May 14, 2012

Dear Senator:

AARP which represents more than 38 million Americans aged fifty and older, appreciates the opportunity to comment on the Food and Drug Administration Safety and Innovation Act. Older Americans utilize a wide variety of prescription drugs and medical devices; thus, access to and safety of these products are of great concern to our members and all older Americans.

In general, AARP is concerned with the high level of vital FDA funding that is generated through user fee programs. We believe that the safety and efficacy of prescription drugs and medical devices is a societal good, and thus sufficient dedicated federal funding should be appropriated to lessen the agency's dependence on user fees. AARP is also concerned about several provisions that would add to FDA's already formidable workload without a corresponding increase in funding. FDA is chronically understaffed and underfunded[i]; it cannot be expected to successfully take on new responsibilities unless Congress is willing to provide additional resources.

Drug and Device Safety

AARP is pleased to see numerous provisions that will help improve and ensure the safety of prescription drugs and medical devices. AARP is particularly supportive of efforts to help improve FDA's postmarket surveillance authority, such as the inclusion of medical devices in its Sentinel postmarket risk identification and evaluation system. All drug and device side effects cannot be anticipated based on preapproval studies; therefore, patient safety is dependent on FDA's ability to identify adverse events that did not appear during the approval process.

AARP also appreciates efforts to improve FDA's ability to verify the safety of prescription drugs that are manufactured outside the United States. The globalization of the pharmaceutical industry has placed increasing demands on the FDA, and while the agency has made progress in conducting more foreign inspections, it still inspects relatively few establishments.[ii] AARP is especially pleased to see the inclusion of a "risk-based" inspection approach that will focus more attention on facilities at greatest risk. AARP believes that an increased focus on inspecting foreign facilities and products—particularly when the changes are mindful of FDA's budgetary and staffing constraints —is greatly needed to help improve the agency's ability to ensure the safety of the drug supply. However, in the interest of patient safety, AARP does not support efforts to clarify the "least burdensome" standard. Instead, AARP believes that the

requirement that the FDA evaluate devices in a manner that is least burdensome upon manufacturers should be eliminated for all device submissions. FDA should be free to make its decisions based on all of the information that is deemed necessary.

Unique Device Identifier System

AARP strongly supports efforts to accelerate the implementation of a unique device identification (UDI) system for medical devices. Unlike medications, medical devices cannot be identified in a systematic and consistent manner. The FDA Amendment Act of 2007 requires FDA to implement a mandatory national UDI system; however, FDA's proposed rule is currently waiting for clearance from the Office of Management and Budget. UDI implementation will strengthen the ability of the FDA, manufacturers, and hospitals to monitor devices associated with adverse events and look for patterns across event reports. Unique device identification will also improve FDA's ability to uncover warning signs of defective devices and respond to device recalls, potentially saving lives.

Drug Shortages

Like many others, AARP is alarmed by the recent increase in drug shortages and is pleased to see provisions that will help FDA prevent future shortages. In particular, AARP supports requiring manufacturers to notify FDA of circumstances that could lead to supply disruptions, as well as authorizing FDA to expedite inspections and reviews that could help mitigate or prevent drug shortages. AARP also strongly supports allowing the Secretary to add biological products to the list of drugs that fall under the notification requirement. Biologic drugs represent the fastest growing segment of the pharmaceutical industry; it is estimated that they will represent 30 percent of branded prescription drug sales by 2014.[iii] Given their rapidly growing market share, there is no reason that biologic drugs should not be treated in the same manner as conventional drugs.

However, AARP is concerned by the requirement that the Secretary weigh the risks of taking an action that could lead to a supply disruption against the risks associated with responding to a Federal Food, Drug, and Cosmetic Act violation. FDA's clear and overriding concern should be safety and efficacy. Further, FDA scientists do not have the expertise to perform the type of cost-benefit analysis that would be necessary.

The *De Novo* Process

While AARP generally supports efforts to streamline the *de novo* process for novel moderate and low-risk medical devices, it remains mindful that FDA is already facing criticism for numerous medical devices that have been recalled after being approved without clinical trials.[iv] Therefore, every precaution should be taken to help ensure that only lower-risk devices are reviewed via the streamlined *de novo* pathway. AARP believes that safety should be paramount and that any changes to the *de novo* process should help ensure that FDA only approves devices that are safe and effective.

