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Commissioner of Food and Drugs

**"Effective Enforcement and Benefits to Public Health"**

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**Food and Drug Law Institute**

Good afternoon. Thank you all for joining me today. I'd also like to thank FDLI for hosting this event.

This is my first presentation to FDLI as Commissioner... and I am looking forward to many more. I expect to discuss a wide range of important issues and efforts with you in the coming months and years.

I have just passed the eight-week mark for my time at the FDA. I can safely say that leading this vital agency is everything that I expected... and a **lot** more.

In my first weeks on the job, I have been especially impressed by FDA's career staff. I have met scores of public servants in our agency's headquarters and field offices who are subject matter experts... committed to their work... and devoted to advancing the health of our country. It is an honor to serve with them.

I have also appreciated the broad external support that exists for the FDA. In a series of listening sessions, I heard from representatives of more than 150 medical, industry, consumer, and patient organizations... including everyone from the Flavor Extract Manufacturers Association to "NAPNAP," the National Association of Pediatric Nurse Practitioners.

During these sessions, I have heard many different ideas and recommendations on a wide range of important issues. But I have also heard a common theme.

Again and again, from all sides of various questions, I heard support for a **strong FDA**... an agency that **protects** the safety of the food supply... an agency that facilitates access to **safe and effective** medical products... an agency for the American public to **count on**.

A strong FDA has credibility with the public.

A strong FDA is transparent in explaining its decisions.

A strong FDA pursues creative solutions to longstanding problems and is always looking for novel ways to prevent illness and promote health.

**And a strong FDA enforces the law.**

Every company with products or activities under FDA's jurisdiction has a duty to comply with the law... to meet the standards that the FDA has set to protect the public. I have been impressed by the commitment to compliance that many companies have made – both in terms of their corporate culture and their investment in compliance systems.

Our goal is for all companies to make and implement such a commitment in order to prevent harm to the American people. We have a responsibility to clearly articulate and explain our rules and regulations, but a key part of the strategy to support private sector compliance is effective enforcement against violations of the law.

Effective enforcement has many clear benefits to public health.

It enables FDA to intercept unsafe or fraudulent products promptly... and prevent additional harm.

By holding violators accountable, enforcement deters others who would put the public at risk or prey upon vulnerable consumers.

Visible and clearly explained enforcement actions inform members of the public about potential dangers.

And enforcement helps industry too – by maintaining a level playing field for safe products. Making sure that offenders are held legally accountable prevents companies from having to choose between doing the right thing and staying competitive.

Ultimately, an effective enforcement strategy creates public confidence in FDA oversight... which in turn keeps trust in the safety of FDA-regulated products from eroding. Such confidence is critical to the long-term interest of both consumers and industry.

I appreciate the opportunity today to provide my perspective on enforcement at the FDA. I will start by describing the elements of effective enforcement. I will then announce six initial steps to strengthen enforcement at the FDA... and discuss two examples of recent enforcement actions taken by the agency. Finally, I will conclude by explaining what the FDA's evolving approach to enforcement means for regulated industry.

An effective enforcement strategy depends on several key elements.

The FDA must be **vigilant**. Through regular inspections and follow-up on signals indicating problems, the FDA must work to identify and resolve problems early. Sometimes problems can arise despite the best of intentions and efforts to adhere to best

practices. When this is the case, our expectation is that companies will work to quickly and thoroughly correct deficiencies and ensure safety. Companies must have a realistic expectation that if they are crossing the line, they will be caught, and that if they fail to act... we will.

The FDA must be **strategic**. The agency must place greater emphasis on significant risks and violations, and use meaningful penalties to send a strong message to discourage future offenses.

The FDA must be **quick**. The agency must be able to respond rapidly to egregious violations or violations that jeopardize public health.

And the FDA must be **visible**. The agency must show industry and consumers that we are on the job. We must publicize our enforcement actions – and the rationale for those actions – widely and effectively. This will increase public confidence, encourage compliance, and educate patients and consumers about potential risks.

In recent years, the Government Accountability Office and others have suggested that the FDA's enforcement efforts may not have always lived up to these principles.

Reports have noted that there has been a steep decline in the FDA's enforcement activity over the past several years. At the same time, many of the enforcement actions that the FDA has undertaken have been hampered by unreasonable delays.

In some cases, serious violations have gone unaddressed for far too long. These include violations involving product quality, adulteration, and misbranding; false, misleading, or otherwise unlawful labeling; and misleading advertising.

These delays do not result from a lack of commitment by FDA career staff. There are hundreds of dedicated investigators, special agents, and other enforcement personnel at the FDA who come to work ready to protect their families, their communities, and the general public from harm.

Rather, the pathways for enforcement action can be too long and arduous when the public's health is in jeopardy.

We are fixing these pathways to improve the effectiveness of our enforcement system.

Today, the FDA is taking several initial steps in this direction.

First, the FDA will set post-inspection deadlines. When the FDA finds that a firm is significantly out of compliance, we expect a prompt response to our findings. Once the FDA provides inspection findings identifying a serious problem, the firm will generally have no more than fifteen working days in which to respond before the FDA moves ahead with a warning letter or enforcement action. This will help FDA issue warning letters on a timely basis and facilitate prompt corrective action.

Second, the FDA will take responsible steps to speed the issuance of warning letters. I have approved a new policy brought forward by the FDA's Chief Counsel to limit warning letter review to significant legal issues. As a result, most enforcement letters will be able to move forward through a more streamlined process. This approach is consistent with the FDA's longstanding historical practice.

Third, the FDA will seek to work more closely with our regulatory partners to develop effective risk control and enforcement strategies. In many food safety cases, for example, local, state, and international officials have more authority to take action quickly than the FDA. When the public health is at risk, the FDA will reach out to our partners to take rapid action while we alert the public and prepare longer-term responses.

