

# Antitrust Measures Support Quality Patient Care

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FROM THE ANNUAL MEETING OF THE AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

CHICAGO — Contrary to common perception, “the nation’s antitrust laws allow—even encourage—doctors to collaborate in ways that lower costs and improve patient care,” according to Jon Leibowitz, chairman of the Federal Trade Commission.

If doctors join forces to fix prices, the FTC will stop them, but if they work together to deliver affordable, high-quality care, “not only will we leave you alone, we’ll applaud you. And we’ll do everything we can to help you put together a plan that avoids antitrust pitfalls,” Mr. Leibowitz said in a speech that sought to dispel any stereotype that physicians might have of the commission as being

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run by “fastidious bureaucrats” and “sur-reptitious socialists,” determined to keep doctors from charging fair prices for their services.

“Too often, I believe, our antitrust enforcement actions are portrayed as a barrier to improved care. If there is any stereotype I would like to disabuse you of today, that’s the one,” he said.

The relationship between organized medicine and the FTC has become strained recently by physician opposition to the “Red Flags Rule” that requires small businesses, including medical practices, to develop policies to detect and prevent identity theft.

The American Medical Association, the American Osteopathic Association, and the Medical Society of the District of Columbia filed suit against the FTC in May to block it from enforcing the rule against physicians. The “bureaucratic burden” imposed by the rule “outweighs any benefit to the public,” Cecil B. Wilson, then AMA president-elect, said in a statement.

Mr. Leibowitz said the commission agrees with physicians that the rule is overreaching, and has urged Congress to provide a legislative fix for the issue as soon as possible. “Fastidious bureaucrats aren’t pushing Congress to work quickly to fix the Red Flags Rule that has unintentionally swept up countless small businesses. ... The FTC is,” he said.

Mr. Leibowitz cited several areas for potential cooperation between physicians and the FTC, all stemming from the Affordable Care Act. The use of health information technology to improve work flow and monitor populations and individuals; clinical integration; and accountable care organizations (ACO) are among the areas that hold po-

tential for collaboration to improve quality and lower health care costs, he said.

Although they are not “a free pass to fix prices,” he said that health information technology systems “can be an important tool” to make patient care more effective and affordable. The FTC recently issued three favorable advisory opinions on HIT use by health care providers.

In the area of clinical integration, the

FTC provides guidance to providers in the form of advisory opinions regarding joint ventures. The FTC will analyze a proposal and, where feasible, provide an opinion on whether it would recommend an enforcement action if the proposal were implemented, he said.

With regard to ACOs (integrated health systems that will be responsible for providing care to defined populations), “there is already talk of their mov-

ing into the private sector,” and “we want to work with you moving forward” to avoid competition issues, he said. “As long as the government purchases the services and unilaterally sets payment levels and terms, there won’t be an antitrust issue.”

Dr. Leibowitz said the FTC will hold a public workshop this fall on competition policy, payment reform, and new care models, including ACOs. ■

## Easy to teach<sup>1</sup>

—Can be used in 6 straightforward steps

## Easy to use<sup>1</sup>

—Only long-acting insulin pen in which dose can be set from 1 to 80 units in 1-unit steps, dialed both up and down  
—Once opened, Lantus<sup>®</sup> SoloSTAR<sup>®</sup> can be used for up to 28 days and is not refrigerated

## Easy to inject<sup>1</sup>

—Dose cannot be dialed past the number of units left in the pen  
—It is important to keep the injection button pressed all the way in and to **slowly count to 10 before withdrawing the needle from the skin**. After a full injection, the number in the dose window will return to zero. These steps help ensure that the full dose has been delivered  
—To help ensure an accurate dose each time, patients should follow all steps in the Instruction Leaflet accompanying the pen; otherwise they may not get the correct amount of insulin, which may affect their blood glucose

## Important Safety Information for Lantus<sup>®</sup>

### Contraindications

Lantus<sup>®</sup> is contraindicated in patients hypersensitive to insulin glargine or one of its excipients.

### Warnings and precautions

Monitor blood glucose in all patients treated with insulin. Insulin regimens should be modified cautiously and only under medical supervision. Changes in insulin strength, manufacturer, type, or method of administration may result in the need for a change in insulin dose or an adjustment in concomitant oral antidiabetic treatment.

Do not dilute or mix Lantus<sup>®</sup> with any other insulin or solution. If mixed or diluted, the solution may become cloudy, and the onset of action/time to peak effect may be altered in an unpredictable manner. Do not administer Lantus<sup>®</sup> via an insulin pump or intravenously because severe hypoglycemia can occur. Insulin devices and needles must not be shared between patients.

Hypoglycemia is the most common adverse reaction of insulin therapy, including Lantus<sup>®</sup>, and may be life-threatening.

Severe life-threatening, generalized allergy, including anaphylaxis, can occur.

A reduction in the Lantus<sup>®</sup> dose may be required in patients with renal or hepatic impairment.

### Drug interactions

Certain drugs may affect glucose metabolism, requiring insulin dose adjustment and close monitoring of blood glucose. The signs of hypoglycemia may be reduced in patients taking anti-adrenergic drugs (e.g., beta-blockers, clonidine, guanethidine, and reserpine).

### Adverse reactions

Other adverse reactions commonly associated with Lantus<sup>®</sup> are injection site reaction, lipodystrophy, pruritus, and rash.

## Indications and Usage for Lantus<sup>®</sup>

Lantus<sup>®</sup> is a long-acting insulin analog indicated to improve glycemic control in adults and children (6 years and older) with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus. Lantus<sup>®</sup> should be administered once a day at the same time every day.

Important Limitations of Use: Lantus<sup>®</sup> is not recommended for the treatment of diabetic ketoacidosis. Use intravenous short-acting insulin instead.

Lantus<sup>®</sup> SoloSTAR<sup>®</sup> is a disposable prefilled insulin pen.

**Please see brief summary of full prescribing information for Lantus<sup>®</sup> on the next page.**

References: 1. Data on file, sanofi-aventis U.S. LLC. 2. Lantus Prescribing Information. September 2009.