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Dockets Management Branch

Food and Drug Administration

5630 Fishers Lane

Room 1061

Rockville, MD 20852

Re: Anti-Counterfeit Drug Initiative (Docket No. 2005N-0510)

Dear Dockets Management,

Aegate Inc submits these comments in response to FDA's questions published as part of the Anti-Counterfeit Drug Initiative Workshop and Vendor Display on 8 and 9 February 2006. As the leading provider of authentication at the point of dispensing services, Aegate is passionately committed to improving patient safety. Aegate shares FDA's concerns for the risk to patient health posed by counterfeit drugs, and welcomes the opportunity to contribute to FDA's leadership in setting standards of behavior that put patient safety first.

Because of its pragmatic approach to the problem and the success of two pilots, one in the UK and one in the US, Aegate has unique experience in the area of authenticating drug products. In 2004 we showed how mass serialization coupled with scanning in UK pharmacies could be combined to deliver a high quality service to pharmacists at the dispensing point. Some of our pilot pharmacists are still scanning product, so much do they value our service. In 2005 we showed how our service could be used by community pharmacists in the US using bulk packs as well as unit of dose packs, and later next month we intend to publish our results in this area. The lessons learned in both pilots should be useful to FDA in showing how mass serialization combined with pharmacy scanning can deliver high levels of security and consumer confidence.

In these comments Aegate responds to specific questions posed by FDA in the areas that we consider ourselves most competent to address, namely implementation of RFID, the role of FDA, mass serialization, and privacy concerns.

As a general statement of principle, Aegate believes that patient safety is of paramount concern, and efforts to ensure this should be ahead of other considerations. We also believe that steps to improve safety should not be deferred while industry standards and technologies mature. Mass serialization of drug product using barcodes combined with scanning at the dispensing point is a simple yet effective

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approach to the counterfeit problem. We endorse unreservedly FDA's logic of a layered approach to safety. Clever applications and technologies can and will address the complexities of product and supply chain needs, as well as providing superior levels of safety over time. However, it is not sustainable in our view to defer increased levels of patient safety because a particular technology or industry standard is immature.

In addition to patients, other stakeholders can benefit from mass serialization of drug products coupled with pharmacy scanning. Healthcare payers have an audit trail of what has been dispensed. In Belgium and Italy, drug products are mass serialized using barcodes by order of the health ministries in those countries, primarily to defeat reimbursement fraud. Mass serialization can also unlock further efficiencies for healthcare payers. Electronic prescriptions combined with electronic product codes can eliminate keying errors and so drive down medical error. In the UK one of the largest IT implementations concerning state healthcare provision is underway. One aspect of this project is to provide for electronic prescriptions and serious consideration is being given to mass serialize drug products to enable the prescription-patient-pack linkage.

A. Implementation of RFID

Questions: What incentives are needed for more rapid and widespread adoption of RFID in the U.S. drug supply chain? How can these incentives be achieved?

Aegate: Aside from financial incentives such as capital allowances or other favorable tax methods that are beyond FDA's jurisdiction, the best incentive would be to mandate mass serialization on drug products and leave it to industry to determine the most appropriate technology to ensure compliance.

What are the current obstacles to widespread adoption of RFID in the U.S. drug supply chain? How can these obstacles be overcome?

Aegate: The greatest barrier to widespread adoption of RFID is uncertainty. The economics of using and reading RFID on different types of drug products in volume remains uncertain and does the interoperability of data systems between different points in the supply chain. Another barrier is the asymmetry of the benefit and burden on industry. Manufacturers arguably face the greatest burden in that they must apply tags and build or license systems to record and manage serial numbers, while entities further down the supply chain get the benefit of reading the numbers. FDA could remove these obstacles by requiring only that drug products be mass serialized by manufacturers using methods proportionate to the risk. Barcodes are considerably less expensive than RFID to implement and the technology to apply and read barcodes is ubiquitous in today's world.

What is FDA's role in further facilitating adoption of RFID across the drug supply chain?

Aegate: We respectfully suggest that FDA's role in this area is to bring clarity to what is a complex topic. If one starts with the basic remit of FDA to serve the people of the United States by making drugs safe, then the emphasis should be on regulating behaviors to accomplish that remit. We believe that the regulated industry should be required to respond to known risks. (The PDMA is an example of such a regulatory response.) Counterfeiting is one such risk; it is difficult to quantify in absolute terms. In relative terms it would appear to be on the increase in the US. The impact of counterfeit drugs on consumers is wide and various but invariably deleterious; confidence is shaken, people feel less inclined to take their medicines, medical conditions are protracted in duration or exacerbated, and in the most serious of cases permanent injury can result. Also the measurable efficacy of drugs is distorted. In addition there is the burden placed on the investigation and enforcement agencies.

