[IACP Logo]

May 7, 2013

Good morning Chairman Harkin, Ranking Minority Member Alexander and Senate H.E.L.P. Committee members. On behalf of the International Academy of Compounding Pharmacists (IACP), I am pleased to stand before your committee to offer the insights of the International Academy of Compounding Pharmacists (IACP) and our recommendations about the draft legislation put forward by the Committee. Specifically, IACP wants to take this opportunity to

comment on the compounding pharmacy legislation and how it will likely impact our industry, patients and practitioners.

IACP applauds the steps the Committee and the U.S. Senate are taking to ensure that compounded medications are as safe as they can be. IACP believes that the safety of patients must always be the first consideration of any pharmacy-oriented public policy.

We have reviewed the draft and we see that there are some aspects that will need further discussion and refinement, and we intend to work with the Committee on these. The draft does not contain any provisions that speak directly to USP standards, which are aimed at raising the quality of compounded medications. Additionally, IACP is concerned that some provisions may reduce patient and physician access to customized medications, the very services that compounding pharmacists provide.

IACP reiterates its position that state boards of pharmacy are responsible for the licensing and oversight of compounding pharmacies and the FDA is responsible for overseeing and regulating pharmaceutical manufacturers. We think the term "compounding manufacturer" and several of the definitions of that new category create more confusion and further blur the jurisdictional authority of

regulators. IACP will recommend improvements in the draft language to make the proposed categories more clear.

Most importantly, IACP is gravely concerned that compounding pharmacies located in hospitals and health systems have been exempted from many of the proposed changes. Such an exemption denies patients

and their families the assurance, regardless of where they receive their medications, of the quality and safety that they deserve.

IACP appreciates the opportunity to work with the Senate HELP Committee to ensure that a tragedy like the one that occurred last year, when compounded preparations dispensed by a Massachusetts licensed pharmacy caused an outbreak of fungal meningitis, never happens again. It is with that crisis in mind that we have reviewed the draft legislation to determine if it will likely prevent a future scenario similar to that which occurred with NECC.

IACP is a non-profit professional association representing more than 2,700 pharmacists, technicians, students, and members of the compounding community who focus on the specialty practice of pharmacy compounding. The IACP is and has been committed to working in collaboration with state and federal officials to ensure the safe practice of pharmacy compounding. Our ultimate goal is to ensure patient safety, while ensuring continued patient access to compounded medication necessary for their particular medical condition.

In December 2012, the Academy issued a series of recommended changes to state pharmacy laws and regulations that it believes will both enhance the protection of public health while preserving the professional decision making of pharmacists in the selection and preparation of customized medication solutions.

These proposed changes address three key areas: inspection authority and adequate funding of all state Boards of Pharmacy; compliance with laws and regulations by all pharmacists and pharmacy

technicians in all practice settings, as well as other health care practitioners involved in compounding; and adherence to nationally recognized quality standards. As you know, many states have already been working to enact or establish new laws and rules governing the practice of pharmacy compounding. IACP has been actively involved in those efforts in an attempt to strengthen and clarify appropriate and safe pharmacy practices. As a matter of fact, IACP has been actively engaged in these discussions – not to lessen oversight on pharmacy practices, but to encourage maximum patient safety protections, while

ensuring that compounded medications do not become distinct as a result of what NECC – a rogue manufacturer – did.

IACP take strong issue with the terminology used throughout the bill to define the new category of manufacturer as a "compounding manufacturer." Not only do we think this causes confusion, but it also seems to make the very practice of compounding synonymous with that of manufacturing. In fact, the practice of compounding is at the very root of pharmacy practice. Thus, IACP recommends that the new

category be called “non-traditional manufacturing” and we have made those edits in the attached draft bill.

We ask the Committee to keep in mind that a significant number of people have unique health needs that off-the-shelf, one-size-fits-all prescription medicines cannot meet. These include children, the elderly, and those for who manufactured drug products are not available in the appropriate strength, dosage form, or composition. For them, customized medications are the only way to better health and those valuable preparations are available only by compounding. Thus, there is

a medical need for variations in medical dosages, delivery forms, the removal of excipients, etc. for various patient groups. That is why the very practice of compounding exists. IACP urges the committee to recognize this and not prohibit physicians from prescribing medications needed by both their human and animal patients.

Unfortunately, there are significant parts of the draft bill that have nothing to do with safety, but have to do with curtailing competition. IACP is aware that a good part of the anti-competitive language (not allowing dosage variations) comes from the large pharmaceutical

manufacturers on both the human and animal side who wish to curtail compounding altogether. IACP hopes that the bill will remain focused on the end goal – that being patient safety, not getting rid of competition in the marketplace. It is not the time to attack compounding pharmacies from a commercial perspective as a result of other (monetary) motives. Safety should remain the objective of this bill.

