Congress Has Full Plate of Drug Legislation:
Some Dishes More Palatable Than Others

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The upcoming battle over legislation involving pharmaceuticals in the new 2007 Congress began on November 13, 2006, the Monday on which Congress resumed sessions after the mid-term elections for the start of the short lame-duck session. That day, GlaxoSmithKline ran a full-page advertisement in CQ Today, the daily online bible of Capitol Hill’s Congressional Quarterly (CQ.com).

The headline read: “Are you buying medicine from north of the border or east of the border?” The ad showed a map of Canada, broken up into geographical areas, namely Greece, India, Israel, Vietnam, and other countries.

The ad, of course, was not directed at senior citizens who live just south of Canada and who can now, because of legislation passed last fall, travel to Canada and bring back a 90-day supply of drugs. Instead, the ad was meant for Republicans and Democrats who, when the 110th Congress begins in late January, are expected to take up a bill with bipartisan support. The bill would allow the Food and Drug Administration (FDA) to approve complicated generic versions of biotechnology drugs and to impose curbs on the marketing of new drugs.

The first major drug-related concern will be to clamp down on Part D drug prices charged by drug companies. It was one of the signature concerns of the Democrats during the 2006 congressional elections. Democrats argued that because the federal government cannot negotiate about price directly with pharmaceutical companies under Part D, drug costs are 15% to 20% higher for Medicare beneficiaries than for Medicaid recipients, a population with whom the government has been very much involved in terms of pricing.

No bill has been written, and the terms of the Democratic initiative are therefore far from clear. But Mark Merritt, President and Chief Executive Officer of the Pharmaceutical Care Management Association (PCMA), the pharmacy benefit manager (PBM) trade group, says that his members would oppose any Democratic legislation. In an interview with P&T, he emphasized the following:

The FDA can approve copies of simple pharmaceuticals in the background is the reauthorization of the Prescription Drug User Fee Act (PDUFA). Under this law, drug companies are required to pay fees to the FDA, with the money going to the FDA’s drug review budget. Its authorization expires at the end of 2007. After a PDUFA bill is introduced, it will instantly become a magnet for all kinds of proposals concerning FDA drug reform. Some of those proposals will have their origin in the Institute of Medicine’s Drug Safety Report of last September. One of the report’s recommendations was to give the FDA more authority to place conditions on companies after their new drugs are approved. Examples include establishing a moratorium on advertising and demanding that specific warnings be incorporated into all promotional materials.

The new Congress will be looking at a full menu of drug bills. For the industry, some bills may be easier to swallow than others.