NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Statement

Of

The National Association of Chain Drug Stores

On

Drug and Device Provisions of the Food and Drug Administration Globalization Act Discussion Draft Legislation

To

U.S. House of Representatives
Committee on Energy and Commerce
Subcommittee on Health

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2322 Rayburn House Office Building

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NACDS thanks the Committee for the opportunity to submit a statement on the drug and device provisions of the Food and Drug Administration Globalization Act Discussion Draft Legislation. The National Association of Chain Drug Stores (NACDS) represents the nation's leading retail chain pharmacies and suppliers, helping them better meet the changing needs of their patients and customers. Chain pharmacies operate more than 37,000 pharmacies, employ 114,000 pharmacists, and fill more than 2.3 billion prescriptions yearly. Other members include more than 1,000 suppliers of products and services to the chain drug industry.

On behalf of the National Association of Chain Drug Stores (NACDS), it is my pleasure to present testimony to the Energy and Commerce Subcommittee on Health regarding the drug and device provisions of the Food and Drug Administration Globalization Act Discussion Draft Legislation. My name is Kevin Nicholson, and I hold the position of Vice President, Pharmacy Regulatory Affairs.

IMPROVEMENTS CAN BE MADE, BUT THE CURRENT U.S. DRUG DISTRIBUTION SYSTEM IS SAFE

Chain pharmacy supports efforts to enhance the safety of the drugs dispensed by chain pharmacies to their patients. We recognize the efforts of the Committee to increase safety and security through the provisions in this discussion draft and we support many of the provisions. Our members have and continue to work diligently to undertake efforts to secure the pharmaceutical supply chain from counterfeit drugs. Our industry takes a back seat to no one in its commitment to the safety of the drug distribution system and the health and well being of our patients and customers. We are supportive of the Committee's efforts and appreciate the opportunity to work with you in this process.

However, we believe it is important for lawmakers to remember that while not perfect, the United States prescription drug distribution system is one of the safest in the world, if not the safest. The Food and Drug Administration (FDA) attributes this fact to an

extensive array of federal and state regulations and proactive safety measures in the private sector. In fact, both the FDA[1] and the World Health Organization[2] agree that prescription drug counterfeiting is rare in the United States. Still, we understand the need to maintain and strengthen the integrity of this highly reliable system and are committed to working with lawmakers to improve existing safeguards.

RECENT ACTIONS HAVE HELPED STRENGTHEN THE SUPPLY CHAIN

We are proud of the systems and initiatives that our members have developed with other industry stakeholders to improve U.S. drug supply chain security. Chain pharmacy has taken a leadership role to further ensure the integrity of the products they dispense. For example, many pharmacies have made changes in their purchasing practices, such as requiring their wholesale distributors to purchase prescription drug products directly from manufacturers. Our industry has supported state-level legislation requiring enhanced wholesale distributor licensure requirements and chain of custody "pedigrees" for drug distributions outside the recognized and safe "normal distribution channel." More than 60% of the states have enacted laws and regulations to strengthen the security for the drug distribution supply chain. We have also supported increased fines and penalties for violations of these state laws. Our members have seen marked improvements in the drug distribution supply chain since the adoption of these initiatives and state laws earlier this decade. While there were several incidents drug counterfeiting in the early 2000's, we are not aware of notices from the FDA of drug counterfeiting in the U.S. normal distribution supply chain since that time. It appears that these initiatives and stricter requirements have removed the bad actors from operating within the legitimate drug supply chain.

Drug manufacturers and the wholesale distribution industry have also taken significant steps to further ensure the integrity of the products they distribute. Many wholesale distributors, including the nation's three largest wholesale distributors, have indicated they would no longer trade with secondary wholesalers. This practice was historically a

[1] *FDA Counterfeit Drug Task Force Report: 2006 Update, June 8, 2006, p.1*
[2] *World Health Organization, Fact Sheet No. 275, "Counterfeit Medicines," Revised 14 November 2006*

potential entry point for counterfeit products and contributed heavily toward drug diversion. The elimination of this practice creates a direct flow of product from the manufacturer, to the wholesale distributor, to the pharmacy, and finally to the patient.

