EMD Serono

EMD Serono Inc. is an affiliate of Merck KGaA, Darmstadt, Germany

EMD

November 7, 2012

Re: Comments on October 24, 2012 Draft Language (Supply Chain Safety)

To Whom It May Concern:

Thank you for the opportunity to comment on the most recent legislative proposal to implement a nationwide supply chain safety system for pharmaceuticals and biologicals. EMD Serono is pleased to see a significant level of compromise, particularly related to Phase Two of the process, reflected in the current draft and appreciates the commitment and efforts of the working group and interested stakeholders in this discussion. We firmly believe that a strong supply chain safety standard is critical to help protect patients from the impact of counterfeiting and diversion, and we have seen the benefits of a robust track and trace mechanism firsthand.

EMD Serono is the U.S. affiliate of an international biopharmaceuticals company with products to combat the effects of complex conditions like multiple sclerosis, HIV and infertility. The products are highly specialized and, as such, are subject to counterfeiting and diversion by illegitimate parties in the U.S. and around the world. For this reason, we have been active on the issue of supply chain safety for over a decade and developed a comprehensive track and trace model that allows us to follow certain products from the manufacturing line to the pharmacy.

Our experience has taught us that having the ability to track our products to the end dispenser by enabling unit-level traceability is imperative to the effectiveness of this system. Like many involved in the prescription drug sector, we believe that a nationwide supply chain safety standard is optimal for enhancing the integrity of products consumed by American patients. We also believe that to reduce risk of counterfeit or adulterated prescription drugs from entering the U.S. supply chain, the pathway for unit-level tracking and aggregation to support operational needs must be timely and must include all of the stakeholders in the product distribution chain. While the current proposal does include some improvements in this regard, there are additional changes that must be made to support patient safety.

In 2002, EMD Serono implemented a secured distribution model including a track and trace program for one of its products and in 2010 incorporated a second. Shipments of these products are restricted to contracted pharmacies that participate in this program. Each unit is uniquely serialized and can be tracked to the pharmacy level.

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Since the California Board of Pharmacy proposed the electronic pedigree and serialization legislation in 2004, EMD Serono has been diligently working on implementing an interoperable system for all products using the GS1 standards and initiating pilot programs with wholesalers. Given the ongoing stakeholder investment in compliance with the California model and the quickly approaching effective date for the related requirements, it is critically important that action at the federal level consider that momentum and investment. At a minimum, a federal approach to supply chain safety should maintain the standards that exist in the California law and, where possible, incorporate the work already being done in California into a nationwide framework. Failure to do so would result in a step backwards on public health and put significant industry efforts to improve supply chain safety in a precarious position.

While we appreciate the inclusion of a more definite timeframe and process for unit-level tracking in Phase Two, we also remain concerned that the timeframe contemplated by the draft is unnecessarily long and deviates significantly from the traditional rulemaking process included in the Administrative Procedure Act. In fact, if Congress chose to enact the longer time options bracketed in the draft, it would be over 15 years before unit-level tracking is incorporated in the U.S. supply chain safety requirements. Given the existing technology and standards available, and the work currently underway to comply with the CA state-mandated supply chain requirements coming online in the next few years, the inclusion of such an extended timeline is simply wrong for patients. Even where those state requirements may be pre-empted by federal law, the movement towards unit-level tracking around the globe means that the technologies and standards needed to implement the system contemplated in Phase Two of the draft are readily available, and many stakeholders are using those technologies today to distribute pharmaceuticals abroad. As such, it seems as though the extended timeline options offered in the draft document prevent implementation of a system that can reasonably be started today.

Specifically, we would recommend a Phase Two timeline that provides federal standards for unit-level tracking that would be effective in 2021. This can be achieved by modifying a number of elements included in the current proposal draft, as illustrated in this letter. Examples of these modifications include the following:

- Allowing FDA to run the specified pilot programs concurrently with the effective date of the legislation beginning in 2014. There is no need for a two-year delay in starting these pilots, especially given that there are a number of manufacturers, wholesalers, 3PLs and dispensers who are already actively engaged in unit-level tracking and could offer their expertise and existing operations in a pilot format immediately.

