilities to expertly address the full breadth of critical issues facing the Agency. NFPA looks forward to working closely with Dr. McClellan and FDA to assure continued protection and enhancement of the U.S. food supply."

The device trade association Advanced Medical Technology Association (AdvaMed) also has weighed in on behalf of McClellan. "Dr. McClellan is keenly aware of the value of medical technology, both as a practicing physician and a health care economist," AdvaMed President Pamela Bailey stated in an AdvaMed press release. "He is uniquely qualified to appreciate the critical importance of timely and thorough FDA reviews of new medical technologies."

AdvaMed also praised Deputy Commissioner Lester Crawford for his leadership, claiming that under his stewardship the agency reached a "landmark" agreement with industry on device user fees, and has launched important regulatory reform initiatives including a formal risk-based approach to facility inspections.

Several observers were puzzled by the Pharmaceutical Research and Manufacturers of America's (PhRMA) quote in *The Washington Post* that it "still needed to learn more about him and his career before commenting," Sources felt that this quote might suggest that PhRMA has reservations about McClellan. A PhRMA spokesman says that the quote solely indicates that the organization is trying to be deliberative before it weighs in, not that it has any reservations.

However, sources seemed surprised at this. An agency source says that PhRMA must be familiar with McClellan by now in light of the active role he played regarding the prescription drug benefit negotiations. A food and drug lawyer adds that the only way PhRMA's quote makes sense is that PhRMA is refraining from endorsing McClellan out of a fear that its support could hurt McClellan's chances.

A Public Citizen source says the consumer advocacy group does not know how McClellan stands on issues that

KENNEDY STOPS SHORT OF BACKING FDA COMMISSIONER NOMINEE

Following President Bush's announcement Wednesday (Sept. 25) that he has selected Mark McClellan to be FDA commissioner, a spokesperson for Sen. Edward Kennedy (D-MA) told *FDA Week* the senator is familiar with McClellan but stopped short of endorsing the White House's top health care advisor.

Kennedy is familiar with McClellan because his office negotiated with McClellan on many health care issues, according to Kennedy's spokesperson.

Kennedy's office has just started researching McClellan's writings and work, the spokesperson said, but added the senator will wait until he has had a chance to thoroughly review McClellan's background to decide if he is the right person for the post. Kennedy cannot schedule a hearing until the administration formally nominates McClellan, which likely will happen next week, the spokesperson said.

In the past, Kennedy has said he would oppose nominees who have worked in industry, and McClellan passes that test.

Despite Kennedy's cautious approach, most observers believe that the Senate will overwhelmingly confirm McClellan. The nominee is widely respected in the health care community and has had the unique experience of working on health care policies for both the Clinton and Bush administrations.

McClellan's current post as White House health care advisor likely will be filled by Bobby Jindal, HHS assistant secretary for Planning and Evaluation (see *InsideHealthPolicy.com*, Sept. 25).

are important to the group such as drug safety and the drug approval process. Public Citizen signed on to a letter opposing Crawford when his name was floated as a possible permanent commissioner because of what the group says was his "bad track record." The group will be tuned into the confirmation hearings to see what positions McClellan takes on issues.

A food and drug lawyer says that what some might see as a handicap – McClellan's lack of familiarity with FDA issues – could actually prove an asset during a confirmation hearing. McClellan may be able to duck difficult questions by honestly saying that he has not studied the particular issues. A person well-versed in FDA issues would not be able to use this approach.

As to McClellan's possible lack of management experience, the food and drug lawyer claims that it is exceedingly rare that someone about to head an agency of FDA's size would have comparable management experience. What McClellan does have, according to the source, is an understanding of how the government operates.

A spokesperson for the White House says that McClellan will bring to the post his diverse experience and unique expertise. The spokesperson points out that McClellan has served on the White House Council of Economic Advisors, is a senior health care advisor, a physician, and widely respected in the health community.