Finally, Congress acted just last year to help further secure the drug supply chain by passing the Food and Drug Administration Amendments Act (FDAAA), which requires FDA to "expand and enhance" its resources to secure the drug supply chain against counterfeit drugs.

DRUG AND DEVICE SAFETY PROVISIONS IN THE DISCUSSION DRAFT

Provisions NACDS Supports

While these actions have helped increase the security of the system, we recognize the need to help further secure the drug distribution system against potential future breaches. We applaud the Committee's commitment to stimulate discussion among stakeholders on the need to increase funding and authority for FDA to ensure the safety of the nation's supply of drugs and medical devices. The discussion draft outlines the following meaningful steps to meet this goal: annual registration and FDA inspections of drug and device producers and importers; restrictions on the entry of importation of drugs lacking assurance of identity, safety and purity; requirements for manufacturers of drugs to test their ingredients for safety; allowing FDA to issue fines for violations of drug safety requirements; extending FDA's recall authority to drugs, and extending FDA's enforcement authority to destroy counterfeit or adulterated commercial imports; requiring drug manufacturers to identify the source of the active pharmaceutical ingredient and its place of manufacture upon FDA's request; and prohibiting false or misleading statements to the FDA. We are encouraged by these common sense improvements included in the proposal that may help prevent unsafe products from entering the market in the first place. We also applaud the Committee's efforts to ensure a robust inspection program by creating a dedicated foreign inspectorate and requiring the FDA to keep its field laboratories and district offices open.

Provisions with Which NACDS Has Concerns

Country of origin labeling: While we understand they are well intentioned, NACDS has concerns with the country of origin labeling requirements for drugs and food products under the proposed bill. Many of our members offer high quality and affordable "private label" products to meet the needs of the American consumers. Such products include, among other things, over the counter (OTC) drugs, vitamins and dietary supplements. Ingredients and manufacturing locations of these products may change frequently to accommodate availability, market forces and consumer behavior. Requiring labels to be updated each time the source of an ingredient or the place of processing changes could discourage proper purchasing or processing practices, and limit retailers' ability to respond to market changes, product availability or perceived threats. Further, we are not aware of any basis to suggest that consumers will find this information useful. In fact, requiring country of origin labeling may cause consumer confusion as the labeling of a product purchased today may be different than the labeling of the same product purchased tomorrow. We believe that such situations are likely under the current proposal.

In addition, further regulation of such items as dietary supplements and vitamins would be superfluous in light of the steps the FDA has taken in recent years to ensure safety of these products. In 2007, the FDA issued a final good manufacturing practices (GMP) rule related to supplements which addressed safety concerns related to their manufacturing, processing, packaging and holding. We believe that the FDA should be allowed to pursue its current approach to dietary supplement and vitamin safety without imposing onerous labeling requirements. A consumer taking a supplement properly manufactured using the FDA's GMP process in an FDA inspected and monitored facility will not care if the ingredient is from Montreal, San Francisco or Sao Paulo (for example) so long as the product meets the FDA's standards and their personal needs. We are aware of no evidence that these products pose high risk to consumer safety. FDA's efforts, including the recent GMPs, appear to be working very well.

Similarly, requiring country of origin information on drugs, including OTC drugs, may be confusing to consumers as the source of the active ingredient may change often because of market forces and other reasons. As a result, different packages of the same product on a retail shelf may contain the names of multiple countries. Consumers will have no meaningful way to resolve whether a particular package of a given product is safer than the next based on the differences of their country of origin, and are not likely to find such information meaningful or necessary for their needs.

The FDA should be equipped with proper tools to ensure safety of consumer products instead of a labeling requirement that does not appear to provide any further value. As the draft legislation aptly proposes, FDA should be provided with additional resources and authority to execute meaningful inspection and monitoring plan that will allow the FDA, with confidence, to conduct inspections and surveillance of manufacturing processes to ensure the safety of drugs before they are introduced into the market. This will maintain the trust and confidence of the American public and retailers.