- Elimination of annual public meetings as required in the current draft. These meetings are not necessary given the ample opportunity that stakeholders will be afforded in the rulemaking process and elsewhere. It is not clear that these meeting will generate any additional insight that could not be offered using existing channels of communication, and they are likely to create additional hurdles and delay in the development of a unit-level tracking standard. Likewise, movement forward with a unit-level tracking standard should not be conditioned upon premature study requirements given the wide array of information that will be available through pilot projects and global supply chain efforts underway by industry stakeholders.

- Reduction of the extended timeframe for development and enactment of regulations related to Phase Two, including the two year delay between issuance of final regulations and effective dates of final regulations (or application of default provisions). The federal rulemaking process that currently exists under the Administrative Procedure Act includes ample time for notice and comment by stakeholders, and it is commonly used for implementation of new federal requirement that exceed the scope of the changes included in Phase Two. There is no need nor is there justification for creating a new rulemaking process for implementation of unit-level tracking.

In the absence of a federal law including pre-emption of state supply chain requirements, the pending system being implemented in California will be effective for all participants in the distribution channel by 2017. The extended Phase Two timeline option included the draft will put federal rules into effect as late as 2028 and make them applicable to a more limited subset of distribution channel participants. Enacting a federal framework that requires federal regulations to take effect no later than 2021 presents a reasonable compromise between these two options and provides the time needed to ensure that impacted stakeholders have sufficient time to prepare for and develop the systems necessary to comply with those federal regulations.

In addition to our recommendations on the timeline for Phase Two, we also encourage Congress to ensure that the proposed supply chain safety system is applicable to all relevant parties in the pharmaceutical distribution process. While the draft does include significant requirements for manufacturers, wholesalers and 3PLs, we are concerned that it does not contain adequate requirements for the parties dispensing products to patients, such as pharmacies. Pharmacists must be part of the verification process for unit-level tracking to be successful- they are the end link to patients and the direct distribution point for a major portion of the U.S. pharmaceutical supply. Most importantly, we believe there are basic standards that pharmacists can achieve with reasonable effort and little monetary investment, making compliance in the near term more than feasible.

Similarly, we strongly believe that Congress should exercise caution in the creation of waivers and exceptions targeted towards arguments of economic hardship. While all stakeholders recognize that an adequate supply chain safety system will require additional investment, it is important to understand that all points in the distribution channel must participate in that system in order for it work effectively. As a company that developed an evolving unit-level tracking system over the past decade, we have learned that it is possible to deploy effective technologies that require relatively modest investment. Moreover, our experience taught us that aside from the public health benefits of these efforts, there is business value for stakeholders. .

As noted previously, EMD is pleased to see the inclusion of a concrete pathway forward for unit-level tracking, and we especially appreciate the inclusion of a default standard should the specified rulemaking process fail to produce final Phase Two regulations by the required deadline. However, we recommend that the proposed default provisions be strengthened and clarified to ensure that the outcome of the Phase Two process does not result in a step backwards from where the supply chain safety effort would have been in the absence of the attempt to enact a federal standard.

As such, the language related to the default provisions must clearly require, at a minimum, the following:

- Unit-level tracking for all downstream, change of ownership transactions involving eligible products
- Appropriate and comprehensive grandfathering protections to ensure fairness (similar to those protections developed by the State of California)
- Aggregation of product information as necessary to reduce operational burden for unit-level reading on downstream partners.
- Inclusion of an adequate "pedigree," including a comprehensive transaction history, as appropriate with the transfer of ownership of a product

In addition to the general comments outlined above, we would also like to offer more detailed suggestions on specific provisions of the draft legislation. For ease of use, these suggestions are detailed on a section-by-section basis in Attachment Two to this letter.

EMD Serono strongly favors the creation of a nationwide standard for supply chain safety. Establishment of one uniform system not only allows for more efficient compliance from the business perspective but also enables the highest level of safety for patients by potentially creating an interoperable system rather than relying on a patchwork of standards. However, a uniform standard must not be achieved at the expense of the strength of a track and trace system. Moreover, we cannot support establishment of a nationwide standard that would lessen the requirements existing in current state law. Although we understand the desire to pre-empt states like California from moving forward with state requirements when a national standard is preferable, pre-emption is not acceptable unless the basic standards in states like California are maintained, or ideally, improved.

