

PSTF Comments on the FDA Anti-Counterfeiting Initiative

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Group Goal: To provide a forum for the healthcare industry in which anti-counterfeiting strategies can be discussed and recommended, thus reducing the threat to patient safety from counterfeit products. Further, to develop and recommend the business requirements necessary for track and trace functionality, a key component in the effort to reduce the opportunity to counterfeit healthcare products. Finally, to create a unified and comprehensive industry recommendation on specific issues for submission to the FDA.

Executive Summary:

The PSTF focuses its comments primarily on technology-based strategies for limiting the incidence of counterfeiting. The coalition's purpose and make-up is aimed at the ultimate goal of developing business requirements and a timeline for track and trace functionality. The PSTF submits its comments to the FDA's Interim Report primarily as it relates to technological approaches to reducing counterfeiting.

The PSTF strongly endorses a multi-pronged strategy, including use of technological, regulatory, enforcement and educational options. The PSTF response should be considered in its entirety as a multi-pronged strategy. However, the PSTF has identified track and trace technology as the key strategy that, both alone and as part of a layered approach, is seen to have the greatest potential in reducing the incidence for counterfeiting healthcare products.

We do not endorse the mandate of any particular approach. While many of these strategies, and the layering of them, are important in eliminating counterfeit opportunities, the PSTF believes that the industry is in the best position to determine optimal individual and collaborative responses to counterfeiting, as the products, vulnerabilities and "solutions" are best known by those creating, delivering and administering the products.

While authentication strategies are important anti-counterfeiting measures in many cases, the PSTF does not recommend a mandate for use of this approach nor a registry of technologies applied to various products. The PSTF also recommends allowing the industry to continue to operate in its current manner, allowing market conditions to continue to drive such issues as market structure and provision of packaging format, for instance. Specifically, we do not recommend any mandated change in the distribution system that would require direct shipping of product from manufacturer to "pharmacy", nor a requirement for unit-of-use packaging.

We do strongly recommend the creation and enforcement of stiffer penalties for counterfeiting, as well as tighter licensing requirements for all registered to do business in the healthcare supply industry. We also recommend, as needed, the review and tightening of due diligence procedures for all healthcare supply chain partners in order to help prevent and eliminate unscrupulous parties from participating in the industry.

The PSTF will strive to develop business requirements for track and trace functionality in the next six months, and welcomes the opportunity to present our end deliverable to the FDA. PSTF would suggest that FDA encourage industry to develop and implement track and trace functionality as a key anti-counterfeiting strategy by endorsing any industry-coalition developed timeline for migration to this technology.

Introduction:

The PSTF would like to compliment the FDA for its approach as outlined in the interim report on anti-counterfeiting technologies. Further, the PSTF applauds the FDA's efforts to liaison with industry stakeholders. The opportunity to continue this partnership between the Agency and industry is an excellent method of ensuring that the most effective and realistic solutions are brought to patient safety and to all other issues in the healthcare industry.

The PSTF agrees with the FDA comment that there is no "magic bullet" for eliminating product counterfeiting threats from our healthcare system. As such, we also agree that the most effective strategy is a multi-pronged approach, thus erecting significant entry barriers for counterfeiters and closing the system gaps that are now and predictably may be exploited. The components of this multi-pronged strategy are outlined below and discussed in detail according to the table of contents immediately following. While the PSTF has delineated the issues in this manner, it is worth noting by way of introduction that many of these issues and strategies are inter-related and therefore overlap. We will make mention of these connections as appropriate below. Finally, it is a central belief of the PSTF that these various approaches are less effective when considered separately, but instead create the most effective defense against the threat of counterfeiting when considered and implemented as essential, linked components of the overall strategy.

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I. Technology

The PSTF defines the term technology similarly to the FDA's usage in the interim report. That is, that there are two types of anti-counterfeiting technologies: Authentication technologies and Track and Trace technologies.