Therefore, we urge Congress to move cautiously with careful deliberation before requiring country of origin labeling on drugs and other products sold in chain pharmacies. We believe further study is needed before we have an understanding of whether these requirements will actually achieve the goal of enhancing drug safety. Finally, the FDA should be adequately funded to provide for proper inspection process to maintain a high level of confidence with the American consumer.

Concerns with Tracking and Tracing for Prescription Drugs: As the Committee may be aware, legislation has been introduced [H.R. 5839] that includes a mandate for tracking and tracing of prescription drugs. While we appreciate that the Committee draft does not contain these provisions, we believe it necessary to state our strong concerns with this approach. First, however, let us clarify that we understand and appreciate that the sponsors of the bill share our goal of helping secure the drug supply chain and we know that their bill is a well intentioned effort to achieve that goal. While we cannot support H.R. 5839 as currently drafted, it does contain certain provisions that we could support. For example, the bill contains provisions that would allow the destruction of adulterated

and misbranded drugs, would increase the requirements for licensure of wholesale drug distributors, and would require a study on threats to the domestic prescription drug supply chain.

Despite these sensible provisions, our overriding concern with the bill relates to its mandate that all prescription drug containers be tagged with "track and trace" technologies. Although emerging technologies (e.g. 2D barcodes, radio frequency identification (RFID) tags) to track and trace the distribution of prescription drugs may provide promise as future safeguards, significant industry-wide challenges must be addressed and overcome before these technologies can be determined to be an integral, reliable, and effective means for drug supply chain security. Simply stated, these technologies need to be properly "road tested" and the "bugs" worked out before any statutory mandates for their use.

We are concerned with mandating use of any technology that is under development and premature. While these technology mandates may sound simple, their adoption would be extremely complex and costly for the health care system, and most importantly there are many issues and concerns regarding their use and operation that remain unresolved. Chain pharmacy is directly aware of these concerns from participation in pilot programs. Chain pharmacy has participated in pilots to test the feasibility of RFID technology, determine its ability to meet the needs of the supply chain, and it's utility to detect and thwart counterfeit product from entering the supply chain. The results identified many issues and areas where improvement was needed and many unresolved issues and concerns. The pilots have shown that they are many years away from being proven reliable, scalable, operational, and effective.

Mandates for Prescription Drug Tracking and Tracing are Costly: In addition, our members have serious and legitimate concerns with the considerable costs that track and trace systems would impose. Some estimate the cost associated with purchasing and installing all the necessary hardware and software related to track and trace could be as much as $30,000 per pharmacy location. With 55,000 pharmacies nationwide, this could cost the pharmacy industry $1.65 billion – a devastating blow to an industry facing

billions in cuts from Medicaid "AMP" payment reductions. Moreover, the costs of these mandates will not be limited to retail pharmacies. Our understanding of these proposals is that track and trace systems will also be required wherever prescription drugs are dispensed, such as hospitals and clinics. To be clear, pharmacy is not averse to making investments to secure the safety of the supply chain. To the contrary, our members make significant investments every year to ensure that the products they provide our patients and customers are safe and effective. Their reputations and the health of their patients are on the line. However, our industry cannot support an unfunded mandate of billions of dollars for systems that are still unproven and that could cause serious disruptions in our ability to efficiently provide prescription drugs to our patients.

DRUG TRACKING AND TRACING SHOULD NOT BE MANDATED DUE TO SERIOUS CONCERNS FOR PHARMACIES AND DELIVERY OF HEALTHCARE

Although emerging technologies such as electronic pedigrees and technologies (such as RFID tags) to track and trace the distribution of prescription drugs may be promising as future safeguards, this has not been proven. Significant industry-wide issues must be addressed and evaluated before any such mandates should even be considered, and these technologies have been determined to be an appropriate and cost-effective means to secure the drug distribution system.

