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ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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June 13, 2013

Dr. Janet Woodcock
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Woodcock:

Thank you for appearing before the Subcommittee on Health on Thursday, May 23, 2013, to testify at the hearing entitled "Examining Drug Compounding."

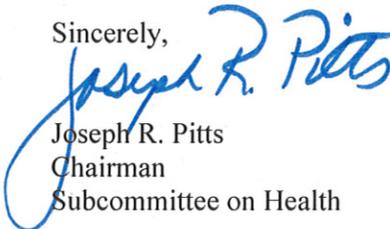
Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

Also attached are Member requests made during the hearing. The format of your responses to these requests should follow the same format as your responses to the additional questions for the record.

To facilitate the printing of the hearing record, please respond to these questions and requests by the close of business on Thursday, June 27, 2013. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Sydne.Harwick@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachments

Attachment 1—Additional Questions for the Record

The Honorable Joseph R. Pitts

1. In your testimony, you reference nine separate incidents where compounded products caused deaths and serious injuries. Please explain the actions that the FDA took following each incident. What happened to the pharmacies where these contaminated products originated?
2. More likely the FDA has gone through extensive self-evaluation to fully comprehend every single regulation related to compounding. You are likely more knowledgeable now about the current compounding regulations than you were six months ago. It would be invaluable for this subcommittee to know exactly what the FDA CAN do before we determine what you cannot do. So, please explain the tools you currently have.
3. Between 2002 and 2012, NECC was the subject of at least 52 adverse event reports. Numerous offenses were documented throughout investigations at NECC undertaken by both the FDA and state regulators. Why did the agency not shut down NECC after these inspections? Did NECC challenge the FDA's authority to inspect?

The Honorable Marsha Blackburn

1. I am concerned about the growing incidence of skin cancer in the United States and the significant delay in providing the latest sunscreen technology to help address this risk from exposure to the sun's harmful rays. According to the Skin Cancer Foundation, Americans are diagnosed with more than 3.5 million cases of skin cancer each year and 1 American dies every hour from melanoma, the most deadly form of skin cancer.

I understand that FDA created the Time and Extent Application process in 2002 to streamline applications for over-the-counter applications, such as sunscreens, however FDA has not made a final decision on any product through the TEA process. In fact, eight new sunscreen ingredients have been waiting for FDA review, some for over 10 years. The TEA process is clearly broken and needs to be reformed.

- a) In light of the public health epidemic regarding skin cancer, please explain the significant delay in making a final decision on any of the 8 pending sunscreen applications.
 - b) Please also explain why taking final action on the 8 pending sunscreen applications has been on the FDA's Unified Agenda as a priority since 2008, however no action has been taken.
 - c) Will you commit to work with Congress and stakeholders to enact reforms to the TEA process that will ensure that sunscreen products receive a transparent review and a predictable timeline for consideration?
2. As you may know, on January 1, 2013, CMS made a technical change to its billing methodology for compounding pharmacies providing drugs used in implanted pain pumps. This change requires pharmacies to sell these compounded medications to physicians who then re-sell them to the patient and bill Medicare. Prior to January 1st, pharmacies were not required to sell the drugs to the physician and instead could bill Medicare directly. To further complicate the matter, the Tennessee Board of Pharmacy does not allow pharmacies to sell these compounded medications to physicians for resale to patients. This practice is also illegal in Mississippi, and other state Boards of Pharmacy are assessing the impact of CMS' change on pharmacy practice. I am concerned that this technical

change has jeopardized access to necessary pain medications for some of Medicare's most vulnerable beneficiaries. Even more, this change – prohibiting pharmacies from billing Medicare directly – eliminates an important accreditation requirement designed to protect patient safety. Pharmacies billing Medicare directly for these drugs must comply with Medicare supplier standards and federal regulations, such as U.S. Pharmacopeia 797. These standards provide an additional layer of quality promotion and patient safety for pharmacies compounding and dispensing sterile products for use in implanted pain pumps.

Saying all of this, do you find it concerning that CMS – in the wake of a tragic outbreak, in spite of state pharmacy law, and in spite of stakeholder opposition – is encouraging pharmacies to sell drugs directly to physicians as opposed to billing Medicare directly and complying with quality accreditation standards?

For at least 20 years prior to 2013, pharmacies had billed Medicare directly for these patient specific compounded medications, and the National Home Infusion Association supports legislation sponsored by Congressman Harper (HR 232) which would restore access to these therapies for beneficiaries. Saying all of this, do you find it concerning that CMS – in the wake of a tragic outbreak, in spite of state pharmacy law, and in spite of stakeholder opposition– is encouraging pharmacies to sell drugs directly to physicians as opposed to billing Medicare directly and complying with quality accreditation standards?