Authentication technologies are generally inherent to the formulation of the medicine or its packaging in some manner, and, per the FDA report, "fall into three groups:

- **Overt** technologies are protective measures that are easily visible to the eye, such as holograms, color shifting inks, and some watermarks.
- **Covert** technologies are protective measures that are not visible to the eye and frequently require special equipment for visualization (and authentication). These include some watermarks, certain inks and dyes that fluoresce or absorb ultraviolet light, and invisible bar codes.
- **Forensic technologies** are protective measures that require sophisticated analytical equipment, usually found in a forensic chemistry lab, in order to be identified. These include chemical markers, taggants, and other unique chemical properties of a substance." (source: FDA's Counterfeit Drug Task Force Interim Report, Section E.1. Types of Anti-Counterfeiting Technologies)

Also per the FDA's report, "track and trace technologies include:

- Radio-frequency identification (RFID) is a technology that involves the placement of electromagnetic chips/tags that contain product specific information onto cartons, pallets, and individual products. The system includes the tags, antennae affixed to the tags, readers to receive the data in the tags, and an information database that is used to authenticate and track the product as it moves through the distribution system.
- Barcodes are symbols (representing an alpha numeric value) printed on labels that are read by a scanner and used to identify drug products. Bar codes can be combined with covert elements (e.g., security ink) that also allow them to function as authentication technologies." (source: FDA's Counterfeit Drug Task Force Interim Report, Section E.1. Types of Anti-Counterfeiting Technologies)

Here, however, PSTF would like to highlight that our usage of the term "barcodes" can include any encoded data that is machine readable via a line-of-sight scanner and can support an information database that is used to track and verify authenticity of a product. While this definition is not exclusive of that given by the FDA, we clarify here in order to differentiate from the common usage of the term barcode as simply a linear symbol containing black and white parallel bars. We specifically intend to include in our definition other data representations such as 2-dimensional symbols or any other standardized, common machine readable code acting as a data carrier.

Finally, it is important to reiterate at this time that the PSTF was primarily convened to and has agreed to develop certain industry-consensus strategies related to anti-counterfeiting technologies, particularly for track and trace functionality. As such, a significant portion of our response will deal with these topics.

1. Multi-pronged

Again, while the PSTF's entire response constitutes our recommendations for a multi-pronged anti-counterfeiting strategy, within the technology component of the

overall strategy, we also recommend a multi-pronged, layered approach. The PSTF believes that no single technology can alone prevent counterfeiting, but that a layering of strategies will create a significant barrier to entry for counterfeit products. The PSTF does believe that certain approaches and strategies are far more effective than others, and we will make note of our consensus opinions as appropriate throughout this response document.

Specifically, the PSTF believes the layering of authentication technologies with track and trace technologies to be one of the most promising strategies available in thwarting the efforts of counterfeiters. Placing several layers of anti-counterfeiting technology onto a package, and rotating certain components, creates a complex and constantly moving target for counterfeiters, thus substantially increasing the sophistication, financing and timing needed to perpetrate a counterfeiting crime. Greater details follow in I.2. Authentication Technologies sub-section immediately below.

While a layered approach is seen to be critical to counterfeiting mitigation, the PSTF does not mandating any particular approach. There are numerous and significant variables that make mandatory usage an undesirable option. While they may potentially be discussed below, some of these variables include the wide disparity in types of healthcare products in the system, including usage, packaging, value, and point of origin, amongst others. This diversity of product, combined with the very nature of the many different options available for authentication technologies would dictate that product suppliers not be required to utilize any particular technology or combination. Finally, where appropriate, and particularly for track and trace functionality, the PSTF believes that market-driven, open design technologies will be the most effective approach for creating healthcare system-wide adoption and effectiveness.

2. Authentication Technologies

Once again, the PSTF agrees with the FDA definitions as cited above in the introduction to this section. Further, the PSTF agrees that the FDA outlined many of the known anti-counterfeiting technologies in Appendix A: Table of Anti-Counterfeiting Measures contained within the FDA report. As such, we will not detail specific authentication technologies here.

The PSTF, as stated above, agrees with the layering of authentication technologies into the packaging of healthcare products, and believes that this should be left to the discretion of the supplier. Suppliers should be able to determine which authentication approaches are best for their individual products and their organizational strategy and competencies. Further, as mentioned above, publicly requiring certain quantities and or types of defined and perhaps “approved” authentication technologies could perhaps allow counterfeiters an opportunity to learn to replicate the “approved” authentication technologies.

The use of authentication technologies, while strongly recommended by the PSTF, is not seen as highly useful for detecting counterfeit product at any point in a patient contact setting, whether at product receipt, prescribing, dispensing or administration. This lack of utility is due to a number of factors related to the nature of authentication technologies themselves, the recommendation that technologies be layered and rotated periodically, and the cost to authenticate at every patient care setting.