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The tools that FDA has at its disposal range from regulation, to education, to dissemination of best practice. Facilitating the adoption of RFID we believe comes under the heading of disseminating best practice. But practice will only take place if there is a need to comply. So firstly there must be regulation. Without regulation, there is no incentive for industry to behave in the way considered most appropriate, or having greatest social utility. Without regulations providing for an environment in which consumers and healthcare professionals can detect counterfeits, or an environment which makes it less economic for counterfeiters to pass off their wares as genuine, patients will remain at risk from unscrupulous persons.

In other words it is the role of FDA to work with the relevant legislature and (where FDA has delegated authority) to pass regulations that have the effect of make drug products safe in the broadest sense of the word. The adoption of methods to keep children safe from consuming adult medicines e.g. child-proof tops on bottles, did not occur because the regulator said there exists a method of child-proof tops; it came about because a regulation was passed that said medicines had to be packaged in such a way that children could not access them.

What is the timetable for widespread adoption of RFID across the drug supply chain, with and without additional incentives?

Aegate: Without incentives, the timetable for widespread adoption is impossible to predict. In the meantime the threat to patient safety from counterfeits continues to exist and, quite possibly, grow. If there was a regulation that said drug manufacturers have a duty to take reasonable steps to ensure that healthcare professionals handling their products, and consumers receiving their products, could reasonably satisfy themselves that the drugs they were handling had not been tampered with and were genuine, then the timetable would be in the control of FDA.

A compliance environment would create the kind of spur to innovation and new product development that FDA seeks at present. Manufacturers would be free to adopt the most appropriate method to deter counterfeiters and strike the right balance between cost, deterrence and patient confidence.

B. RFID Standard Setting

Who should set the standards for RFID? Currently we are aware of the efforts of only one organization, EPCglobal, to develop standards for the use of RFID in the drug supply chain. Are there other entities within the United States or abroad that are also developing standards for the use of RFID for the drug supply chain?

Aegate: RFID is a technology and not an objective or an end in itself. Standards for a technology serve a useful purpose in that they allow for interoperability and hence lower overall costs for adopters and users of technology. Therefore standards that users of RFID should follow should be set and agreed by the users. EPCglobal is one forum with a lot of experience of the process by which standards are set. ISO is another. These groups are representative of users, not regulators. We respectfully suggest that a regulator sets the standards by which people behave towards each other. Technology should serve the people and not the other way round.

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Role of FDA.

Is there a role for Federal leadership by FDA to advance the standard setting efforts? What is that role? Is there a role for other Federal entities, such as the Drug Enforcement Administration or the Department of Defence? Should standards remain voluntary? Why?

Aegate: We respectfully suggest that FDA confine its efforts to specifying the standard of behavior that is expected and set industry a date for compliance.

C. Specific Drug Supply Chain RFID and E-pedigree Issues

Mass Serialization.

What numbering conventions currently are being used or considered for mass serialization?

Aegate: In the global pharmaceutical industry today a number of conventions are in use. In Belgium, drug products carry a barcode containing a numeric code comprising a 7 digit registration code, 8 digit unique serial number with a single digit check. The Aegate authentication process can work with any numbering convention. In our view it is essential that the numbering convention used provides for a random number to be generated. This is to prevent counterfeiters from predicting valid mass serialization numbers from a few genuine packs. Unless the numbering convention is random we do not believe the security offered will be sufficient to state that the product is authentic. Many labeling systems provide for printing of randomized codes at no extra cost. Our own system ensures that only data-sets meeting a minimum level of randomization will be entered as valid identities on the Aegate database.

Should there be a single numbering convention or are different conventions compatible?

Aegate: In our view it is essential to allow for multiple conventions. It will also be critical as in our view it is unlikely that one size will fit all and a supply chain that allows for a wide degree of flexibility in the choice of convention will have lower barriers of accessibility to stakeholders as well as raising the barrier to counterfeiters.

Should the national drug code (NDC) be part of the unique identifier or should the identifier be a randomly generated number?

Aegate: In our view it is important that both the NDC code and mass serialization number be on the drug product. The two could be separate or combined. If RFID tags are used it should be noted that inserting the NDC raises the cost of the tag and the processing required.

In Belgium the product identity (NDC equivalent) and mass serialization identity are combined in a single linear printed code 128 bar code format. The Aegate process reads the Belgian labels, and separates the codes into the product (NDC part) and the mass-serialization part.

We also support a convention where the NDC and the mass serialization number are different technologies. This means that a company can keep the same pack artwork and design which already shows the NDC number printed and, for example, add a read-only RFID 13.56MHz tag to the pack for serialization purposes. Our scanning technology can read both at the same time, interpret the information and display the result in real-time.

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Concerns have been raised that use of the NDC raises privacy issues.

What is the extent of these concerns and how should they be addressed?

Aegate: Concerns have been raised that drug product could be identified by anyone if an NDC code is incorporated into an RDID tag. For example a passer-by in the street could read the products in the pharmacy bag being carried.