IACP wants to make sure that any final bill moving through the Senate balanced in a manner that does not restrict a doctor's ability to prescribe and obtain compounded medications for those patients who

require them as part of their necessary therapy. Moreover, manufacturers often discontinue a number of FDA-approved drugs that serve a limited population. In many of these cases, the only option left for doctors and their patients is to have a compounding pharmacist make the discontinued drug pharmaceutical grade ingredients obtained from an FDA-registered supplier.

IACP remains concerned about language in the bill that further brings practices under the domain of manufacturing.

(ii) that repackages a drug using sterile preservative-free single-dose vials or by pooling sterile drugs.

This is problematic for several reasons. Under this language, physicians who repackage in their offices would automatically become manufacturers. Additionally, this language was clearly added at the behest of a pharmacy manufacturer which has been trying to deter doctors from prescribing one of their drugs in lieu of another of their more expensive products. This language seems to have been added for competitive reasons, rather than safety reasons. This provision would

also include a large number of home infusion pharmacies who fall under these criteria (the pooling provision) for administration of parenteral nutritional therapies. They would, under this provision, have to register and comply with the law as a manufacturer. IACP strongly recommends that this section be stricken.

While the IACP continues to strongly believe that the regulation of compounding should continue to be overseen by state Boards of Pharmacy and that improvements may need to be made to current state pharmacy laws (many of states have already made changes, which

IACP urges the Senate not to make moot), we understand the importance in determining what greater clarity in differentiating between drug compounding and drug manufacturing may be needed.

What we find interesting about this bill is the fact that you are taking away two existing regulatory authorities and streamlining it under one – the FDA (whose track record is not at all impressive – take Ameridose and their many problems as an example).

State Boards of Pharmacy, through their ongoing regular inspections, knowledge of unique state laws, regulations and rules, as

well as having practicing pharmacists as their members who are engaged in day-to-day patient care, are in the best possible position to determine whether a pharmacy has exceeded its scope of practice or engaged in activities that may constitute manufacturing. That said, IACP recognizes that the oversight and regulation of prescription drug manufacturing rests with FDA, and that the Agency has the authority to identify and require the registration of any entities it believes are engaged in such activity.

IACP believes that language should be included in the legislation which requires a clear (and formal) exchange of information from the FDA to the State Boards and in the reverse – from the State Boards to the FDA if and when a pharmacy may be suspected of operating outside the parameters of pharmacy practice. Efficient and effective communication with state Boards of Pharmacy is essential to prevent the Agency's unilateral determination that a pharmacy's professional and business activities exceed the state specified scope of practice.

Without such coordination any proposal is unlikely to achieve its goal or to improve public health safety.

The Academy also believes that some language contained in the bill micromanages the State Boards of Pharmacy on issues related to "office use" and "anticipatory compounding." Since many states have already taken action to address these issues, IACP does not believe it is appropriate for the federal government to regulate the practice of pharmacy. By specifically requiring only patient-specific prescriptions as part of the "test", the FDA appears to circumvent those individual

state's laws, regulations and rules that enable prescribers to obtain compounded preparations for administration to or treatment of patients within their practices.

Office-use dispensing is the preparation, labeling, and dispensing of a medication by a pharmacist and pharmacy upon the receipt of a prescription *or* medical order from an identified authorized prescriber (e.g. physician, nurse practitioner, dentist, veterinarian, etc.) for that prescriber's use in the treatment of or administration to a patient during their normal course of medical practice. Office-use dispensing includes

both manufactured prescription drug products and compounded preparations. Many states currently have provisions permitting office-use dispensing and other states are actively reviewing, clarifying, and issuing regulations on this very issue. Under the FDA concept, those appropriate state actions would essentially be nullified.

With regard to anticipatory compounding, the mere act of preparing a compounded medication prior to the receipt of a valid prescription or medical order issued by an authorized prescriber incorrectly places the focus on the preparation, rather than on the

dispensing, shipment or distribution of a compounded medication. The true test should be whether or not a pharmacy has distributed a prescription medication in the absence of such a prescriber directive as defined within state law. This is a much more appropriate test as it provides a potentially more accurate indicator of activities that may be deemed drug manufacturing.