HHS Secretary Tommy Thompson states in a press release that McClellan has the right combination of "scientific knowledge" and "strong compassionate leadership." "Dr. McClellan has a strong background in medicine, science, public policy and economics. This experience would serve him well at the FDA as it continues its efforts to create a more responsive FDA, enabling it to better serve the needs of the American people with even greater efficiency and greater scope," according to the press release.

In an agency-wide email, Crawford called McClellan "an excellent choice to lead the Agency." Crawford added: "I know all of you will join me in an enthusiastic welcome for Mark McClellan. I very much look forward to working with Mark as all of us continue to make FDA a better place to work and the greatest place to serve."

The agency has been absent a confirmed commissioner since Jane Henney vacated the position shortly after President Bush came to office.

McClellan's current post as White House health care advisor likely will be filled by Bobby Jindal, HHS assistant secretary for Planning and Evaluation (see related story).

JINDAL MAY REPLACE McCLELLAN AS WHITE HOUSE HEALTH CARE ADVISOR

HHS Assistant Secretary for Planning and Evaluation (ASPE) Bobby Jindal is the leading candidate to replace White House health care advisor Mark McClellan in the wake of President Bush's announcement that he intends to nominate McClellan to be FDA commissioner, according to sources.

Over the last several months, speculation has grown that McClellan would be tapped as the next FDA Commissioner and the administration made it official yesterday (Sept. 25). [*InsideHealthPolicy.com* first reported that McClellan was the leading candidate for FDA commissioner (*InsideHealthPolicy.com*, July 17.)]

One of the key reasons why Bush delayed McClellan's nomination to FDA is because he has been working with Congress to move provider payment/prescription drug legislation.

McClellan has played a major role in shaping the Bush administration's health care policies. He worked closely with House and Senate Republicans on prescription drug legislation and helped draft the White House's position

statements on various health care bills.

On March 28, 2001, Bush announced his intent to nominate McClellan to be a member of the Council of Economic Advisors. The Senate subsequently confirmed McClellan's nomination.

If he replaces McClellan, Jindal's role in the administration would be significantly increased. At ASPE, Jindal has worked closely with the White House on a variety of issues, including health care legislation, regulatory reviews, and strategic planning.

Jindal, who formerly worked as Louisiana's Department of Health and Hospitals Secretary, was a leading candidate for CMS administrator. Last year, Sen. John Breaux (D-LA), House Energy and Commerce Committee Chairman Billy Tauzin (R-LA), and Rep. Jim McCrery (R-LA) strongly urged the White House to appoint Jindal as CMS chief (*Inside HCFA*, Jan. 18, 2001, p1). House Ways and Means Committee Chairman Bill Thomas (R-CA) also signed on to a letter supporting a Jindal nomination (*Inside HCFA*, Jan. 18, 2001, p20) but a source close to Thomas later downplayed the letter and added that the House lawmaker favored Tom Scully for the position.

Jindal declined to comment.

It is unclear who else is being considered to replace McClellan.

In 1998, Jindal was named executive director of the National Bipartisan Commission on the Future of Medicare. Prior to joining HHS, he was the President of the University of Louisiana System, which is one of the largest higher education systems in the nation. — *Inside CMS*

PhRMA URGES CA SUPREME COURT TO TACKLE FDA CASE . . . begins on page one

DOJ, CMA and the trade associations have written to the California Supreme Court in support of an Aug. 21 petition for review that asks the California Supreme Court to examine the appeals court decision. The law firm Morrison & Foerster submitted the Aug. 21 petition on behalf of the drugmakers and distributors involved in the case, including: GlaxoSmithkline, McNeil Consumer Products Company; Pharmacia & Upjohn, Inc; Alza Corporation; Aventis Pharmaceuticals, Inc; Costco Companies, Inc.; Lucky Stores, INC; Rite Aid Corporation; and Safeway, Inc.

[The Aug. 21 petition can be found on *InsideHealthPolicy.com*; see page 5 for details.]