3. As you may or may not know, the State of Tennessee recently passed legislation that allows pharmacies to compound products for use in a practitioner's office for administration to that prescribing practitioner's patients – a practice known as “office use” compounding. It is my understanding that 43 other states also allow for office use compounding.
 - a. What is the Agency's position regarding traditional compounding taking place in an office setting?
 - b. Should this be regulated by the FDA or State Boards of Pharmacies? Please explain.

The Honorable Renee Ellmers

1. Are compounders making the same products that drug-manufacturers make? I know it may be in a different form, but is it the same product?
2. Currently, do compounders have the same regulations and requirements that drug manufacturers have? Why or why not?
3. What are the changes to compounding you propose making in order to prevent the meningitis outbreak last year and ensure compounded products are safe?
4. Is there a limit to how much product a compounder can make?
5. You testified before the Senate HELP committee regarding their legislation on May 9, 2013. Under this legislation, would compounded drugs manufactured by the new entity (compounding manufacturer) be subject to the same requirements as current manufacturers under the Federal Food, Drug, and Cosmetic Act?
 - a. If yes, can you describe those requirements?
 - b. If no, how are the standards different – and why are they different?

6. How do drug manufacturers today assure the raw materials (or Active Pharmaceutical Ingredient “API”) used to create a drug are safe? What is the certification process?
7. How do compounders access the API they use? Is their API FDA –approved?
8. Don’t drug manufacturers pay much more than a compounding manufacturer would under the User Fee structures? Why aren’t compounders paying more if they are making the same product? Or more importantly, if I’m an FDA –licensed drug maker, why don’t I just become a compounder? It would be cheaper and a lot less paperwork?
9. There is some talk that compounding manufacturers could be utilized to help end drug shortages. Currently, how are drug shortages determined? Are there different levels of drug shortages?
10. Is the FDA drug shortage list the only list used?
11. How does a drug get off the drug shortage list? Who determines that?
12. For products on the drug shortage list, many of which are sterile injectable drugs, should a compounder be held to the same level of standards and requirements as the current manufacturers?
13. How many drug shortages would be relieved if compounders mass-manufactured product?
14. How would the safety of these compounded drugs be assured? What are the testing processes?
15. Will there be any differences between the standards and regulations of the compounding manufacturer and today’s manufacturers?
16. Can you provide more clarity/detail on the differences between the two levels of standards between today’s manufacturers and the compounding manufacturer?
17. If the full requirements and standards are different for products on the drug shortage list produced by a compounding manufacturer than those of today’s manufacturers, how will this ensure the greatest level of confidence and safety in these products?
18. Do doctors and hospitals tell a patient that the drugs they are receiving are manufactured by a compounding manufacturer?
19. Should hospitals and providers require a patient to sign a release for any liability if the hospital or provider gives a compounded drug that is not manufactured under the same safety requirements of drug manufacturers?

Attachment 2—Member Requests for the Record

During the hearing, Members asked you to provide additional information for the record and you indicated that you would provide that information. For your convenience, descriptions of the requested information based on the relevant excerpts from the hearing transcript regarding these requests are provided below.

The Honorable Joseph R. Pitts

1. You testified during the hearing that several companies have challenged your authority while the FDA was conducting inspections. Please provide a list to the committee of the companies that the FDA inspected, those that challenged your authority, and the grounds by which the companies challenged your authority.

The Honorable Michael Burgess

1. There was a discussion regarding the level of difficulty of obtaining an injunction from a judge. Please provide a list of how many times you have not prevailed in obtaining an injunction? (pg. 35)

The Honorable John D. Dingell

1. Please explain the authority the FDA needs to require all compounding pharmacies to register with the agency.
2. Please explain the authority the FDA needs to require all compounding pharmacies to report adverse events.
3. Please explain the authority the FDA needs to require all compounding pharmacies to follow good manufacturing practices.
4. Please explain the authority the FDA needs to require nontraditional compounders to be subject to appropriate good manufacturing practices the way manufacturers are.
5. What authority does the FDA need to ensure risk-based inspection schedules are appropriate for non-traditional compounders?
6. Please explain the authority the FDA needs to see all records when inspecting a compounding pharmacy.
7. Please explain the authority the FDA needs for a fee system for the approval of pharmaceuticals and medical devices.
8. Please explain the need for a strong user fee program.

The Honorable H. Morgan Griffith

1. The FDA was prepared to release guidance proposals in August of 2012. Please explain why this guidance does not adequately address pharmacy compounding.