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August 31, 2006

Dr. Andrew C. von Eschenbach, M.D.
Acting Director
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville MD 20857-0001

Dear Dr. von Eschenbach:

I am writing to direct your attention to a potentially alarming situation in which young patients and their parents may not be receiving the information needed to make fully informed decisions about antidepressant medications. Specifically, it has been brought to my attention by constituents in my New Jersey district that FDA-required Medication Guides are not distributed when antidepressant medications are dispensed, even though such distribution is required under a regulation introduced by your agency on October 15, 2004 and finalized February 3, 2005.

In examining this issue, my staff has spoken with FDA officials and representatives of the National Association of Chain Drug Stores, the National Community Pharmacists Association, the New Jersey Pharmacists Association, the New Jersey State Board of Pharmacy and two of the pharmaceutical companies, Eli Lilly and Company and GlaxoSmithKline, that manufacture antidepressant medications.

At this point in my examination, it appears that a significant breakdown has occurred between the FDA and state regulatory authorities – a breakdown that is depriving parents of children to whom antidepressant medications are prescribed of their ability to make fully informed decisions. For example, it is impossible to determine with certainty that the Medication Guides are in fact being distributed with the prescribed antidepressant medications because regulatory authorities at the federal and state levels are not enforcing the FDA's stated protocol on Medication Guides.

As you know, the use of antidepressant medication is controversial, particularly by children and adolescents. In September 2004, I participated in hearings conducted by the House Energy and Commerce Committee's Oversight and Investigations Subcommittee concerning the pediatric use of antidepressants. At that hearing, I strongly advocated that the FDA issue "black box" warnings – the highest FDA warning on prescription drug labels – regarding the potential serious side effects of the pediatric use of antidepressants.

Later that month, the FDA's Psychopharmacologic Drugs Advisory Committee and Pediatric Drugs Advisory Committee discussed and ultimately issued recommendations concerning these drugs and their use by children and adolescents – which included the black box warnings.

The FDA on October 15, 2004, echoed the advisory committees' recommendations and issued a Public Health Advisory announcing a "multi-pronged strategy" to warn the public about the increased risk of suicidal thoughts and behavior in children and adolescents being treated with antidepressant medications. The strategy's main components were the issuance of the black box warning, the creation of a Medication Guide to be distributed with each prescription dispensed to a child or adolescent and the formulation of "unit of use" packaging for ease in disseminating information.

As part of the oversight responsibility of the FDA by the House Energy and Commerce Committee, I have maintained strong interest in issues concerning these drugs and their use by children and adolescents.

It was my belief in 2004 during the congressional hearings, and it remains so now, that these drugs must be administered to children and adolescents under the strictest scrutiny. I believe that the Medication Guides are a vital component to the overall strategy of ensuring that fully informed decisions are made by parents before their child begins a regimen of antidepressant medications. Indeed, it is for this reason that I find deeply troubling the apparent lack of regulatory oversight to ensure the Medication Guides in fact reach parents.

An FDA representative told my staff that the FDA's policy on all Medication Guides is as stated:

> 21 CFR 208.24 (e): *Each authorized dispenser of a prescription drug product for which a Medication Guide is required under this part shall, when the product is dispensed to a patient (or to a patient's agent), provide a Medication Guide directly to each patient (or to the patient's agent) unless an exemption applies under 208.26.*

Although the FDA had the authority to issue the above regulation, an FDA representative told my staff that the agency did not have the authority to enforce the regulation and that oversight of pharmacists falls to state regulatory authorities.

When my staff contacted a representative of the New Jersey State Board of Pharmacy, the official, after reviewing the federal regulation, acknowledged the state has the authority to enforce the regulation and would indeed take steps to ensure its requirement is carried out. But, the representative also said that, until contacted by my staff, the state agency was unaware of the specifics of 21 CFR 208.24, the strong Medication Guide distribution goals for antidepressants outlined in the October 15, 2004 Public Health Advisory and had received unclear and confusing correspondence from the FDA about enforcing the distribution of Medication Guides for antidepressants.

