Generating Antibiotic Incentives Now (GAIN) Act
Legislative Summary

Summary

On September 29, 2010, Representative Phil Gingrey (R-GA-11) introduced the "Generating Antibiotic Incentives Now (GAIN) Act." Additional cosponsors at introduction were Representatives Diana DeGette (D-CO-1), Gene Green (D-TX-29), Mike Rogers (R-MI-8) and Ed Whitfield (R-KY-1)—all experienced Members of the House Energy and Commerce Committee. The legislation provides new incentives for the development of "qualified infectious disease products," including:

- Extend the Hatch-Waxman provisions related to data exclusivity by 5 years while maintaining the current paradigm for an abbreviated NDA paragraph IV certification.
- Providing six months of additional exclusivity for products with companion diagnostics;
- Providing priority review by the Food and Drug Administration (FDA);
- Making products eligible for fast-track designation by the FDA;
- Requiring a review and possible revising of FDA guidelines regarding clinical trials and other requirements for approval of antibiotic drugs.

This legislation is in response to the series of hearings the House of Representatives Energy and Commerce Subcommittee on Health held this past summer that highlighted antibiotic resistance as a public health threat and the need to spur new development of innovative products.[1] The sponsors wanted to release the bill in order to generate additional commentary from stakeholders and plan to reintroduce the bill in the 112th Congress with appropriate modifications and additional original cosponsors.

Qualified Infectious Disease Product (QIDP)

The legislation defines a QIDP as an antibiotic any drug for treating, detecting, preventing, or identifying a qualifying pathogen. "Qualifying pathogen" is defined as:

(A) resistant gram positive pathogens, including methicillin-resistant Staphylococcus aureus (MRSA), vancomycin-resistant Staphylococcus aureus (VRSA), and vancomycin-resistant enterococcus (VRE);
(B) multi-drug resistant gram negative bacteria, including Acinetobacter, Klebsiella, Pseudomonas, and E. coli species;
(C) multi-drug resistant tuberculosis; or
(D) any other infectious pathogen identified for purposes of this section by the Secretary as a significant threat to public health because of drug resistance or other factors (or likely to become such a threat)."

[1] "Antibiotic Resistance and the Threat to Public," April 28, 2010; "Promoting the Development of Antibiotics and Ensuring Judicious Use in Humans," June 9, 2010; "Antibiotic Resistance and the Use of Antibiotics in Animals," July 12, 2010; all available at http://energycommerce.house.gov/index.php?option=com_content&view=category&layout=blog&id=132&Itemid=72.

Note that (D) allows for additional pathogens to be added in the future and creates a new role for groups like the Infectious Disease Society of America.

Additional Exclusivity

The legislation creates an additional five years of exclusivity for QIDPs first approved or licensed on or after enactment of the bill. Prior to approval, a sponsor of an application may request a determination by the FDA that its drug is a QIDP and thus qualified by the additional exclusivity; a request the FDA must respond to within 30 days. The additional 5 years of exclusivity is added to the base exclusivity granted products under current federal statute.

The additional exclusivity does not apply to:

1) Supplement applications;
2) Subsequent applications filed by the same sponsor for a change (not including a modification to the structure of a QIDP) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device; or
3) Modifications to structure that do not result in a change to safety and efficacy (or safety, purity and potency).

Hatch-Waxman ANDA Approval

The legislation also also maintains the current paradigm within Hatch-Waxman whereby an abbreviated NDA with a Paragraph IV certification may be accepted by the FDA one year prior to the expiration of the reference product's data exclusivity.

Priority Review

The legislation creates a new FDCA section 524A that requires priority review of QIDP applications. This requires FDA review and action to occur within six months of submission, versus the standard review time of 10 months.[2]

Fast-Track Review

The legislation also includes QIDPs as a category of products eligible for 'fast track' designation under FDCA section 506, which triggers facilitated development and expedited review procedures by the FDA. A product must fill an unmet medical need or demonstrate some advantage over existing therapies (superior effectiveness, improved risk profile, etc.) to receive fast track designation. The fast track process allows for more frequent meetings with the FDA during drug development, greater communication regarding clinical data requirements as well as rolling review of a product application. Fast track in turn triggers eligibility for 'Accelerated Approval,' another FDA program that allows approval based on an effect on a surrogate endpoint.

Clinical Trial Guidelines

The legislation lastly requires the FDA to revisit its guidelines for clinical trials for antibiotic drugs with one year and continuously review its guidelines every four years. "At a minimum,

[2] Note that the current priority review procedure requires the drug sponsor to request priority review and is awarded to product providing significant advancements in treatment.

the review …shall address the appropriate animal models of infection, in vitro techniques, valid micro-biological surrogate markers, the use of non-inferiority versus superiority trials, and appropriate delta values for non-inferiority trials." The bill also allows a sponsor of qualified product to request and for the FDA to provide written recommendations for the clinical and nonclinical data necessary for approval.