We urge you to continue working on this proposal to accelerate the unit level tracking and include all of the elements necessary to the process of securing the U.S. drug supply. We also urge you to refrain from pre-empting states like California from moving forward unless the prevailing policy is as strong, or stronger, than those state laws.

Thank you for your time and efforts in this process, and we remain willing to offer technical advice to the committees about all facets our program, including implementation of a unit level verification system. If you have any questions, please do not hesitate to contact either David Nichols at (202) 626-2594 (David.Nichols@emdserono.com) or myself at (202) 626-2598 (Lynn.Taylor@emdserono.com).

Sincerely,

Lynn Taylor
Vice President, Government Affairs

cc: Chairman Tom Harkin
Ranking Member Mike Enzi
Chairman Fred Upton
Ranking Member Henry Waxman
Senator Lamar Alexander
Senator Michael Bennet
Senator Richard Burr
Senator Charles Grassley
Senator Diane Feinstein
Senator Sheldon Whitehouse
Representative Brain Bilbray
Representative John Dingell
Representative Jim Matheson
Representative Frank Pallone

ATTACHMENT: Additional Specific Comments

Section 2

Section 581 (Definitions):

- A number of the relevant terms are similar or identical to terms being used in the context of the California state supply chain requirements, and the stakeholder community has been active in achieving a consensus around a number of those terms. As such, we recommend that Congress consider adopting the definitions used for similar terms under California law where they are available and appropriate. For example, the terms "manufacturer," "repackager," and "third party logistics provider" are all defined in California statute in a comprehensive fashion, and those definitions could be appropriately used in the federal context as well.
- The definitions of "illegitimate product" and "suspect product" should incorporate language similar to that found in CA statute, which specifies that, " If a manufacturer, wholesaler, or pharmacy has reasonable cause to believe that a dangerous drug in, or having been in, its possession is counterfeit or the subject of a fraudulent transaction, the manufacturer, wholesaler, or pharmacy shall notify the board within 72 hours of obtaining that knowledge.
- The exemption from the definition of "transaction" specified in subparagraph (xii) should be deleted because this type of transaction is indeed a change of product ownership and should not be considered exempt.
- The "transaction information" definition should also include product identifier information as a requirement in Phase Two.
- The "transaction statement" should be defined as a certified document (such as a signed transaction statement). The definition should also specify that the signature is a certification under penalty of perjury from a responsible party of the source of the product that the information contained in the pedigree is true and accurate.

- Section 582 (Requirements)
- The bracketed language included in section a(1) should be retained.
- The two years specified for publication of standards under section a(2) is too long. Such standards currently exist and are widely used and, therefore, there is no need to wait to two years before publishing the standard.
- The availability of a waiver for "undue economic hardship" found at section a(3)(A)(i) should be removed because it is not needed nor is it sufficiently defined. If removal is not possible, the term "undue economic hardship" should be qualified and defined to provide more clarity on the standard for a waiver.
- The language at a(3)(A)(ii) should be amended to include more clarity around the process that the Secretary may use to determine exceptions.

- Section a(5) should be significantly revised to reflect an appropriate grandfathering mechanism, and the Secretary should be required to develop regulations within one year. We recommend this language incorporate the standard that is reflected in California statute, which provides the following:

  (1) A manufacturer, wholesaler, or pharmacy lawfully possessing or owning dangerous drugs manufactured or distributed prior to the operative date of the pedigree requirements, specified in Sections 4034 and 4163, may designate these dangerous drugs as not subject to the pedigree requirements by preparing a written declaration made under penalty of perjury that lists those dangerous drugs.

  (2) The written declaration shall include the National Drug Code Directory lot number for each dangerous drug designated. The written declaration shall be submitted to and received by the board no later than 30 days after the operative date of the pedigree requirements. The entity or person submitting the written declaration shall also retain for a period of three years and make available for inspection by the board a copy of each written declaration submitted.

  (3) The board may, by regulation, further specify the requirements and procedures for the creation and submission of these written declarations. Information contained in these declarations shall be considered trade secrets and kept confidential by the board.

