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EDITOR'S PAGE

Not Your Mother's FDA

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Today in *JACC: Heart Failure,* we initiated the first of a series of Perspective papers titled "FDA in the 21st Century" (1). These are invited summaries from U.S. Food and Drug Administration (FDA) leadership in the field of heart failure, highlighting processes and mechanisms of drug and device development in the new FDA 2016 and beyond. As we all know, the FDA is responsible for protecting us by ensuring the safety and efficacy of drugs, biological products, and medical devices; making sure that our nation's food supply is safe; ensuring that products that emit radiation are not harmful; and regulating the manufacturing, marketing, and distribution of tobacco products. Beyond this, the FDA also is a strong advocate of public health by fostering innovative approaches and solutions for some of the country's most difficult health and medical problems. FDA-regulated medication and devices are among the most common therapies used to treat patients with heart failure. In this mission, the FDA is committed to getting accurate evidence-based information in the hands of the people who are affected by cardiovascular disease to improve health and avoid other products that may be harmful.

The *JACC: Heart Failure* FDA series will highlight and foster greater transparency and openness of the new FDA policies and initiatives and will educate clinicians, clinical investigators, and patients on the processes of how therapies come to market, how we monitor therapies when they are on the market, and how we protect against harm from food and tobacco products.

In this first of the series, Dr. Hillebrenner (1) focuses on device development, safety surveillance, and innovation. As you can see, enormous energy and emphasis has been placed on the device side of the FDA to improve value, efficiency, and opportunity for the patients we serve and for the innovators who bring forth novel devices. Our goal this year is to stimulate an interaction between the broader audience of heart failure and cardiovascular specialists and the FDA so that we can accomplish our mutually beneficial goals of improving heart failure human health.

This series of invited papers by leading scientists begins with today's issue with device review, followed by a review of drug products, the third on tobacco products, and the fourth on food and nutrition, which is particularly timely following new policies regarding tobacco products and new guidance on sodium restriction and food labeling. As the FDA approval process is the final stage of development, it may also be surprising to learn they are among the fastest in the world, meaning many Americans do have first access to new drugs and devices, information on food products, and avoiding harm from tobacco products. Just in the past year, over 50 new molecular entities and biological products were approved, including several orphan drugs for rare diseases. It is the additional goal of this series to stimulate innovation by demonstrating the joint collaboration of the FDA with the academic and practicing community, patient groups, and industry. It is this type of collaboration that will help move the needle forward in our effort to jointly improve the health of our heart failure patients that they so importantly deserve.

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