Aegate has worked with privacy groups including Caspian to develop a code of practice for use of RFID with drug products. Our code of practice recognizes the benefit of RFID in ensuring supply security and patient safety, and respects patient privacy. It states that only read-only tags are in use and that the tags will only contain the mass serialization number.

Anyone reading that tag only sees a number with no meaning. This has been successful and our US pilot has raised no privacy concerns, either locally, nationally or internationally.

To address privacy concerns we suggest that the product identifier should not be included as a write function in the RFID tag and that the tag should be read only, containing the random mass serialization number only.

What is the timetable for widespread mass serialization for prescription drug products, with and without additional incentives?

Aegate: Given the political will mass serialization of drug products could take place quickly, and manufacturers could adopt appropriate technologies and develop processes to carry it out.

However, we respectfully suggest that FDA must consider the impact on all manufacturers and ensure the way is open for all to participate, not just the largest companies. This means ensuring that mass serialization can be applied using a variety of technologies from the simple linear code (as used very successfully to combat fraud in Belgium) to the more sophisticated and expensive RFID technologies.

The other factor to consider is that mass serialization without the capacity to read the numbers is not a solution. The Aegate process reads the mass serialization number and NDC component of the codes as product is dispensed to patients. In this way we provide a critical final check on the security and authenticity of that product protecting patients from fraudulent supply.

D. Privacy Issues

Disclosure of Information

Is it possible for someone to read the information from an RFID tag on a drug product without the possessor of the product knowing it? If it is possible, what information would they learn, and how could the information be used?

Aegate: Yes it is possible. There are concerns that surreptitious scanners could be concealed, for example in doorframes. The implications of this in healthcare are for example if someone goes for a job interview and in their pocket or bag there is an HIV product, the employer could decide not to employ someone based on this information and the person concerned has no idea that this information has been revealed. This largely depends on what information has been added i.e. written to the tag. Our view and our code of best practice

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agreed with privacy groups is that no information other than the unique random serial number already embedded in the silicon chip should be added to the tag. This way any surreptitious scanning would only reveal a meaningless number. This would also suggest that read/write RF tags are not appropriate for the application to individual items of medicines.

Turning off the RFID Tag

Some people have suggested that the RFID tag could be "turned off" before it leaves the pharmacy, or that patients could be given the choice of whether it is "turned off." Is it possible to "turn off" the RFID tag? What are the advantages or disadvantages of "turning off" the RFID tag?

Aegate: It is possible in theory to turn off the tag, however in practice this has proven to be extremely unreliable. Metro Stores in Germany attempted this with spectacular failure rates and privacy rights campaigners in their stores. We believe it would be impractical to expect a pharmacist to remember to ask each patient if they would like the tag turned off. Some will be missed as pharmacists are under extreme pressure to achieve dispensing efficiency at peak times of the day. Also the act of turning off the tag will re-expose the medicine to additional potential heating effects that as yet are not fully understood. In conclusion, this is not a workable solution.

Consumer Education

What type of consumer education is needed as the use of RFID in the drug supply chain becomes more prevalent? What messages should be conveyed? Who should develop consumer education program(s)? Should there be a notice on the product package that an RFID tag is affixed to the product package? If so, what should the notice say?

Aegate: We have carried out some consumer surveys that identified that there is little recognition or understanding of what an RFID tag is or the privacy issues associated with its use. Having written the code of best practice with privacy groups both in Europe and the US, the issue is wider than just the tag, care must be also be taken to identify both the location of the scanner and those authorized to use it. Developing a consumer education program around the reasons for usage of RFID to prevent counterfeits will need to be handled with care as it could raise more alarm and discourage people from taking their medicines. Aegate's experience in this area should be useful to FDA in setting guidelines or best practice.

Conclusion

As discussed above, Aegate is a supporter of a layered approach to patient safety. Mass serialization coupled with scanning is the bedrock upon which improved levels of patient safety can be delivered. The technology to deliver this is available today and there can be no justification for deferring its adoption beyond today. The same approach has been adopted by the financial services industry with charge and credit cards to defeat fraud. Simple magnetic strips were initially used, to be replaced by silicon chips and now the combination of chip-and-pin. The methods have evolved as technology evolved. Track-and-trace technologies and pedigrees have the potential to be a cornerstone of anti-counterfeiting and drug integrity efforts in the long-term, but will not by themselves adequately protect the American public. Other important changes are also needed to insure the integrity of the system. These include enhanced business practices and stronger regulatory oversight in order to ensure greater discipline and control of the U.S. drug supply chain.

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Aegate is grateful for the opportunity to provide these comments to FDA, and looks forward to continuing to contribute to this important debate.

Sincerely

A handwritten signature in black ink, appearing to read 'Richard French'. The signature is written in a cursive style with a large loop at the beginning.

Richard French
General Counsel