Fourth, the FDA will prioritize enforcement follow-up. After a warning letter is issued or a major product recall occurs, we will make it a priority to follow up promptly with appropriate action, such as an inspection or investigation to assess whether or not a company has made required changes in its practices.

Fifth, the FDA will be prepared to act swiftly and aggressively to protect the public. The FDA will no longer issue multiple warning letters to noncompliant firms before taking enforcement action. If we find that we must move quickly to address significant health concerns or egregious violations, we will consider **immediate** action – even **before** we have issued a formal warning letter.

These five procedural changes will help to ensure that violations are taken seriously, that warning letters and enforcement actions occur in a timely manner, and that steps are taken to protect consumers in cases where immediate enforcement action is not possible.

A sixth new practice is a little different from the others. It relates to our response to firms **after** they have made necessary corrections.

At my direction, the FDA is developing a formal warning letter “close-out” process. If the FDA can determine, usually based on a re-inspection, that a firm has fully corrected the violations raised in a warning letter, we will provide to the firm a “close-out” letter, indicating that the issues in the warning letter have been successfully addressed. To keep the public informed, we will indicate on our website when a firm has received a “close-out” letter.

Not every type of warning letter will be eligible for a “close-out” letter. But for ongoing violations, it could play an important motivating role in spurring corrective action.

I hope that receiving a “close-out” letter quickly becomes a top industry priority.

These six changes are significant steps in the right direction. The FDA is fortunate to have received significant funding increases for the current and next fiscal year that will be devoted to additional inspection and compliance activities that will support the elements of an effective enforcement strategy that I have outlined.

But I recognize that there is more to be done.

Internally, we must better integrate field and center efforts for more effective and timely enforcement.

With the public, we must explain our enforcement efforts as well as possible... and work with the public and other stakeholder groups to determine where we could be more effective in fostering compliance and enforcing the law.

With regulated industry, we must listen to concerns about where our enforcement efforts do not yield improvements for public health.

With our national and international partners, we must find ways to ensure that global and domestic companies secure their increasingly complex and ever-growing supply chains.

And with Congress, we must seek more effective enforcement tools. I was heartened by the House's passage of a major food safety bill last week. The proposed legislation would greatly enhance our ability to prevent food-borne illness through standard setting and inspections and would, among other things give the FDA mandatory recall authority for tainted foods. I thank the President and the Secretary of Health for their strong leadership on these issues.

In recent months, the FDA has taken some key enforcement actions. To illustrate some of the points I am making today, I would like to turn to two specific examples.

Soon after identification of the H1N1 influenza virus, several websites began to promote products that fraudulently claimed to diagnose, prevent, or treat the virus. These products included everything from a shampoo that claimed to protect against H1N1... to a costly electronic device that claimed to use "deeply penetrating mega-frequency life-force energy waves." Many of the products made claims that sounded more plausible, but were still fraudulent.

There is no question that these deceptive websites could confuse consumers and prevent them from seeking appropriate and necessary medical treatment.

On May 1, the agency issued a general warning to consumers about Internet sites and other promotions for products that claimed to diagnose, prevent, or treat the H1N1 virus. As of early this week, the FDA had issued sixty-five warning letters to offending websites, covering over 125 fraudulent products.

Eighty percent of these websites have complied with the FDA's requests. By mid-June, the rate at which new websites were cropping up had slowed from ten per day to about two per week.

Our approach caught the attention of the blogosphere and the trade press. One blogger wrote, "This is a definite change that I am a little **surprised** to see." ... A trade press op-

ed said, “FDA is taking **extraordinary** measures to protect the public from illegal H1N1 products....”

I hope that in the future, effective FDA enforcement actions will **not** be surprising... or out of the ordinary.

Last week, we took action against companies selling anabolic steroids under the guise of dietary supplements.

One manufacturer, American Cellular Labs, sells eight of these products on its website. The site promotes the products with claims like, “MASS Xtreme is perfect if you are focused on adding muscle mass, power and strength to your physique,” and “ESTRO Xtreme... You get two estrogen blocking effects in one fantastic product!”

In fact, these over-the-counter body-building products have been associated with serious and life-threatening adverse events, including liver injury, stroke, kidney failure, and pulmonary embolism.

These are unproven and unapproved drugs, not dietary supplements.

In addition to sending warning letters, the FDA has posted a Public Health Advisory and other materials urging consumers to stop taking body-building supplements from any manufacturer that are labeled as containing androgen-, estrogen-, and progestin-related active ingredients. By pairing enforcement action with education, we hope to prevent others from being harmed by these products.

This action is not the end of our efforts on the illegal sale of anabolic steroids, nor is our work on H1N1-related fraud complete.

But I mention them to point out how specific enforcement actions serve key public health goals – to promote effective management of influenza... and to help people avoid illegal and potentially dangerous anabolic steroids.

Ultimately, the FDA’s success should be measured **not** by the number of warning letters or injunctions or seizures ... but by our impact on the health and welfare of the public. Enforcement of the law is not simply an end in itself... enforcement is critical to the agency’s public health mission.

This connection between the law and public health is as true for industry as it is for FDA.

When you fail to meet the standards that the FDA has set to prevent harm... then you are putting the public at risk. You are also jeopardizing the public’s confidence in your industry.

The solution is a commitment to compliance backed by a strong compliance program. Now is a good time to reassess whether you have such an effort in place.

As I enter my third month at the FDA, I thank you for your support and look forward with enthusiasm and optimism.

Ensuring the safety of FDA-regulated products is a shared responsibility... and the FDA is ready to do its share.

Thank you for your time and attention.