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November 1, 2010

Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Attention: Division of Dockets Management (HFA-305)
Submitted electronically to <http://www.regulations.gov>

Re: Office of the Commissioner; Request for Comments on the Food and Drug Administration Fiscal Year 2011-2015 Strategic Priorities Document; Request for Comments
Docket No. FDA-2010-N-0506

To Whom It May Concern:

The American Nurses Association welcomes the opportunity to offer comments on the "United States Food and Drug Administration's (FDA) "Strategic Priorities 2011-2015".

The American Nurses Association (ANA) is the only full-service professional organization representing the interests of the nation's 3.1 million registered nurses, the single largest group of health care professionals in the United States. We represent registered nurses in all roles and practice settings, through our constituent member nurses associations, organizational affiliates and workforce advocacy affiliate. ANA is actively involved in forming public policy that affects human health and patient advocacy, and has long recognized that air, water, soil, food, and products, that are free of potentially harmful chemicals, are fundamental requirements for ensuring and maintaining the health of our patients, our families, and our community.

ANA applauds the FDA's priorities identified in its draft document to ensure safer food and products. ANA offers the following comments.

1.3 Guiding Principles

The FDA cites science-based decision making as one of its guiding principles. The ANA agrees with this decision and supports it fully. However, the Precautionary Principle should be considered as well. This principle states that "when an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if

some cause and effect relationships are not fully established scientifically” (Wingspread Conference, 1998). Precautionary measures can include but are not limited to clearer labeling, further research for a product or process that has conflicting studies on its safety, and concise, easily identifiable warnings for products that contain chemicals that may cause harm.

2.3 Strengthen Compliance and Enforcement Activities to Support Public Health

This section speaks about ensuring that products are safely manufactured, distributed, developed and delivered to the American consumer. This section needs to include the assurance that products are safely packaged as well. Harmful chemicals that can leach out of products and out of packaging need to be replaced with safer alternatives. For context, consider Bisphenol A (BPA). This chemical is used in food and beverage containers, some baby bottles and other products. BPA can leach out of products, particularly when exposed to heat, acidic conditions and excessive washing with harsh detergents. Many studies have linked exposure to BPA with cancer, obesity and behavioral disorders. Many cities, states, and municipalities either have bans in effect or pending to restrict the use of BPA in baby bottles, sippy cups, infant formula cans, baby food jars and reusable food and/or beverage containers. ANA has requested a ban on BPA in food, health care products and children’s products from the FDA. BPA is an excellent example of a chemical that poses concerns about its safety in food and beverage packaging. BPA serves as a reminder that the FDA needs to ensure the safety of food packaging to help ensure American public health.

In addition to packaging, the FDA needs to ensure that all cosmetics and personal care products are free of chemicals that are known or strongly suspected of causing cancer, mutation or birth defects and replaced with safer alternatives. The FDA should also require pre-market safety testing for carcinogenicity, mutagenicity, and reproductive hazards while continuing to test for skin irritation, allergenicity and sensitivities. As with foods, cosmetics and personal care products also should have stricter labeling, including the requirement of all ingredients to be listed on the label. When a cosmetic is found to be harmful, there should be streamlined processes for it to be removed from the market immediately.

Section 2.4 Expand Efforts to Meet the Needs of Special Populations

The American Nurses Association is in full agreement with the FDA’s efforts to meet the needs of special populations, such as women, minorities, and children. Since FDA specifically speaks about “the long term safety of products, including devices used chronically in children”, (Strategic Priorities, p. 9). ANA recommends liberal use of the Precautionary Principle when approving chemicals for use in products with which children come in contact. Again, ANA would like to invoke the example of BPA. BPA is found in many child products including sippy cups and baby bottles, several studies have linked it with chronic diseases. Also di(2-ethylhexyl) phthalate (DEHP) is used in many products that children use. Animal studies have raised concerns about the impact on development of the male reproductive system and production of normal sperm with exposure to DEHP, as well as other adverse effects. FDA did put out an advisory notice on DEHP in 2002, suggesting the use of safer alternatives, particularly with male neonates, pregnant women carrying male fetuses, and peripubertal males, but DEHP is still in use. These two examples demonstrate FDA’s need for stronger regulation to protect the most vulnerable. All products should be free of harmful chemicals, but particularly those that are in use for infants and children.

Section 3.1 Advance Food Safety and Nutrition

The American Nurses Association offers the following suggestions for improved food safety and nutrition.

- Ensure safe food and beverage packaging, avoiding the use of harmful chemicals that can leach out of packaging.
- Eliminate the use of artificial hormones such as recombinant bovine growth hormone and other inappropriate food additives.
- Support the American public's right-to-know with appropriate food labeling, including: country of origin, genetic modification, and nutritional information.
- Ensure an efficient and coherent food safety regulatory system through Federal legislation.

3.2.1 Advance Human Drug Safety and Effectiveness

The FDA speaks about preventing intentional and unintentional misuse of human drugs. A key initiative to accomplishing this would be an effective, safe, HIPAA-compliant, ongoing, accessible unused drug disposal program(s) or methods that are also healthy for the environment and compliant with all applicable regulations.

3.2.3 Advance Medical Device Safety and Effectiveness

The FDA addresses their protection and promotion of public health by safety, effectiveness and quality assurance of medical devices. The FDA specifically remarks on taking a closer look at products' total life cycle. ANA would like to see specific language inserted on the reprocessing of single use medical devices. The safety and effectiveness of *reprocessed medical devices* needs to be approached as well. Since FDA is seeking "to proactively facilitate device innovation to address unmet public health needs" (Strategic Priorities, p. 24), research on manufacturing multi-use medical devices and the ethical and safety issues associated with utilizing single used devices and reprocessing of these devices is needed. End of use management, including the reprocessing of appropriately identified FDA-labeled single use devices, based on law and regulation needs to be clearly identified. Best practices for the various reprocessing methods of single use devices needs to be developed and disseminated.

3.4 Manage for Organizational Excellence and Accountability

ANA supports FDA employing high-quality staff, having adequate financial resources and effective information technology.

Conclusion

On page 6, the FDA mentions many challenges such as outdated FDA laws, a workload that exceeds FDA resources, insufficient FDA authority and enforcement abilities, and lack of corporation accountability. ANA believes with that with updated FDA regulations, sufficient and motivated staff, adequate funding, best science use, the guidance of the Precautionary Principle and agency transparency (which these comment opportunities help provide), the FDA will meet its mission of protecting public health through safe drugs, medical devices, food, cosmetics and other products.

Thank you for the opportunity to comment on this topic.

Sincerely,

A handwritten signature in black ink that reads "Marla J. Weston". The script is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Marla J. Weston, PhD, RN
Chief Executive Officer

cc: Karen A. Daley, PhD, MPH, RN, FAAN
President