Overt technologies have been shown to be vulnerable to sophisticated counterfeiting efforts. Further, there is a question as to how dispensing professionals and particularly patients are to be certain that a particular overt technology is to appear to them and thus how it is to be utilized by them for authentication. While an ongoing educational effort could be initiated, this is an arduous undertaking given the hundreds of manufacturers supplying product, particularly when paired with the need to rotate overt usage in order to stay ahead of counterfeiters. This rotation is critical to the success of overt usage, but creates possible confusion for dispensers and patients.

For covert and forensic, the cost of authenticating at the point of patient contact is rather high in many cases. Per the definition of these technologies, special equipment or sophisticated lab analysis is needed to authenticate the product, and these are capabilities that may not be readily or cost effectively available at the point of administration. Related to this difficulty, and particularly in the case of covert and overt technologies, a final limitation of authentication technologies is the relative complexity of real-time verification of product validity at the point of care.

The need to “register” a product’s usage of authentication technologies may be possible, but introduces a further burden to providers and may also jeopardize the security of the product. With technology rotation, the amount of information exchange required to continually update a central registry would be formidable, and unless the security of the submission, review, storage, sharing and usage of this authentication information could be insured, it again may create a product vulnerability. Further, due to the objective for using these technologies themselves, the level of information to be exchanged may well need to be limited simply for security reasons.

Finally, as will be discussed further in Section II: Packaging Issues, below, the prominent role of repackaging in the US healthcare industry makes the usage of and any mandate for use of authentication technologies by the original manufacturer a difficult decision. This is because, in many cases, particularly where products are dispensed in quantities that differ from those in which it is originally packaged, the authentication technologies applied by the manufacturer may not reach the pharmacist or ultimate consumer. Thus the authentication technologies applied to the package by the manufacturer may not travel as far through the supply chain as may have been presumed during the investment and legal review process.

3. Track and Trace

The ability to know where a product has been and where it is currently located is critical to counterfeit mitigation. Track and trace functionality refers to the ability to determine if a product is valid, track its movements through the supply chain and have the ability retrace those steps if required. As defined above and in the FDA report, there are primarily two methods to achieve track and trace functionality: those that, in identifying products, rely on line-of-sight (i.e. data encoded into a bar-code) and those that do not require line-of-sight (i.e. data encoded onto a chip which has an antenna which is activated via radio frequency.)

In all cases, the key component of track and trace is the ability to uniquely identify individual items. It is this core system element that, in the opinion of the PSTF,

makes track and trace the most powerful single strategy currently known for reducing the threat of counterfeiting. When products can be uniquely identified, with a serialized number that serves as a “fingerprint” for only that item, it creates a very high barrier for entry to counterfeit product.

Track and trace functionality requires these unique product identifiers as well as an information management system which enables the accessing of information related to that product identifier. The unique identifier simply points to a record in a database which contains other information about that particular item (e.g., lot number, expiration date, manufacturing location, etc.) This serves as a security feature onto itself as certain information is not carried on the package itself but rather in a controlled database. It is actually a security feature of certain track and trace technologies that the authenticating information is not carried on the package, a vulnerability of the “authentication technologies” discussed above. Further, reducing the amount of information carried by the RFID chip and/or bar code results in substantial cost savings in the creation and use of the encoded data, including acquisition cost, production-related issues, and systemic costs for databases and data sharing and storage.

A key feature of track and trace is the ability to verify all supply chain participants who took ownership of and/or handled the product during its lifespan. This capability is due to the uniqueness of product identification and the registry of all industry participants utilizing a universal track and trace system. As mentioned above, under these conditions, obtaining information about the product would be facilitated by a scan of the product id and connection to a system which would locate all relevant information for the product. While specific functional details must be developed, even historical gaps in the product’s lifecycle could be identified and easily investigated. This important feature is a better option than the use of paper pedigrees, as verification of pedigree information would be built into the system and almost instantaneous, and since the paper version can be and has been easily counterfeited. Developed properly, an electronic pedigree would be nearly impossible to duplicate or fake. Further, as mentioned elsewhere in this document when discussing possible technology migration paths, the possibility of creating an electronic track and trace system at the pallet and case level and/or for certain high-risk products may be feasible in the near term.

The PSTF has agreed that its key objective is to develop business requirements for track and trace functionality and to discuss the migration path for industry adoption of such a technology. This process is expected to take at least six months to complete, and the PSTF has notified the FDA of this commitment to development requirements and the anticipated timeline. However, at this time, we can comment on the generalities of how electronic track and trace functionality could commence in the near term and what the requirements would be to move to a fully functional, item-level system.