Pharmacies face particularly difficult challenges with implementing such technologies. Concerns at the pharmacy level are more sensitive than for manufacturers and wholesalers, as pharmacies are the only members of the pharmaceutical supply chain that would have to balance their resources between electronic tracking compliance and direct patient care. Requiring pharmacies to adopt immature technologies will cause pharmacists and pharmacy personnel to be distracted with complex compliance issues, thus taking time away from providing pharmacy services to their patients.

As the last link in the supply chain, pharmacies would be responsible for enforcing the tracking and tracing compliance of previous possessors of that product including researching discrepancies and malfunctions of upstream systems. This research would

take precious time from already busy pharmacists and pharmacy personnel, allowing less time for professional pharmacy responsibilities, such as patient counseling and prescription processing. As we stated above, any tracking technologies must be extensively tested before we can even consider mandating their use by pharmacies.

Under existing proposals, pharmacies could receive many different types of track and trace systems creating burdensome and unworkable requirements that would add formidable costs and disrupt the delivery of pharmacist patient care services. The cost burden for implementing these as yet unproven technologies will be very high across the health care system and would likely raise the prices of drugs with resulting negative effects for the delivery of healthcare. Therefore as discussed previously, we are of the opinion that our proposed measures to prevent counterfeiting provide optimal cost and security benefits for the health care system. We propose a three-pronged approach to fight counterfeiters as discussed below.

TRACK AND TRACE TECHNOLOGY WOULD NOT HAVE PREVENTED THE HEPARIN INCIDENT OR ENHANCE THE DRUG RECALL PROCESS

Some proponents of mandatory track and trace systems cite this year's recall of contaminated heparin to build support for their proposals. While the deaths associated with this incident are tragic and heart wrenching and we extend our condolences to anyone affected by this incident, we believe that track and trace technologies would have done little to prevent or improve that unfortunate situation. Four key points are crucial to this understanding: (1) the heparin incident was caused by *contamination* in China of the *active ingredient* used to manufacture the finished heparin product ; (2) tracking and tracing the finished heparin product would not have prevented the *contamination of the active ingredient used in the heparin*; (3) the FDA recall process for the contaminated heparin was immediate, robust, and effective; and (4) the tracking and tracing technologies would not replace the need for the FDA recall process, and a thorough FDA inspection and investigation. A significant point is that the tracking and tracing technologies have no ability to replace the FDA manufacturing inspection process or the FDA mandates and inspections for compliance with good manufacturing practices. We

fear the technologies could provide a false sense of security because they would be applied to the finished product.

It is essential to understand that the FDA investigation shows that the heparin contamination incident relates to events in the manufacturing of the active ingredient, and not to the post-manufacturing drug distribution of the finished labeled prescription product in the U.S. drug distribution system that would be subject to the tracking and tracing technologies. As such, tracking and tracing of the finished drug product through the U.S. distribution system would not have prevented the heparin contamination incident. FDA has indicated that the heparin incident was caused by a "heparin-like" contaminant found in the *active ingredient* used to make the heparin prepared at Chinese facilities. The contaminant was not detected during the routine required testing process that occurs before manufacturing of the finished product. FDA is investigating how the contamination occurred.

For those concerned about whether tracking and tracing is necessary for the recall of products such as the recent contaminated heparin, FDA already has an efficient, extensive, and quick recall process, and *one that includes effectiveness checks on all of the company's actions to determine that the recall is complete*. When FDA orders a recall, notices are immediately sent out to wholesalers and pharmacies to instantly pull the affected product from their inventory. As a result, we have hundreds of thousands of hands at the drug manufacturers, wholesalers and pharmacies working immediately to pull recalled products from the entire U.S. distribution system. Handling drug recalls by scanning tracking tags would not hasten the recall process. The recent heparin contamination is evidence of the effectiveness.

- On January 9, 2008, FDA learned of the adverse events related to heparin from CDC investigators.
- On January 16, 2008, FDA initiated inspection of the drug manufacturer's manufacturing plant and the drug manufacturer initiated the heparin recall.
- On January 17, 2008, FDA initiated notice of the recall. In addition, FDA launched and is continuing an extensive in-depth investigation.