Meanwhile, lawyers representing Paul Dowhal, the individual who originally brought the case against the manufacturers and distributors, are fighting to ensure that the California Supreme Court does not hear the case. Lawyers from the Lexington Law Group submitted a Sept. 10 answer to the petition for review asking the court not to hear the case. The law firm also sent a Sept. 23 letter responding to arguments made by the trade associations and the California Medical Association.

[Dowhal's Sept. 10 answer to the petition for review and the Sept. 23 letter can be found on *InsideHealthPolicy.com*; see page 5 for details.]

Sources familiar with the California Supreme Court agree that the court only accepts a small fraction of the cases that people ask it to review. The sources agree that DOJ's letter could increase the odds that the court will examine the case. However, one source points out that the judges are not obligated to read the letters that support or oppose the petition for review.

The California Supreme Court has 60 days to decide whether to accept a case, unless the court says it needs an extension, in which case it is allowed a 30-day extension. In total, the California Supreme Court is allowed 90 days to make up its mind on whether it will tackle the case.

At issue in the case is the intersection between the FDCA and the Safe Drinking Water and Toxic Enforcement Act of 1986, which is better known as Proposition 65. Under the California law, manufacturers must warn consumers if their products contain ingredients listed by the state of California to cause cancer, birth defects or other reproductive harm.

In *Paul A. Dowhal v. SmithKline Beecham Consumer Healthcare et al.*, a private individual sued the drug companies and distributors, including the company now known as GlaxoSmithKline Consumer Healthcare, L.P., for making or selling products that do not include a pregnancy warning on smoking-cessation products that is in line with Prop. 65 requirements.

As explained in their Aug. 21 petition for review, the drug companies say there is a conflict between the warnings the agency has decided to allow and the Prop. 65 warning. FDA designed a product-specific pregnancy warning intended to avoid "overwarning," according to the drug companies. FDA was concerned that overly strict warnings might lead pregnant women to forgo smoking-cessation products and instead continue to engage in the riskier behavior of smoking, because of concerns about how the smoking-cessation products would hurt their babies.

FDA repeatedly instructed defendants to use only the agency's mandated pregnancy warning, according to the drug companies. Moreover, the agency repeatedly rejected Dowhal's position and prohibited the use of a Prop. 65 warning message on those products, the firm argues.

In its Sept. 10 answer to the review petition, Dowhal maintains that it is not accurate to portray the agency's

stance regarding warnings for smoking-cessation products as "carefully designed." "[I]n the past six years, FDA has reversed itself no less than three times regarding the 'harm your baby' warning," Dowhal's lawyers assert. The law firm says that Prop. 65 does not stipulate the exact warnings that must be used. FDA did not ban all the warnings that could have satisfied Prop. 65, according to Dowhal.

Earlier this year the U.S. Superior Court of the State of California County of San Francisco ruled that FDA's warnings preempt the Prop. 65 warning. This summer, despite the intervention of DOJ, the Court of Appeals for the State of California First Appellate District Division Five overturned the lower court ruling.

In July, the drug companies and distributors involved in the case asked the appeals panel to reconsider its decision. A lawyer says that these petitions asking for a rehearing are almost never granted, however, they must be filed in order to appeal to a higher court. For this reason, petitions for rehearing are often filed at the appeals level, despite the fact that they are rarely granted. The appeals panel denied the July petition for rehearing.

Although all three judges agreed that in this particular instance the FDA label does not preempt the Prop. 65 requirements, the judges differed in their rationale. Specifically, two of the judges disagreed with the third judge on how to interpret language in the FDA Modernization Act regarding preemption.

FDAMA has a provision that mandates national uniformity for nonprescription drug product labeling, it exempts from that uniformity requirement any public initiative or referendum enacted before Sept. 1, 1997, which includes Prop. 65. Two of the judges said that the statutory language was clear: The law exempts Prop. 65 from the national uniformity requirement, therefore the Food, Drug and Cosmetic Act cannot preempt Prop. 65.

