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October 4, 2010

The Honorable Dr. Margaret Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

RE: *Docket No. FDA-2010-N-0348: Center for Devices and Radiological Health 510(k) Working Group Preliminary Report and Recommendations, and Task Force on the Utilization of Science in Regulatory Decision Making Preliminary Report and Recommendations; Availability; Request for Comments*

Dear Dr. Hamburg:

The National Association of Manufacturers and the U.S. Chamber of Commerce, appreciates the opportunity to comment on the preliminary report and recommendations of both the Center for Devices and Radiological Health 510(k) Working Group and the Task Force on the Utilization of Science in Regulatory Decision Making. Signatories to this letter, trade associations representing the interests of businesses, small and large, from all sectors of the economy employing tens of millions of Americans, as well as the medical device industry, strongly believe that an appropriate balance should be struck between government regulation and free enterprise. We are committed to working with the FDA to ensure that private industry is not adversely affected by the recommendations issued in these reports.

Our organizations are deeply committed to policies that will support a vibrant and successful manufacturing sector—a critical ingredient in U.S. economic growth and standards of living. The medical technology industry, comprising manufacturers of medical devices and diagnostics, is a sector of manufacturing where the U.S. leads the world. This industry represents the eleventh largest manufacturing sector in terms of exports, and is one of the few manufacturing sectors that has consistently maintained a favorable balance of trade. The sector, like other manufacturing industries, provides jobs that substantially exceed U.S. average wages and is an engine for jobs in supporting manufacturing and service industries. The prosperity that the medical technology industry brings to many American workers is dependent on an FDA review process that assures efficient and consistent reviews, while protecting patients against unsafe or ineffective products.

Current trends in FDA review of 510(k) products show a troubling pattern of inefficiency and larger burdens on manufacturers that threaten American manufacturing leadership in this vital sector. Whether the issue is total review times, the number of review cycles, the amount of time manufacturers spend answering FDA questions after products are submitted for review, or the withdrawal of applications before a final decision, FDA statistics show performance has declined

substantially since 2003, despite the significant additional resources that the FDA has received from expanded user fees and appropriations.¹


At the same time, the current 510(k) process has an exemplary safety record that does not demonstrate a case for sweeping reforms that would add to manufacturers' burdens in developing products and securing FDA approval. Recent studies by the Battelle Memorial Institute,² Professor Ralph Hall of the University of Minnesota³, and Dr. William Maisel of the Medical Device Safety Institute at the Beth Israel Deaconess Hospital in Boston⁴ have all demonstrated that only a very small proportion of approved 510(k) products subsequently show safety problems.

With this backdrop, the National Association of Manufacturers and the U.S. Chamber of Commerce are concerned that many of the proposals developed by the 510(k) working group undermine U.S. manufacturing employment, growth, and competitiveness while not significantly increasing the protection of public health. Our organizations urge the FDA to reject proposals, such as imposing arbitrary limits on acceptable predicates, redefining the term substantial equivalence, and eliminating the separate classification of intended use and indications for use, that alter basic aspects of the current program. These proposals will increase development time as well as costs for manufacturers substantially without a demonstrated need for these additional burdens. Additionally, these proposals could worsen public health by depriving patients of timely access to new treatments and cures. Changes that will increase approval difficulty or time should only be proposed for product types where there is a demonstrated need for additional requirements.

At the same time, we urge FDA to implement proposals on a priority basis that will address the current problems with the review process, including better training of reviewers and managers, and the issuance of more guidance documents.

Finally, FDA should consider the capacity of an already stressed system to absorb additional changes. With more than 50 changes proposed by the task force, any attempt to implement a large proportion of them rapidly would create confusion and necessitate retraining of reviewers and manufacturers that could be extremely destructive to the review process for many years.

Sincerely,



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¹ FDA statistics: FDA 510(k) Working Group, *Preliminary Report and Recommendations*, Center for Devices and Radiological Health, U.S. Food and Drug Administration, August, 2010.

² Battelle: Battelle Memorial Institute, "510(k) PreMarket Notification Evaluation," September, 2010.

³ Hall, Ralph F. Hall, "Using Recall Date to Assess the 510(k) process," University of Minnesota, Institute of Medicine 510(k) workshop, July 28, 2010.

⁴ Maisel: William H. Maisel, M.D., "Premarket Notification: Analysis of FDA Recall Data," Institute of Medicine 510(k) workshop, July 28, 2010.