IACP strongly opposes the draft bill's exclusion of health system pharmacies. We would note that health systems were the primary client of NECC and they purchased these injections in large quantities,

without a patient script and without a doctor's order. In addition, they purchased these medications due to their low coat – not because of their quality. All legislation or regulation pertaining to compounding should cover all pharmacy practices, whether they are free-standing or located within a hospital or health care facility. There is no reason that patients within a hospital system should receive a substandard of care and safety. Indeed, many hospital patients assume they are more protected in health system environments when this has simply not been the case. ALL patient populations should be equally protected either within or without

a hospital system. Exempting any practice site, such as hospitals, creates two distinctly different categories of patient safety protection. This is especially questionable in light of the volume and types of compounding done in hospital pharmacies, a substantial amount of which includes sterile compounded preparations.

Additionally, by creating a large loophole in a law designed to enhance safety for patients, the true goal of patient care is not achieved for all patients. Additionally, health systems are actively purchasing and acquiring other practices – they would, thus, fall into a different

category and would no longer have to be compliant with this Act. The language also creates a potential concern for the Federal Trade Commission regarding restraint of trade and one could argue that this language allows for an uneven playing field and potential danger to patients in those health systems. Please see the attached documents discussing the rate of infection in health systems and the sheer volume of sterile compounding done in these institutions.

IACP urges the Committee (if the goal is to truly enhance safety for *all* patients) to consider the implications of such an exemption on

public safety and the perception of exempting any entity on the mere basis that it is located in a hospital or health care facility. While we understand that the application of any new rules and regulations may have to be modified to take into consideration other existing regulatory agencies and quality assurance agencies that oversee hospital safety and practices (i.e., the Joint Commission), such a challenge is manageable and should not outweigh the overall interest in ensuring patient safety.

With respect to an identifying label, IACP has formal guidelines for its members that requires all compounded preparations be labeled as

such so that the prescriber and/or patient is readily aware that the medication has been compounded. IACP supports the labeling language included in the draft bill.

The IACP continues to point out that the recommendation to create and maintain a "do not compound" list by the FDA based upon patient safety already exists under FFDCA Section 503A(d)(1). Such a list was created by the Agency and is continually promoted to the compounding profession by the IACP to educate its members and others. The Academy respectfully points out to the Committee that even

given such authority under Section 503A(d)(1), the Agency has not updated the current "do not compound" list in more than ten years. The draft bill neglects to require a regular review and update of this list (allowing for public comment). IACP recommends that – given the fact the FDA has largely let this list lapse, that such language be included in the bill. In fact, several manufactured FDA-approved drug products have been withdrawn from the market for reasons of significant threat to patient safety; the Agency has never included those medications on the existing "do not compound" list. IACP believes that any changes to this

list must be done in an open, structured and, most importantly, timely manner that solicits and accepts the position and opinions of the medical and pharmacy community. IACP also believes that if the collective professional community and the FDA determine that a product should not be compounded due to evidence of patient safety, it should also not be available from a manufacturer.

With regard to animal drug compounding, IACP strongly believes that the laws and regulations governing human compounding should be synonymous with those governing animal drug compounding. IACP

believes that the bill should include language to statutorily permit compounding with bulk ingredients for both human and animals. The FDA should be allowed to continue to produce a list of permitted bulk drugs in food-producing animals only. IACP does not believe there should be a "positive list" developed by the FDA to allow certain specified ingredients from which animal compounds could be formulated. Rather, it should maintain the same "negative" list it does for the human side detailing those ingredients which have been removed from the market for safety or efficacy reasons and, thus, which should

not be used in veterinary compounding. This would make human and veterinary compounding laws and regulations consistent and far less confusing.

IACP applauds the steps the Committee and the U.S. Senate are taking to ensure that compounded medications are as safe as they can be. IACP believes that the safety of patients must always be the first consideration of any pharmacy-oriented public policy.

We have reviewed the draft and we see that there are some aspects that will need further discussion and refinement, and we intend to work with the Committee on these. The draft does not contain any provisions that speak directly to USP standards, which are aimed at raising the quality of compounded medications. Additionally, IACP is concerned that some provisions may reduce patient and physician access to customized medications, the very services that compounding pharmacists provide.

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regulators. IACP will recommend improvements in the draft language to make the proposed categories more clear.

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and their families the assurance, regardless of where they receive their medications, of the quality and safety that they deserve.

In closing, IACP applauds the Committee for addressing areas of federal law that may need to be updated and clarified. Again, IACP would also urge you to not lose sight of the fact that pharmacy compounding is vital to our health care system and to ensuring patient access to appropriate medications for a variety of medical conditions. We appreciate the opportunity to provide our testimony to the

Committee on its draft bill and look forward to continuing our work with you on this important issue.