But the third judge took issue with this rationale. The third judge argued that even if Prop. 65 is not explicitly preempted, if there is a conflict between state and federal law, the federal law would still prevail. The third judge said that to interpret the law otherwise would be "unprecedented." However, the judge maintained that in this particular instance, no conflict between federal and state law had been demonstrated.

DOJ claims that the appeals court decision undercuts the agency's ability to regulate drug products. "[T]he decision undermines FDA's authority in the field of drug regulation, which reflects the agency's unrivaled expertise. Consequently, it creates uncertainty for drug manufacturers subject both to the FDCA's requirements and to conflicting requirements imposed under California law about how to proceed where compliance with both federal and state law is impossible," states DOJ in its Sept. 12 letter brief to the California Supreme Court.

Robert McCallum, assistant attorney general, and several other DOJ lawyers signed the Sept. 12 letter-brief. HHS general counsel Alex Azar and FDA Chief Counsel Daniel Troy are also listed as signatories on the letter-brief.

[DOJ's letter-brief can be found on *InsideHealthPolicy*; see page 5 for details.]

DOJ maintains that the appeals decision raises important legal questions. "First, it addresses whether a federal statute that expressly preempts state law generally, but excepts certain state laws, precludes application of implied preemption, a corollary of the Supremacy Clause."

DOJ continues: "Second, the decision addresses whether a federal statutory amendment, the Food and Drug Administration Modernization Act ('the Modernization Act') limits FDA's authority to regulate the warnings on drug product labeling where California state law requires labeling that conflicts with federally approved labeling, and that labeling violates the misbranding provisions of the FDCA."

Several trade associations agree with DOJ that the California Supreme Court should review the case. [T]he Court of Appeal decision undermines important legal principles regarding the preemptive effect of mandates issued by the federal Food and Drug Administration, and would have wide-ranging implications for the products at issue in this litigation and other FDA-regulated foods and drugs. Indeed, if left undisturbed, the decision would adversely affect fundamental principles of federalism going well beyond the preemptive effect of FDA's actions," according to a Sept. 10 letter written by law firm Covington and Burling.

Covington and Burling sent the letter on behalf of the Consumer Healthcare Products Association, a group representing OTC drugmakers; the Pharmaceutical Research and Manufacturers of America, which represents brand-name prescription drugmakers; the Cosmetic, Toiletry; and Fragrance Association and the Grocery Manufacturers of America.

[The Covington and Burling letter can be found on *InsideHealthPolicy.com*; see page 5 for details]

The DOJ Sept. 12 letter-brief is consistent with recent statements made by FDA's Troy that FDA hopes to convince federal judges in three ongoing cases that state courts should not be able to second-guess the agency's scientific determinations. Speaking before the Food and Drug Law Institute earlier this month, Troy said FDA had decided to participate in these cases to protect its congressionally mandated role to regulate labeling. The Prop. 65 case is one of those cases.

Saying biologics regulators should also do research...

RESEARCHER BLASTS FDA PLAN TO MOVE ALL THERAPEUTIC REVIEWS TO CDER

A well-known gene therapy researcher is blasting FDA's plan to shift responsibility for reviews of biologic therapeutics from the Center for Biologics Evaluation and Research (CBER) to the drug center. The researcher stresses that it is important that regulators of biologics also conduct research on the subject, and faults those who list the fact that the biologics center conducts research as a flaw.

"I think the breaking up of CBER is wrong, its shortsighted, and it approaches being irresponsible," W. French Anderson, director of the Gene Therapy Laboratories at the University of Southern California, told attendees of a CBER symposium celebrating the centers centennial.

Anderson observed that one of the criticisms of CBER has been that it does research. He said those who think that regulators of biomedicine do not need to do research do not know much about biomedicine. We are dealing with biological areas where we do not know what is going to happen, according to Anderson. Anderson said that while this is also the case with drugs, it is especially true with the emerging field of biomedicine.

Anderson opposes the idea of having regulators who do not conduct research. When you are dealing with areas that are dramatically different, knowledge has to be research-based, he said.