It is not necessary to build an optimal, fully functioning track and trace system with complete industry adoption in order to create a significant barrier for counterfeiting. While certain costs may be lower under the scenario of full and simultaneous industry adoption, this may not be possible or practical, as strategic implementations will provide important education for more wide-spread deployment, can reduce the

threat to the most endangered consumers and products, and allow market forces to prove the technology and applications and drive adoption.

The PSTF agrees that a possible migration path for adopting track and trace functionality could contain several steps. These steps may include the determination of highly vulnerable products, a subject on which the FDA has requested information, as well as continued participation in an industry forum that would create and display support and guidance for initiating the process of implementing e-track and trace, creating momentum and relationships for collaborating and piloting initiatives. The PSTF is one such industry forum, and the group continually discusses other similar efforts in order to not duplicate effort as well as to learn from and liaison with these efforts.

Determining a list of highly vulnerable products is seen by the PSTF as a strategy of uncertain value, with distinct possible positive and negative outcomes. One benefit relating to the development of track and trace functionality is that such a list could provide a valuable pilot environment for track and trace testing, development and implementation, thus aiding in technological migration. However, creating the list could be contentious for a variety of reasons, such as which products made the list, what the ramifications are to various industry stakeholders, merging the list to other regulatory initiatives, and the creation or expectation of anti-counterfeiting technology requirements for "listed" products versus the approach desired by those manufacturing, handling and maintaining liability for the products. Nonetheless, should FDA wish to explore this idea further, the PSTF would welcome the opportunity to discuss such a list as part of our commitment to develop track and trace functionality. The very scenario of piloting track and trace in such a manner is likely to be a topic during our requirements development process.

The continued building of industry momentum on the deployment of track and trace, as mentioned above, is being achieved at a number of forums, both within the healthcare industry and in parallel or supporting industries and standards organizations. While this seemingly is not a definable component of the migration path, as it is difficult to quantify certain results or timelines, it is obviously a critical process. Again, the PSTF will work to further develop the specifics of track and trace requirements and migration timelines in the months ahead, and in collaboration with other efforts, but the basics of adoption have already been generally identified. In addition to the possibility of creating a high-risk list, whether at product item level or some higher level of packaging, all industries currently initiating track and trace implementation are beginning at the pallet and case level. It is assumed by the PSTF that this is a worthwhile approach for the healthcare industry as well. When track and trace is fully implemented at this level, it creates the opportunity for distributors to serve as the authenticators of product. They will be able to validate each stop a product has made in its life cycle, thus providing an electronic pedigree. When purchased from a supply chain member who can provide track and trace functionality, any patient care provider (purchaser) can be assured of the authenticity of the product.

A central database and/or relational and distributed databases are seen to be critical to the full functionality of electronic track and trace. While this is certainly true for the eventual fully interoperable system, it does not necessarily need to be a short-term hindrance in the drive to implement track and trace for select products and/or at the

pallet and case level industry-wide. Further, this critical need is becoming the subject of much focus across industries where this technology is being examined, and thus solutions are in development. If the healthcare industry were to adopt track and trace prior to the resolution of this key issue, there would either be significant information available from which to build a scalable and interoperable data exchange functionality, or there could be a process defined that would follow current data exchange protocols and standards in order to facilitate track and trace at the scale initially undertaken. In any event, the solution to these concerns will be determined as the technology is continually explored and developed over the upcoming months and years. Work to define costs associated with any implementation, short and long term, will need to be completed in the months ahead.

Finally, another possible portion of the migration path from current-day technologies to possible full-industry adoption of RFID for unique, item-level identification is the utilization of current automated identification technologies and standards. There are a variety of bar codes and electronic data exchange protocols in wide use now that can be utilized as key elements in the technological transition that must occur. In the near term, placing bar codes (defined as above in I.Technology, paragraphs 3 and 4) on products throughout the supply chain and at various packaging levels will help to identify them more accurately. A possible short- to mid-term next step would be to expand the bar codes and their use to allow for carrying unique identifying information at various packaging levels, including at the item-level. However, the FDA's pending final rule on bar coding at the bedside for patient safety may have a dramatic impact on industry's ability to utilize these powerful anti-counterfeiting and patient safety measures. This issue will be discussed in greater detail in Section IX below.