Infectious Disease Incentives

AARP is pleased to see efforts to increase the availability of qualified infectious disease products (QIDPs). According to the Infectious Disease Society of America, drug-resistant infections cost the U.S. health care system as much as $34 billion annually.[v] However, due to a perceived lack of revenue opportunity, the pharmaceutical industry has not focused on the development of new antibiotic drugs. Since 2006, only three of 111 drugs approved by the FDA were antibiotics.[vi] While investment in new infectious disease products is clearly needed, AARP strongly believes that any incentives should only be awarded if the new product answers an unmet need; we should not use scarce resources to reward the development of drugs that are not a substantial improvement over products that are already available.

AARP also strongly supports allowing the Secretary to revise the list of qualifying pathogens; defining the list of pathogens in legislation would needlessly limit FDA's ability to consider infectious disease needs on a real-time basis.

However, AARP is concerned by the provision of an additional five years of market exclusivity for new QIDPs. It is unclear whether this incentive will have the intended effect. For example, this extended exclusivity period could be used to increase profits by encouraging the overuse of the QIDP, thereby undermining its usefulness.[vii] AARP strongly suggests that the FDA monitor the development of new QIDPs and subsequent markets and, if necessary, consider supporting alternative methods of incentivizing the development of new QIDPs.

Accelerated Approval

AARP supports efforts to expedite the availability of drugs that are intended for the treatment of a serious or life-threatening disease or condition. However, AARP strongly believes that expedited review should only be granted for drugs that meet an unmet need and/or demonstrate substantial improvement over existing therapies.

AARP also believes that, while accelerated approval may be useful and beneficial under certain circumstances, FDA's safety and efficacy standards must remain the same.

Online Advertising

AARP is pleased to see that FDA would be required to issue guidance on online promotion, including social media, of FDA-regulated medical products. Spending on online drug advertising is expected to grow substantially over the next few years,[viii] and exposure to online media, including a brand's website and online advertisements, has been shown to significantly improve consumers' awareness and favorability.[ix] And while some types of direct-to-consumer advertising are helpful to consumers, AARP is concerned that, absent strong guidelines, online advertising will not be accurate, balanced, or inform consumers of all the risks associated with taking the advertised drug.

Conflict of Interest

AARP is also concerned by efforts to relax the conflict of interest rules for FDA advisory committee members. While AARP appreciates that there are certain circumstances where it may be difficult to find non-conflicted appointees, we believe that there are enough non-conflicted experts who can serve on advisory committees. In addition, FDA itself has asserted that Congress should not loosen conflict of interest rules.[x] More importantly, eliminating the questions that can arise from appointing conflicted experts will help maintain the public's faith in the integrity of FDA's work.

Access to Generic Drugs

Older Americans use more prescription drugs than any other segment of the population, making access to less expensive generic drugs extremely important to both their health and pocketbooks. Accordingly, AARP supports efforts to prohibit brand name drug companies from using elements in risk management and evaluation strategies to prevent other drug companies from procuring a supply of a drug for use in the testing needed to support a generic drug application. AARP strongly believes that brand name drug companies should not be allowed to unreasonably delay access to safe and effective generic drugs.

AARP appreciates the opportunity to comment on the Food and Drug Administration Safety and Innovation Act. If you have any questions or need additional information, please do not hesitate to call me, or have your staff contact Ariel Gonzalez on our Government Affairs staff at (202) 434-3770 or agonzalez@aarp.org.

Sincerely,

Joyce Rogers
Senior Vice President
Government Affairs

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[iii] G-C.F. de La Horie, "Making Biologic Drugs More Affordable," *Drug Discovery & Development*, July 12, 2010.
[iv] G.D. Curfman and R.F. Redberg, "Medical Devices—Balancing Regulation and Innovation," *New England Journal of Medicine*, Vol. 365(11): 975-977; Institute of Medicine, *Medical Devices and the Public's Health: The FDA 501(k) Clearance Process at 35 Years*, 2011.
[v] Infectious Diseases Society of America, "Combating Antimicrobial Resistance: Policy Recommendations to Save Lives," *Clinical Infectious Diseases,* Vol 52(S5):S397–S428.
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[viii] M. Iskowitz, "Pharma poised to up online spend," *Medical Marketing & Media*, April 27, 2011.
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