Finally, it is far from clear that these technologies would improve the existing robust and time-tested recall process significantly, if at all. An efficient, robust and quick FDA recall process already exists, and it has worked very well in the past and in the current heparin incident. Even if these technologies would enhance any facet of the recall process marginally, a point which has not been established, these technologies are not ready for implementation and cannot play a role in ensuring product safety.

NACDS SUPPORTS A THREE-PRONGED PROACTIVE APPROACH TO ENHANCE SECURITY OF THE DRUG DISTRIBUTION SUPPLY CHAIN

While today's emerging drug tracking technologies, such as RFID, show promise in providing future improvements to the drug supply chain integrity, significant time will be required to fully develop and standardize these technologies and understand their capabilities. In the meantime, we offer a proposal that provides practical and immediate initiatives to enhance the security of the drug supply chain. We are of the opinion that our proposal is the optimal approach to secure the U.S. drug distribution system from counterfeit and adulterated prescription drug products and for the safety of consumers.

The measures proposed until now to secure the U.S. drug distribution supply chain from counterfeit prescription drug products have been technological in nature from identification and tagging, such as RFID and 2D bar-coding. However, the investment costs across the supply chain required to implement these technologies is formidable for drug manufacturers, wholesale drug distributors, and pharmacies. Because criminal behavior is the basic component of counterfeiting and adulteration, it is doubtful that technological measures are likely to stop these wrongful acts.

Unlike proposals for tracking prescription drugs, we believe that our proposal is workable and would prevent the introduction of counterfeit drugs in the first place. A system of tracking prescription drugs would only be helpful after the fact when a counterfeit incident occurs, not with preventing the introduction of counterfeit drugs. A tracking system would only be secure until counterfeiters figured out ways to exploit the system for their gain. We frequently hear about breaches of supposedly secure systems. Our

proposal does not rely on undeveloped technology that may be exploited at some point in the future.

Since these technologies are directed at authenticating genuine drug products, we support measures to prevent counterfeiting through the strict controls of a certification process of all partners in the U.S. drug distribution system. Our opinion is that certification of all partners in the U.S. drug distribution channel is the optimal means to prevent counterfeiting by providing a sustainable and cost-effective solution.

Our three-pronged proposal would prevent the introduction of counterfeit drugs into the prescription drug supply chain by proactive steps that would raise the security for drug distribution across the nation. All drug distribution supply chain participants would be required to meet strict standards. Our proposal would do the following: (1) require uniform comprehensive standards for state licensure of wholesale distributors across all 50 states rather than allowing differing state requirements; (2) require all drug distribution supply chain stakeholders at the company level (e.g. drug manufacturers, wholesale distributors, and pharmacies) to be certified periodically through a Food and Drug Administration program for compliance with "secure drug distribution practices" ("SDDPs"); and (3) require uncertified entities to provide prescription drug pedigrees. Our proposal is discussed in more detail below.

Uniform National Enhanced Wholesale Distributor Licensure Requirements

Chain pharmacy's proposal would amend federal law to require states to establish enhanced requirements for licensure of wholesale distributors and to establish uniformity of these strong and secure wholesale distributor licensure requirements for all states. It would set comprehensive stringent requirements rather than federal law's current "minimum" requirements. By providing national uniformity, it would benefit the drug distribution system and provide wholesale distributors (where many operate in a number of different states) with similar requirements in each state. The increased licensure provisions would add extensive requirements. These include comprehensive licensure information to obtain or renew a license as a wholesale distributor. This will allow state licensing authorities to have adequate and necessary information when granting licenses.

Examples of minimum information include complete business information, owner information, and lists of other licenses. In addition, wholesale distributors would be required to have a designated representative for each wholesale distributor facility who would be responsible for ensuring that the operations are in compliance with applicable requirements. The designated representative would be required to meet certain requirements, such as age and experience, and would be required to provide a personal information statement under oath concerning the representative's history, such as residences, occupations, and any misdemeanors or felonies related to drug distribution. These requirements will assure that the person is suited to manage the facility.