Similarly, representatives of the National Association of Chain Drug Stores, the National Community Pharmacists Association and the New Jersey Pharmacists Association told my staff that they, too, had received vague correspondence from the FDA alerting them to the regulation and its enforcement. In conversations with my staff, the organizations each pointed to the regulatory responsibilities of the state boards of pharmacy and the importance of continuing education received by pharmacists to update them on requirements. In addition, a representative of the National Association of Chain Drug Stores mentioned a number of proactive steps member companies were taking to make it easier for pharmacies to provide Medication Guides to patients, but also pointed to a perceived lack of cooperation by the FDA as a hindrance to their effort to improve the distribution system of Medication Guides.

Representatives of Eli Lilly and Company and GlaxoSmithKline told my staff that they are complying with the regulation on Medication Guides. But with the apparent breakdown between the FDA and state regulatory authorities, it cannot be said with certainty that your agency's regulation is in fact being carried out. Are the pharmaceutical companies, as required by the regulation, in fact printing and distributing the Medication Guides to pharmacists? What steps do the pharmaceutical companies take to ensure pharmacists receive the Medication Guides? Despite some proactive steps to improve distribution, are pharmacists distributing the Medication Guides to patients as required by the regulation?

It appears that the regulatory authorities involved are not exhibiting the necessary attention needed to answer these questions. It may well be that many – perhaps the overwhelming majority – of the antidepressant medications dispensed include the Medication Guides. But if it cannot be said with certainty that the Medication Guides reach parents 100 percent of the time, the regulation is broken and public safety is jeopardized. Even if one parent failed to receive the required Medication Guide, that parent through no fault of their own cannot make a fully informed decision about whether antidepressant medications are appropriate for their child – and the consequences of a less than fully informed decision could be deadly.

Therefore, I respectfully ask that you respond in writing by September 15, 2006, to the following questions:

1. If in fact the FDA lacks the statutory or regulatory authority to enforce its regulation on Medication Guides, do you recommend that Congress consider giving the FDA such authority to ensure pharmaceutical manufactures are delivering the Medication Guides and that pharmacists are dispensing them? If not, please explain why granting the FDA such authority would undermine the public policy objectives of seeking to ensure that this particular regulation is enforced.

2. What FDA statutory or regulatory authority currently exists that would permit the agency to contact state regulatory authorities, national pharmacist trade associations and professional associations, and individual pharmacists themselves to inform them of the Medication Guide regulation and ensure its compliance? If none exists, beyond publishing the regulation in the Federal Register, does the

FDA recommend that Congress enact legislation giving the agency such authority, and if so what specific steps does the FDA recommend to ensure uniform education among all stakeholders and uniform compliance?

In separate correspondence, I am asking the New Jersey State Board of Pharmacy whether it has the statutory authority, under state law, to enforce this regulation, whether it has the resources to enforce the regulation, and the specific steps it will take to ensure the regulation is enforced. I also am contacting the National Association of Chain Drug Stores, the National Community Pharmacists Association and the New Jersey Pharmacists Association to determine if in fact they are receiving the Medication Guides and what steps their members are taking to ensure that the Medication Guides are distributed when antidepressant medication is dispensed.

Representatives of GlaxoSmithKline and Eli Lilly and Company have told my office that they are in fact providing the Medication Guides by attaching it to the bottle when shipping their pharmaceutical products to drug wholesalers. In separate correspondence, I am also contacting GlaxoSmithKline and Eli Lilly to request in writing details of how they provide the Medication Guides in house, including best practices, and what review, if any, they are performing to ensure they are distributing the Medication Guides in compliance with the regulation.

Your responses to the above questions, along with the responses of the other stakeholders, will allow me to complete my examination and determine whether to request that the Oversight and Investigations Subcommittee, on which I serve as a member, hold hearings on this issue and/or whether I will introduce legislation in the House to rectify the existing breakdown and ensure your agency's regulation is fully implemented.

Of course, I want to ensure all patients, including children, have access to the safest and most effective therapies, including, as appropriate, antidepressant medication. Still, your agency has rightly implemented strict requirements on the prescribing of these drugs with the black box warnings and the Medication Guides. Those and other requirements are necessary to ensure that those to whom antidepressant medications are prescribed – including the parents of children and adolescents – have the information they need to make fully informed decisions. If these needed requirements are not being fully implemented, however, the public cannot make fully informed decisions and therefore may be placed at risk.

I look forward to your complete and timely response.

Sincerely,

Mike Ferguson
Member of Congress