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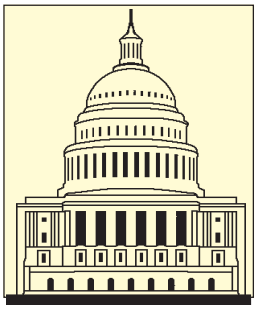
Politics & Policy

Patients want more than safety

By Steve Usdin
Washington Editor

Senators Edward Kennedy (D-Mass.) and Michael Enzi (R-Wyo.) are tweaking their drug safety legislation for the second time since it was introduced in 2006 in response to politically potent patient groups that are pressing them to reduce its potential for slowing drug development or reducing patient access to novel therapies.



Friends of Cancer Research (FOCR), the National Health Council and other patient groups have sent detailed proposals to Kennedy and Enzi for modifications to the Enhancing Drug Safety and Innovation Act (S. 484). Kennedy chairs and Enzi is the ranking minority member of the Health, Education, Labor and Pensions (HELP) Committee.

FOCR and the National Health Council have asked the lawmakers to revise the trigger for imposing risk evaluation and mitigation strategies (REMS), scale back expectations of what the risk mitigation plans can achieve, and eliminate provisions giving FDA authority to restrict off-label uses.

FOCR is a prominent patient advocacy organization and the National Health Council is an umbrella organization that includes patient groups, professional societies, non-profit health organizations and drug companies.

Separately, FDA, patient groups and industry lobbyists are working with HELP staff to incorporate into S. 484 provisions in a Republican bill that would create a so-called active postmarket surveillance system.

FOCR is "very supportive of the intent of S. 484, but is very concerned that it could slow down drug development," the non-profit advocacy group's chairperson, Ellen Sigal, told BioCentury.

These concerns center on the REMS, which S. 484 would make mandatory for all new drugs and some marketed products. The bill gives FDA broad authority to require that REMS include restrictions on access and distribution.

Kennedy and Enzi already have revised the legislation to make clear that a REMS could be as simple as labeling and postmarket vigilance, and that the most stringent risk mitigation tactics should be reserved for exceptional instances. Patient groups, however, worry that ambiguity and flexibility may lead FDA to default to overly burdensome risk mitigation techniques.

Rather than require a REMS for every new drug, FOCR and the Health Council have asked that the plans "be negotiated and approved only for products that display a causal relationship to serious adverse drug experiences and when usual surveillance and labeling strategies cannot adequately limit serious risk."

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Indeed, FOCR is asking Kennedy and Enzi to create a trigger for REMS plans. This approach would require the risk mitigation plans only when a known relationship between a serious adverse drug experience and the use of a drug has been established, or when there is a need to characterize safety in a special population such as pregnant women or children.

The patient groups also want the law to specify that a "routine, population-based surveillance system" should be the standard option for identifying and characterizing safety signals following approval. Phase IV trials would only be required if FDA determines that observational studies are not adequate to characterize a potential safety problem.

Language in S. 484 asserting that pharmacovigilance plans should be designed to identify unexpected serious risks of drugs should be removed "because REMS strategies will not sufficiently do so," the patient groups told HELP Committee staff.

They also have asked for removal of provisions specifying that REMS plans can include restrictions on which patients can use a drug, stating that these would "interfere with the doctor patient relationship and jeopardize off label use of drugs."

The patient advocates have distributed a report on Capitol Hill that attempts to inject the urgent need for medical innovation into the drug safety debate. The report, "Drug Safety & Efficacy, Two Sides of the Same Coin," warns against an over-emphasis on safety.

"To focus solely on drug safety without consideration of drug benefit, including the severity of the underlying disease or condition, effectiveness of the product under evaluation, and availability and utility of alternative therapies, will create a chilling effect on the development of new treatments for patients most in need of innovation," according to the white paper, which has been endorsed by 27 patient and medical groups, including the American Cancer Society and the American Society of Clinical Oncology.

One of the report's key recommendations is the creation of "a routine and automated approach to safety surveillance."

This recommendation dovetails with legislation introduced by three Republican members of the HELP Committee, Sens. Judd Gregg of New Hampshire, Richard Burr of North Carolina and Tom Coburn of Oklahoma. The Safer Drug Assessment Technology Advancement Act of 2007 (S. 1024) would require FDA to collaborate with the private sector to create an active post-market drug safety surveillance system.

The system would be capable of collecting data from patient records, healthcare provider and insurance databases, Medicare, and other sources in real time. Procedures would be established to automatically scan the data sources to identify risks, and FDA would collaborate with academic institutions to assess the data.

The legislation is modeled on a proposal from former FDA Commissioner Mark McClellan.

The active surveillance system provisions of S. 1024 are likely to be incorporated into the drug safety bill, which itself would be coupled to PDUFA reauthorization, according to Senate staff.