Other requirements include: (1) a security bond to be posted by the licensure applicant of at least $100,000 or similar security that will ensure that the state licensing agency can collect assessed penalties for any violations. A publicly-traded company that files a form 10K with the Security and Exchange Commission would be exempt; (2) mandatory physical inspections of wholesale distribution facilities for initial licensure and periodically thereafter, to ensure that the facilities are legitimate, and have adequate resources and a proper environment to serve as a wholesale distributor of drugs; (3) criminal background checks of designated persons to ensure legitimacy of persons seeking to operate wholesale distribution facilities; and (4) a license for each facility operated by the applicant. The state licensing agency would have the ability to restrict, suspend, or revoke the license.

The proposal would preempt state laws and regulations that are different from the federal requirements. This will foster a uniform system of wholesale distributor licensure that will best serve the interests of the public in providing a safe and secure drug distribution supply chain through uniformly high standards for licensure.

FDA Certification Program for Drug Distribution Participants to Assure Security of the Drug Distribution System

Our proposal would amend federal law to add a new requirement for drug distributors to be certified in accordance with FDA developed "secure drug distribution practices" ("SDDP"). It would replace the authorized distributor of record system with a more

secure system that would require all participants in the drug supply chain to be certified for compliance with secure distribution practices. These requirements would assure a safe drug distribution supply chain through compliance with safe secure distribution practices, such as purchasing directly from the manufacturer, or from a wholesale distributor that purchases directly from a manufacturer or from other certified distributors.

The proposal would establish an FDA administered certification program requiring drug manufacturers, wholesale drug distributors, pharmacies, and other participants in the drug distribution system to certify compliance with the safe and secure drug distribution practices. A business entity as a whole would apply for certification, not each individual location.

Certification would provide a safe and secure drug distribution supply chain to prevent counterfeit, adulterated, misbranded, expired, and recalled drugs from entering the drug distribution system. Certified entities would be required to provide proof of certification to upstream and downstream entities upon request and to provide evidence of certification through a certified statement on any documentation that accompanies, or provides advance notice of, any distribution. The provision would also contain a preemption provision in relation to state laws. The preemption clause would be required to establish a national uniform system to certify compliance with secure drug distribution practices.

Pedigrees Required for Drug Distributions by Uncertified Lacking FDA Certification of Compliance with Secure Drug Distribution Practices (SDDPs)

Chain pharmacy's proposal would amend current Prescription Drug Marketing Act provisions to remove the exemption for manufacturers and Authorized Distributors of Record from passing a pedigree. This proposal would provide numerous benefits to secure the drug distribution supply chain. It would eliminate the concerns with the current law in which pedigrees are not required from manufacturers and ADRs and replace it with a secure system that would require that any distributor of a drug that is not certified by the FDA for compliance with secure distribution practices would be required to provide a "pedigree" (i.e. a statement of distribution history back to the drug

manufacturer or to the certified entity that purchased the drug directly from the manufacturer).

The ADR and manufacturer exemptions would be removed so that there is a uniform certification system for all participants in the drug distribution supply chain. It would create a certification system that allows for easy and certain recognition of drug distribution participants that have met FDA established standards, and thereby foster a safe secure distribution system. This change would assure that drug products are distributed in accordance with secure distribution practices, and if not, the drug must be accompanied by a pedigree showing the distribution history back to the drug manufacturer.

This would also preempt state laws that are different from the federal law to establish a uniform national security system for the drug distribution supply chain. A uniform national system would avoid a patchwork of different pedigree laws across the supply chain and provide certainty to regulators to know when a pedigree is required.

We believe that our three-pronged proposal offers an effective, practical, efficient, and timely solution to prevent counterfeit drugs from the U.S. drug distribution supply chain. It would establish a reliable and operational check on the drug distribution supply chain with both immediate and long standing benefits for the safety and security of the drug distribution supply chain. Furthermore, it is not contingent on technologies that will require years to develop, standardize, test, and evaluate, and need further investigation. In addition, it is not yet known whether these technologies will ever be a reliable, scalable, practical and cost-effective solution for guarding the drug supply chain.