II. Packaging Issues

There are several points to consider in the area of product packaging, specifically, the practice of repackaging and the issue of package quantity (i.e. unit-of-use, unit dose, etc.). These are important topics for industry, and are issues on which the FDA justly is requesting comment relevant to anti-counterfeiting techniques.

1. Repackaging

Repackaging serves an important role in the supply chain at this time, providing alternative packages and dosing formats than those provided by the manufacturer. It is important to distinguish between the two primary types of repackaging, repackaging for resale and repackaging pursuant to a prescription. Repackaging pursuant to a prescription is primarily undertaken in a pharmacy setting just prior to administration, and is done to provide the patient with the exact prescribed course of therapy. While this practice may remove, prior to patient usage, the authentication or track and trace technologies applied to the original product at point of manufacture, the PSTF will not comment on this topic, except to recommend that all healthcare industry partner organizations take steps to utilize anti-counterfeiting methods, particularly track and trace, and to mention that the PSTF will discuss track and trace applications for repackaging pursuant to a prescription while developing business requirements.

Repackaging for resale, which is undertaken in the “middle” of the supply chain, is when a company which must follow all federal GMP requirements removes product from its original container, and then places the product into a new container, reselling it into the supply chain in this new packaging format. This portion of the industry supports the different needs of the variety of settings in which pharmacy is practiced. This type of repackaging can take on many forms, both increasing and decreasing the quantity of product available in a “unit of sale.” This market niche is important for avoiding instances where the manufacturer-supplied quantity exceeds the common prescriptive needs of a portion of the market, and allows manufacturers to avoid the costs of providing product in all market-driven quantities and packaging formats.

The PSTF suggests that the important commercial repackaging process be considered as part of the system and solution. As is now the case, with repackagers needing to comply with GMP requirements, any recommendations to utilize authentication and/or track and trace strategies to secure the supply chain should be instituted by commercial repackagers as well. They should also practice full due diligence in the qualification of their suppliers and customers.

The use of authentication technologies has been discussed above as a valid and important component of a multi-layered anti-counterfeiting strategy. While these measures would be important in determining the authenticity of a product throughout the supply chain, there is a concern that the cost of creating and implementing these techniques could be wasted if the product is repackaged by a commercial operation. This is certainly a valid concern, although the existence of authentication technologies can potentially help validate product at all points in the supply chain, and not just during prescribing or administration, which, as stated above, is not a highly useful point at which to utilize authentication methods. Thus, the PSTF believes that authentication technologies should be applied by all packagers until such time that track and trace functionality can replace the need for covert, overt, and forensic techniques on product that will be repackaged.

There is a related concern that repackaging of either type could also remove the track and trace features of RFID and/or “bar codes” as applied by upstream supply chain partners. Again, this is a valid concern, part of the solution to which will be discussed and potentially resolved during the PSTF process of developing business requirements for track and trace functionality. However, PSTF once again recommends that all participants in the healthcare supply chain initiate the technological development and inter-operability needed to participate in industry track and trace capability, and that all packagers apply universal, open-standard track and trace technology to their finished product. It is a key feature of track and trace technology, however, that allows for the authentication of the product and each stop it has made in the supply chain. While the practicalities of this will need to be developed further as part of the business requirements, it is the uniqueness of the product id that provides the power to the system, since the “disappearance” of a unique id, and thus a product, will need to be justified within the universal track and trace system, and the location at which the product id was last seen can be ascertained. The development of business requirements for track and trace will also certainly deal with the issue of connecting inbound unique product id’s with outbound reconfigured products, where ever that process occurs in the industry.

2. Unit-of-use packaging

The utility of requiring unit-of-use packaging as an anti-counterfeiting technique has been discussed by the PSTF to some extent. Since it is not closely related to our core focus of exploring and developing track and trace functionality, it has not been discussed in great detail. However, as it relates to track and trace, requiring unit-of-use packaging could create a hurdle to industry adoption. Resource allocation could be contentious as the costs to convert manufacturing lines and distribution models in response to a mandate for unit-of-use would compete with the investments needed to implement track and trace. While the PSTF does not have and does not plan to provide any data on the economic impact of requiring unit-of-use packaging, it is broadly agreed that this mandate would dramatically impact industry at all levels, with significant costs to manufacturers and to distribution. Finally, although the PSTF sees value where appropriate in increasing the availability of unit of use packaging, the PSTF does not believe that a mandate to do so will be nearly as effective in reducing counterfeiting as will adoption of track and trace functionality.