- Any dangerous drugs designated on a written declaration timely created and submitted to the board may be purchased, sold, acquired, returned, or otherwise transferred without meeting the pedigree requirements, if the transfer complies with the other requirements of this chapter.
- The timeframe for the manufacturer requirements found at (b)(1)(A) should be revised from one year to six months.
- The bracketed language at (b)(1)(A)(ii) should read "upon each transaction"
- The language at (b)(1)(A)(iii) should be revised to require information be maintained for not less than 7 years.
- The language at (b)(1)(A)(iv) should read 18 months.
- The manufacturer requirement found at (b)(1)(A)(iv) should be amended to include aggregation in addition to the package and homogenous case requirement.
- The timeframe included in (b)(2) should be 3 months.
- The timeframe included in (b)(3)(A) should be 18 months.
- The timeframe included in (b)(3)(A)(ii) should allow 72 hours after receiving the verification request rather than 24 hours to account for requests that occur over a weekend, etc. In the alternative, the statute could reference business days rather than hours.
- The language found at (b)(3)(D) should be revised to accurately reflect manufacturer practices. Typically, manufacturers do not redistribute product that has been returned, although wholesalers do frequently redistribute product that has been returned to them.
- The timeframe included in (b)(4)(A) should read 6 months.
- The timeframe included in (b)(4)(C) should read 7 years rather than 2 years or 10 years.
- The timeframe included in (b)(4)(D) should read 72 hours rather than 24 hours.
- The timeframe included in (b)(5)(A) should be 6 months.

- The language at (b)(5)(A)(ii) should be clarified to provide more explanation of what constitutes "reasonable steps."
- The timeframes included in (b)(6) should read 72 hours rather than 24 hours.
- The timeframe included in (c)(1)(A) should read 6 months.
- The language at (c)(1)(A)(ii) should read "upon each transaction."
- The timeframe included at (c)(1)A(iii) should read 7 years rather than 2 or 10 years.
- The timeframe included at (c)(1)(A)(iv) should read 30 months.
- We recommend the use of Option 4 language under the saleable returns standard found at (c)(1)B)(i).
- The language at (c)(1)(B)(ii) should be amended to specify that all transaction history should be included with returns.
- The timeframe included at (c)(2) should read 3 months.
- The timeframe included at (c)(3) should read 30 months.
- The timeframe included at (c)(4)(A) should read 6 months.
- The timeframe included at (c)(4)(C) should read 7 years.
- The timeframe included at (c)(4)(D) should read 72 hours.
- The timeframe included at (c)(5) should read 6 months.
- The timeframe included at (c)(5)(C) should read 7 years.
- The timeframe included at (c)(6) should read 6 months.
- The timeframe included at (c)(6)(C) should read 72 hours
- The timeframe included at (d)(1)(A) should read 6 months.
- The language at (d)(1)(A)(ii) should read "upon each transaction."
- The timeframe included at (d)(1)(A)(iii) should read 7 years.
- The timeframe included at (d)(1)(A)(iv) should read 3 years.
- The language regarding saleable transactions at (d)(1)(C)(i) should be amended to require that the information under subparagraph (B) be included.
- The language regarding nonsaleable transactions at (d)(1)(C)(ii) should be amended to require that the information under subparagraph (A)(i) be included.
- The timeframe included at (d)(2) should read 3 months.
- The timeframe included at (d)(3) should read 3 years.
- The verification language at (d)((3)(B)(ii) should be amended to delete the 10% verification requirement and require every product to be verified at the unit level that is suspect.
- The timeframe included at (d)(4)(A) should read 1 year.
- The timeframe included at (d)(4)(C) should read 7 years.
- The timeframe included at (d)(5) should read 1 year.
- The timeframe included at (d)(5)(C) should read 7 years.
- The timeframe included at (d)(6) should read 1 year.
- The timeframe included at (d)(6)(C) should read 72 hours.
- The timeframe requirements for Third Party Logistics Providers (3PLs) found in section (f) should be aligned with the timeframes for manufacturers. Generally, we recommend selecting the shortest timeframe included in the bracketed options.

Please note: Our comments on the provisions of Section 3 are included in the body of our comment letter.