CONCLUSION

NACDS thanks the Committee for consideration of our and allowing us to share both our concerns about the problem of counterfeit drugs as well as our comments on chain pharmacy's proposal for a proactive 3-pronged approach to enhance the security of the pharmaceutical drug supply chain.

Attachment

Executive Summary

The United States prescription drug distribution system is one of the safest in the world, if not the safest. Chain pharmacy is committed to working with lawmakers to maintain the integrity of this reliable and safe system. We are proud of the systems and initiatives that our members have undertaken to maintain and improve the security including changes in purchasing practices and working with their wholesale distributor partners to require purchasing directly from drug manufacturers.

Chain pharmacy supports the Committee's efforts through this discussion draft to increase the safety and security of U.S. drugs and devices. We particularly want to highlight the provision in the discussion draft that calls for a certification program for foreign and domestic food facilities that aligns with NACDS' proposal. NACDS is offering a proposal for enhancing the safety of the drug distribution supply chain through certification of supply chain partners in the U.S. drug distribution supply chain.

NACDS offers a three-pronged approach to prevent introduction of counterfeit drugs by proactive steps that would raise the security of the drug distribution supply chain across the nation. Our proposal would do the following: (1) require uniform comprehensive standards for state licensure of wholesale distributors across all 50 states rather than differing state requirements; (2) require all drug distribution supply chain stakeholders at the company level (e.g. drug manufacturers, wholesale distributors, and pharmacies) to be certified periodically through a Food and Drug Administration program for compliance with "secure drug distribution practices" ("SDDPs"); and (3) require uncertified entities to provide prescription drug pedigrees.

NACDS is concerned with legislative mandates for unproven and immature prescription drug tracking and tracing technologies. Their adoption would be extremely complex and costly for the health care system and many issues and concerns regarding their use and operation remain unresolved. Chain pharmacy is directly aware of these concerns from participation in pilot programs. Such technologies are many years away and present a number of challenges that have yet to be address and resolved.

Pharmacies face a number of particularly difficult challenges with implementing such technologies. Pharmacies are frontline health care providers and would have to balance their resources between compliance with drug tracking and tracing and providing medications to patients. As health care providers, pharmacies would be responsible for enforcing and clearing up problems if the technology did not operate as intended. As a result, patients may experience delays in obtaining their prescription medications. These activities would take precious time away from pharmacists in providing patient care such as patient counseling, medication therapy management, and prescription dispensing. Additionally, as the technologies are immature, pharmacies would receive many different types of track and trace systems and likely face constantly changing systems.

Track and trace systems would not have prevented the contaminated heparin incident. The heparin incident was caused by contamination in China of the *active ingredient* (derived from pig intestines) used to manufacture the finished heparin product. Tracking and tracing the finished heparin product would not have prevented this contamination. The FDA recall process for the contaminated heparin was immediate and robust. A significant point is that the tracking and tracing technologies have no ability to replace the FDA manufacturing inspection process or the FDA mandates and inspections for compliance with good manufacturing practices.

We urge Congress to carefully examine all proposals and not prematurely mandate technologies that are still under development. Efforts to enhance the security of the drug supply chain must be feasible, practical, reliable, and cost-effective. We further urge Congress not to include proposals that would interject drug identification and tracking requirements into this bill. Lawmakers should proceed cautiously before imposing additional requirements on the drug distribution supply chain and consider the impact on the health care system. Issues of such great importance to the health care system deserve significant deliberation.

Requiring country of origin labeling on drugs and food products will provide no additional value in ensuring their safety. In fact, consumers are likely to be confused by such information. Instead, the FDA should embark upon a thorough inspection and

surveillance of manufacturing processes and controls to ensure that harmful products never enter the market in the first place. Finally, we applaud the Committee's recognition of the need to increase the FDA's funding and inspection authority to ensure the safety of regulated products.