Under FDA's planned reorganization, review of biologic products other than vaccines, blood cells, tissues, gene therapy and related products will be transferred to the drug center. Scientific staff and support functions, including laboratories associated with review of these products, will be consolidated within the drug center, according to a Sept. 7 e-mail from FDA Deputy Commissioner Lester Crawford to agency staff outlining the reorganization plan.

[The e-mail is available on *InsideHealthPolicy.com*; see page 5 for details.]

FIRMS WOULD HAVE TO SAY DEVICES WERE REPROCESSED . . . begins on page one

listed, companies would have 15 months to submit the required data.

These devices also would have to submit "validation" data that sponsors would submit to show that a reprocessed device is properly clean, sterilized and works as well as the original device for as many times as it is meant to be reprocessed.

FDA would have a year to determine what devices that already are submitting premaket notification must also submit validation data.

The legislation also would require that both original devices and reprocessed devices carry the name or trademark of a device maker or the reprocessor unless the secretary exempts them. Reprocessed devices also will be required to carry the statement, "Reprocessed device for single use. Reprocessed by (name of reprocessor)."

The legislation also would allow hospitals to reuse certain class III devices that currently are not generally reprocessed (see *FDA Week*, Sept 20, p1).

Currently, if a new device requires premarket approval (PMA), a reprocessor also must submit a PMA application to reprocess the device. But reprocessors do not have access to the proprietary manufacturing information included in a PMA, making it impossible to reprocess such devices.

The legislation would create a 510(o) submission. The new plan would require information such as safety data that normally would be required in a PMA. However, it would not require confidential design data, removing the market barrier.

House Energy and Commerce Committee staffers also have worked out a deal on device user fees (see related story). The device user fee/reform legislation originally was slated for committee mark-up this week, but the mark-up was delayed until next week so staffers could tweak language addressing third-party inspections.

BRAND-NAME, GENERIC DRUG INDUSTRIES GO HEAD-TO-HEAD OVER PhRMA AD

Brand-name and generic drug trade groups are in a heated argument over a print ad campaign by the Pharmaceutical Research and Manufacturers of America (PhRMA) claiming that generic access legislation would damped the chances of a cure for critically ill children. The ad is the most recent development in the battle over pending drug patent reform legislation.

The PhRMA ad shows a photo of a critically ill boy and states "Pray For A Miracle" "Because Generic Drugs Will Never Cure Him."

"If your child has a disease with no know cure, don't look to the generic drug manufacturers for help," the ad continues in much smaller type. "They don't discover new medicines. They don't do research. That's why Congress must protect the patent system that allows research-based pharmaceutical companies to develop breakthrough drugs that save lives. The Senate-passed generic drug bill weakens intellectual property rights, reduces the incentive to discover new cures, and threatens medical progress."

The ad, which has appeared in the *Washington Post* and *The Hill*, started running the day before House Demo-

cratic leaders announced their plans to bypass the committee process and take generic-access legislation straight to the floor through a discharge petition. To date, Democrats have collected 140 of the 218 signatures needed to get the legislation on the floor for a vote. The Senate already has passed its version of the legislation.

The Generic Pharmaceutical Association (GPhA) is furious and has asked PhRMA to pull the ads. PhRMA refuses.

"To exploit the suffering of a small child, serves no purpose in advancing the debate regarding Hatch/Waxman – the GAAP [Greater Access for Affordable Pharmaceuticals]Act," wrote GPhA President Kathleen Jaeger in a Sept. 20 letter to PhRMA President Allen Holmer. "The juxtaposition of a critically child with America's penchant for innovative cures is indeed nothing more than a shameless public relations tactic designed to obfuscate the real issues, and ignore other realities."

PhRMA's Holmer shot back, saying that the generic drug industry-backed patent reform legislation would increase the chances of death for those waiting for medical science to find a cure for their diseases, such as his own children who have cystic fibrosis.

