Patient, Consumer, and Public Health Coalition Comments on "Incentivizing New Antibiotic Development" Discussion Draft (GAIN Act)
April 9, 2012

The above listed members of the Patient, Consumer, and Public Health Coalition appreciate the opportunity to comment on the bipartisan HELP committee's "Incentivizing New Antibiotic Development" discussion draft.

Despite honorable intentions, the HELP Committee's current discussion draft version will not benefit patients and may harm them. That is because the incentives the draft provides will encourage drug companies to develop antibiotics that are not necessarily needed or life-saving, and may promote even more antibiotic resistance toward existing drugs.

The Coalition strongly opposes the current version of the Discussion Draft, but would support it if the following changes were made:

- **Give Priority to Drugs that Save Lives.** The Discussion Draft should clearly specify that priority review and additional exclusivity requires meeting unmet medical needs based on clinical trials in humans. As currently written, the list of organisms implies that data from test tubes and animal studies are sufficient to grant designation as a "qualified infectious diseases product (QIDP)." Unfortunately, most drugs with promising test tube data fail to fulfill that promise when studied in humans with diseases. A recent example is the increased risk of mortality from tigecycline compared to other antibiotics, despite promising test tube data and animal studies.

  As currently written, any drugs granted the QIDP designation cannot have it rescinded for any reason. As a result, new drugs that are no longer needed will have priority review forever. This should be deleted.

- **Antifungals.** Antifungals do not belong in the Discussion Draft, because these drugs do not need such incentives. The current high cost of antifungals is incentive enough. The number

of antifungal drug approvals for serious diseases has increased over the last decade, and antifungal drugs for serious diseases are prescribed for long periods of time, sometimes costing hundreds of thousands of dollars per patient. The incentives in the Discussion Draft should be confined to drugs for which financial incentives are needed, namely antibacterial drugs.

- **List of Organisms.** The list of organisms does not ensure that drugs meet unmet medical needs, because it does not specify that new drugs need to be safer or more effective than other drugs in the treatment of diseases caused by these organisms. In addition, many patients die of disease due to "susceptible" pathogens. "Resistance" is often based on test tube data and not on worse clinical outcomes in patients. Instead, priority should be given to drugs that benefit patients, rather than greater strength in a test tube. Antibiotics that work better in a test tube do not necessarily save lives.

- **Preventing Future Resistance.** Currently, new antibiotics are widely promoted and extensively used in patients who don't need them, and as a result, resistant bacteria flourish. The Discussion Draft could save lives and billions of healthcare dollars by promoting "stewardship" – the smart use of antibiotics. The Discussion Draft does nothing to reduce the over-use of antibiotics and the resulting rise of antibiotic resistance. Instead, the bill gives companies more time to sell their product at top dollar for broad uses while bacteria develop more resistance. By the time generic versions are available, the antibiotics developed under the Discussion Draft will probably no longer be effective compared to older drugs.

- **Discussions with Medical Experts.** The Discussion Draft should require that discussions with "medical experts" within or outside FDA be done through the Federal Advisory Committee Act, with appropriate controls for conflict of interest and public meetings. The current version encourages discussions with medical experts but does not require transparency or limit conflicts of interest.

The Patient, Consumer, and Public Health Coalition appreciates the bipartisan work that has gone into this Discussion Draft, and strongly urges the above revisions. We look forward to working with you on this Discussion Draft and all of the PDUFA/MDUFA-related legislation.

Sincerely,

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Center for Medical Consumers
Connecticut Center for Patient Safety
Jacobs Institute of Women's Health
National Physicians Alliance
National Research Center for Women & Families
Our Bodies Ourselves
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