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Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
[Docket No. FDA-2013-D-1446]
[Docket No. FDA-2013-D-1445]

RE: Self-Monitoring Blood Glucose Test Systems for Over-the-Counter Use; Draft Guidance

To Whom It May Concern:

The U.S. Chamber of Commerce (the “Chamber”) submits these comments in response to the two draft guidance notices for Industry and Food and Drug Administration Staff (“Notices”) issued by the Food and Drug Administration (“FDA”) regarding two different types of blood glucose monitoring test systems: one regarding self-monitoring blood glucose test systems for over-the-counter use and a second regarding blood glucose monitoring test systems for prescription point-of-care use. The first draft guidance describes studies and criteria FDA recommends in premarket submissions for self-monitoring blood glucose test systems (SMBGs) which are for the over-the-counter (OTC) use by lay-persons.¹ The second draft guidance describes studies and criteria FDA recommends for blood glucose monitoring test systems (BGMSs) which are for prescription point-of-care use.²

The Chamber is the world’s largest business federation, representing the interests of more than three million businesses and organizations of every size, sector and region, with substantial membership in all 50 states. More than 96 percent of the Chamber’s members are small businesses with 100 or fewer employees, 70 percent of which have 10 or fewer employees. Yet, virtually all of the nation’s largest companies are also active members. Therefore, we are particularly cognizant of the problems of smaller businesses, as well as issues facing the business community at large. Besides representing a cross-section of the American business community in terms of number of employees, the Chamber represents a wide management spectrum by type of

business and location. Each major classification of American business – manufacturing, retailing, services, construction, wholesaling, and finance – is represented. These comments have been developed with the input of member companies with an interest in improving the health care system.

OVERVIEW

In representing the interests of private sector businesses in nearly every industry, the Chamber works closely with administrative agencies as they promulgate, monitor, and enforce regulations that directly and indirectly affect business, their employees and our country’s health care system. Our goal in working with agencies as they consider, finalize, and implement rules is to promote innovation, protect the ability of businesses to operate and compete, and push back against unnecessary restrictions that will undermine innovation and competition. In order to help achieve these goals, the Chamber weighs in through comments to protect the regulatory process as articulated and required by the Administrative Procedure Act, to advance appropriate substantive policy and to mitigate harmful ramifications. For these general reasons, we have significant concerns with the two draft guidance notices.

PROCEDURAL CONCERNS

First, the Chamber has significant concerns about the process that has led to the issuance of these Notices. The regulatory action on this issue is unexpected given that historically the International Standards Organization (ISO), a collaborative committee of technical experts and stakeholders, has been the entity to issue standards on blood glucose monitoring strips. Not only is it unexpected, it is unnecessary given that the ISO recently updated their own BGMS standards (ISO 15197:2013), an earlier version of which (ISO 15197:2003) the FDA had been using as a reference standard until January of this year. It is hard to imagine why, given the collaborative process that the FDA participated in as part of ISO, those collaborative recommendations were ignored by the FDA. FDA similarly ignored a collaboratively developed reference standard for point of care products (CLSI POCT 12-3-A3). In addition to unexpectedly ignoring the updated standards, the FDA revealed no additional clinical justification for its decision. We believe industry and patients would benefit from uniform and consistent standards based on clinically meaningful improvements. Issuing these updates to regulatory standards through ‘non-binding’ guidance documents will no doubt cause confusion across the health care spectrum.

In issuing these Notices, the FDA is: usurping the longstanding authority that had been granted to the ISO in setting these standards; overreaching its authority by proposing a set of standards that will confer no apparent additional benefit to individuals, and; failing to achieve the purported goal of better quality. These Notices will not help diabetes patients access high-quality devices to monitor their blood glucose. The FDA has acknowledged that some portion of currently marketed meters do not operate at the same performance level to which they were submitted for FDA clearance. However, higher standards will not fix that problem. Instead of enforcing the current standards, creating a new set of higher standards that simply raises the bar for product performance will not help improve access to quality devices. We would recommend finding ways to enforce existing standards, instead of layering on more burdensome regulations that hinder our innovators.
SUBSTANTIVE POLICY CONCERNS

Unachievable Standards for Accuracy Will Hinder Innovation and Limit Access

To improve our health care system, patients must have access to the best innovative products, services, and treatments available on the market. Instead, the FDA’s draft guidance will impose an unattainable standard of accuracy on new devices that will halt glucose monitoring device innovation in the United States. In fact, critical experts have indicated that the standards proposed have not been scientifically justified and are virtually unachievable. Specifically, Dr. David B. Sacks, the Chief of the Clinical Chemistry Service in the Department of Laboratory Medicine at the National Institutes of Health (NIH) has said that ‘no (blood glucose) meter’ could meet the requirements and if the FDA does not make them more lax, “there will be no glucose meters approved in the future.”

Burdensome Testing Criteria without Better Clinical Outcomes

In addition to imposing unjustified and unachievable standards, the guidance includes clinical research and testing criteria that place new burdens on manufacturers with no evidence suggesting that this will result in development of products that will meaningfully advance the clinical management of diabetes. Faced with unreachable standards, and increasingly burdensome research criteria, many manufacturers may stop investing in the areas of diabetes management. Quite simply, without technology and innovation, our health care system gets worse.

Harms Patients and Increases Costs

In addition to imposing barriers to innovation and undermining the ability to advance new technology to help patients better manage their disease, this guidance fails do anything to control increasing health care costs. Diabetes is one of the biggest drivers of rising health care costs, and constructing more barriers to new technology will not help patients better manage their disease. In fact, it could lead to the use of less convenient, less practical tests that will increase burdens and cost. It could also force patients to wait longer for diagnoses and treatment in the hospital setting, making health care less efficient and more confusing for both patients and providers.

Rapid glucose testing provides immediate results that change the way people with diabetes live their daily lives. In the hospital setting, health care providers can more effectively manage their patients with diabetes when they have easy access to glucose readings. When consumers and hospitals don’t have convenient access to that information, poor treatment decisions follow, and our entire health care system could suffer.

CONCLUSION

In summary, there are already significant requirements that businesses need to satisfy as they research and develop new technology and products. This guidance would make it exceptionally more difficult to get new technology into the hands of the people who need it most, hurting American businesses and patients and benefiting foreign global competitors. Instead, the FDA should: enforce current standards first; use internationally recognized and clinically based
standards as the basis for any update; and explore ways to foster innovation to cultivate a healthier population, reduce unnecessary health care costs, and strengthen the nation’s economy.

Withdrawing these Notices is an important and necessary first step. We look forward to working with the FDA to explore ways to improve the health of our country’s population, strengthen efficiencies, spur innovation, and reduce costs throughout the health care system.

Sincerely,

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