"I also know the passion of a parent who prays every day for a cure for his child who suffers from a life-threatening disease," writes Holmer in a Sept. 24 response to Jaeger. "PhRMA's ad makes others aware of what it will take to answer those prayers — and of how they are less likely to be answered if your industry's bill passes."

CALIFORNIA HEALTH OFFICIALS UPGRADE CANCER RANKING OF PROP. 65 TOXINS

California's health hazard assessment office has upgraded the cancer-causing ranking and health risks of several toxins covered by the state's landmark toxic labeling program, known as Proposition 65.

Three carcinogens and two reproductive toxins, including nicotine, have been elevated to high-priority status based on new information and the potential for exposure to the public, according to a report by the Office of Environmental Health Hazard Assessment (OEHHA). The carcinogens are bromate, naphthalene and pyridine; the reproductive toxins are nicotine and triphenyl tin hydroxide.

With the exception of nicotine, the four chemicals recently identified as high priority are newcomers to the Prop. 65 list, an OEHHA source said. Bromate is a byproduct from disinfection of water treatment of drinking water. Pyridine is widely used in solvents; the synthesis of vitamins in drugs; as a denaturant in alcohol; in anti-freeze; as an intermediate used in the manufacture of insecticides, herbicides and fungicides; and in dyes and flavoring agents, the source said. Naphthalene is a natural constituent of coal tar and crude oil and an ingredient in some toilet bowl deodorants and moth repellants.

"So there's some potential for exposure with all three" carcinogens recent elevated to high priority by OEHHA, the source said. The reproductive toxin triphenyl tin hydroxide is a pesticide but is not used much in California, the source added.

OEHHA ranks the chemicals for their safe harbor numbers by four prioritization levels. The no significant risk level (NSRL) is the daily intake level calculated to result in one excess case of cancer in an exposed population of 100,000, assuming a 70-year period of exposure. The maximum daily dose level (MADL) is the level at which the chemical would have no observable adverse reproductive effect assuming exposure at 1,000 times that level.

CDC UNVEILS PLAN FOR STATES TO RUN MASS VACCINATION CLINICS

The Centers for Disease Control and Prevention (CDC) on Monday (Sept. 23) released its updated guide on smallpox vaccination that recommends how state and local agencies should set up and run large-scale voluntary smallpox vaccination clinics within five to 10 days of an outbreak.

[The updated guide is available on *InsideHealthPolicy.com*; see page 5 for details.]

However, federal officials stressed that the decision to mass vaccinate has not been made.

During a teleconference, CDC officials said the decision to mass vaccinate would depend on the magnitude, duration and the mode of attack. While ring vaccination would be done through contact tracing, mass vaccination would depend on the assessment of the situation. This decision would be made after consultation with state and local health officials. CDC and HHS officials said they would drive the process of invoking the federal response plan in case of an attack.

CDC sent manuals of the guidelines to all 50 states and Washington, DC.

The guide provides details on all aspects of immunization clinic operations and staffing and includes an example of a model smallpox vaccination clinic, according CDC's website. According to the manual, staffing requirements could be altered to maximize clinic output and human resource utilization.

CDC officials said the guide, which has been called a logistical blueprint, has been through three revisions and the third revision is more specific about guidelines for mass vaccination clinics and contains new information for communication planning. The guide advises states and local bodies on maintaining effective communication with the public, with medical community and within each other. The officials said that the finer details about modes of communication — such as whether to communicate through television ads, fliers or newspapers — is up to the states and local bodies.

While the guidelines are prepared for a 10-day period, the time could vary depending on a state's level of preparedness. The guide states that following a smallpox outbreak in the country mass vaccination may be required to: 1. supplement priority surveillance and containment control strategies in areas with smallpox cases; 2. reduce the number of people who are at risk from the virus if another attack is considered likely; and 3. respond to the public or political concerns about the access to voluntary vaccination.

The guide cautions that current smallpox vaccines are available under an Investigational New Drug protocol only and adds that the informed consent process should be followed.