III. Security:

The term security here refers to several concepts relating to control of healthcare products in the supply chain. The FDA asks for comment in the interim report about the feasibility of mandating that products be shipped directly from point of manufacturer to point of use. It has been documented, by HDMA amongst other sources, that the healthcare distribution model currently in effect is actually more efficient, more cost effective and therefore more controlled than would be the case under a scenario of direct distribution. While there may be alluring anti-counterfeiting benefits to a direct distribution model, the PSTF did not find merit in this strategy. Causing manufacturers to focus on distribution of product to the extent that would be necessary in order to implement such a mandate would place a severe strain on the healthcare system overall, as well as the manufacturers' resources and perhaps their focus on development of new healthcare products. Instead, the PSTF again believes that a universal track and trace system, which would be desirable even when distributing directly, is a better anti-counterfeiting approach.

Another issue in security is physical site security. While this has not been discussed at any length by PSTF to date, track and trace may help in this issue as well, as unauthorized product movements or disappearance could be detected by industry organizations employing a universal track and trace system. In addition, the PSTF would simply recommend that all industry stakeholders become educated on and implement best practices for site security as pertains to their operations.

IV. Education:

The PSTF did not feel that large-scale educational initiatives would be highly effective as an anti-counterfeiting effort. Particularly, there was a strong consensus that educating consumers could actually create more concern and confusion than is warranted, that instead the industry should continue to collaborate to bring about significant changes that will reduce the threat. It was agreed that educational efforts should focus on positive messages, avoid creating the potential for increased false alarms, and most importantly, not create an environment where consumers are

needed to catch counterfeit product. Instead, strategies should be employed that allow consumers to completely trust the products they use. Building a “culture” of awareness regarding various potential and/or suspected changes in products utilized by the public, and how to properly respond to suspicions or discovery, can be accomplished as part of a broader educational initiative, possibly including terrorism, food-related and/or general health and medicine-interaction education.

The PSTF felt that, while educating pharmacists and other healthcare practitioners is necessary and important, it is in itself not an effective strategy in preventing counterfeiting. Certainly not to the extent of making these key patient touch points aware of every type of anti-counterfeiting technology in use on each product. An educational strategy carried to this length was thought to be confusing at the point of care. Greater general education about the types of strategies in use would be highly beneficial to this audience, increasing confidence in the healthcare system which they would pass on to patients.

As to track and trace, the PSTF felt that it would be important to create educational messages about the numerous benefits of the technology and to mitigate and correct misperceptions about privacy concerns related to the technology. It was a key discussion point amongst the PSTF that the healthcare industry is already following some of the most stringent consumer privacy standards in existence, as there are many rules protecting sensitive information of patients. These same standards would need to be followed regarding the use of information derived from a track and trace system. As such, in the healthcare industry, it would be a violation of law to obtain, fail to safeguard and/or publish patient-specific information without consent. As such, the PSTF felt that including this message in anti-counterfeiting educational efforts was important, and thus will revisit the issue as track and trace requirements are developed.

V. Rapid Response Network:

The PSTF did not have sufficient time to adequately discuss a Rapid Response Network or mechanism, and thus will offer only very brief comments on this issue. The overriding thought was that the integrity of the healthcare system cannot depend on such a system, as end-stage reports of this type do little to prevent counterfeiting. Such a mechanism was seen to be useful and worthwhile, although not nearly as all-encompassing and preventative as a track and trace system. The connection between the two strategies seems to be that track and trace functionality could ultimately replace the need for such a system, as the ability to determine where product is and has been should make redundant the need to notify industry stakeholders of a counterfeiting or other event. The “front end” of such a system could still prove to be useful as a suspicion-reporting mechanism in any future environment, though. Further, until track and trace is fully functional to the item level at all industry participants, a Rapid Response Network could be very useful.

VI. Regulations, Legislation and Enforcement:

While the PSTF did discuss this issue at some length, our comments will be brief since: 1) this topic has little connection to our core focus on track and track and; 2)

the group strongly agreed that this is a key component of the overall multi-tiered anti-counterfeiting strategy.

The licensure process was seen to be a very critical component of any effort to reduce the incidence of counterfeiting. In too many jurisdictions, it is far too easy to obtain a drug distribution license and maintain it without any inspections and little oversight. While the ability and willingness to participate in a universal track and trace system may eventually help to eliminate illicit operators, it is not the responsibility of industry companies and organizations to re-validate the qualification and due diligence work that is the responsibility of licensing bodies.

That said, industry members do take very seriously the due diligence process for qualifying trading partners, particularly in light of the recent surge in counterfeiting and since they cannot rely on the fact that a license to distribute drugs in certain jurisdictions is any validation of the licensee. Individual companies as well as industry organizations are revising their trading partner review criteria, for both new relationships and for ongoing business.

The PSTF recommends that relevant state regulatory and governing bodies perform a similar review of their licensure and oversight practices and significantly tighten the process. Without a license on record at the appropriate state regulatory agency, it is nearly impossible for a counterfeiter to operate. The lack of on-site inspections either during licensure or for periodic subsequent renewals, while understandably difficult to perform on a limited budget, must be seen and addressed as one of the key system failures.

The PSTF would also mention here the danger to the system from the current consideration of importation legislation. While drug costs are of concern in this country, there are other strategies for dealing with this issue that would not substantially increase the risk of counterfeit and adulterated products entering our system, as current importation legislation considerations almost certainly would. Allowing importation without having means for inspecting the product, validating its manufacturing origination, or attesting to the efficacy and authenticity of the product in any way is seen as prohibitively dangerous to the PSTF. Without safeguards in place, and with lax licensing requirements in wide practice, the counterfeit problem will certainly increase if importation is allowed to move forward. Even if it was actually possible to limit imported products to personal use, that still places a high risk on unprotected patients and introduces potentially suspect products back into the US system via returns of imported product.

Finally, the PSTF strongly agrees that criminal penalties need to be significantly enhanced in order to deter counterfeiting. Current law and various loopholes provide insignificant penalties for those caught counterfeiting. The risk-reward equation is unfairly balanced towards the continuation of counterfeiting.

VII. International:

The PSTF strongly agrees that, where at all possible, international cooperation and collaboration should be sought in the anti-counterfeiting struggle, as it is truly a global problem. The PSTF will be doing this in the development of track and trace

requirements, by collaborating with global organizations, including PSTF member companies, research initiatives and standards development organizations. Included in this global collaboration should be efforts aimed at increasing the enforcement of and seriousness of counterfeiting penalties.

VIII. Financial:

Since the PSTF has been formed only recently, there has been limited ability to obtain or evaluate any data on the financial impact of these various anti-counterfeiting strategies. Thus, we will offer little comment on this topic. There was some discussion about the cost to a brand name related to counterfeit implications, but that is a calculation best done by individual organizations. Certainly, there is the human cost from adverse events related to counterfeiting, which is the underlying issue at stake here for all industry participants. There are the technological costs related to the various strategies supported in this document as well as those considered by the FDA. The PSTF may generate or discover some quantifiable financial data during the process of business requirements development, but have not found usable industry data at this point in time.

Likewise, while there are considered to be numerous additional benefits that will accrue to industry and individual implementers of track and trace technology, there is not significant data at this time to validate the scope of those gains and the time frame for return on investment. As the PSTF continues its work, we will make FDA aware of any data that would be useful in this regard.

IX. Comments on connection between bar code rule and counterfeiting strategies

One issue of note for PSTF, as we focus on track and trace functionality, is the connection between the counterfeit issue and the pending final rule on patient safety via bedside barcode scanning. While it is understandable that, in the bar code rule, there is some concern related to non-linear bar code usage, mandating only linear codes could hamper the efforts to reduce counterfeiting at the lower levels of packaging in the near and mid-term, before RFID is standardized for and implemented in hospitals and pharmacies. Linear codes, in the size needed for dose-level applications, are generally not capable of carrying enough information to provide for unique identification, which is the cornerstone of track and trace functionality. If the language in the bar code rule is not broadened to allow for non-linear symbols, the migration path for track and trace will be significantly hampered. Migration may then have to include a step wherein the item-level identification was approached and implemented in one massive process, due to the costs to procure chips at this level, apply them to packaging and perform the system "go-live". The migration also may have to include an FDA review and re-issue of the bedside bar code rule. Two-dimensional symbols can much more easily carry a unique item number than can bar codes, as well as substantially more information such as lot and expiration date, if so desired, and thus could be an excellent migratory step towards a fully functional track and trace system.

Attachments: ["EPC Network: Securing the Pharmaceutical Supply Chain"](#)
["White Paper: Securing the Pharmaceutical Supply Chain"](#)