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Leyla Rahjou-Esfandiary
Center for Drug Evaluation and Research
Food and Drug Administration
Bldg. 51, Rm. 2262
10903 New Hampshire Ave.
Silver Spring, MD 20993

RE: Future Format of the National Drug Code; Public Hearing; Request for Comments; Docket FDA-2018-N-2610

Dear Ms. Rahjou-Esfandiary:

Thank you for the opportunity to respond to the FDA's request for comments on the need for a new NDC format in the next 10 to 15 years. I am writing on behalf of myself as a citizen and patient, but I have a fair amount of career experience and personal interest in healthcare product identification and supply chain automation and efficiency. I am currently employed as a Global Regulatory Strategist for Systech International, a pharmaceutical serialization, tracing and brand protection solutions developer. I am also the founder and author of the independent RxTrace website where I write regularly on topics related to healthcare supply chain technology, standards and regulations like the DSCSA. I am the author of the book, "The Drug Supply Chain Security Act Explained", First and Second Editions. I have written extensively on RxTrace.com about the history of the National Drug Code and how it works within GS1 GTINs and barcodes, including the problems you are currently facing and more. And I spoke at the FDA Public Meeting on this topic on November 5, 2018.

I'd like to remind you of the points that I think are most important for your consideration as you make decisions about this necessary change.

1. The paramount importance of moving to a *single identifier* for pharmaceuticals, for use by all stakeholders;
2. Possible ways of achieving a single identifier for pharmaceuticals;
3. The timing of your actions.

The paramount importance of moving to a *single identifier* for pharmaceuticals, for use by all stakeholders

FDA should recognize that there are currently *four different identifiers* in use for every drug package. Three different identifiers are now being *printed* on most prescription drug packages. These include:

- **the 10-digit NDC recognized by the FDA**
  This number is in the FDA NDC database and is printed on the label of most prescription and many over-the-counter drug packages.
- **the 12-digit GS1 Global Trade Item Number (GTIN) that is used by drug manufacturers to meet the FDA's Linear Barcode Rule from 2006**
  This number is printed in human readable form under or above the *linear barcode* that encodes

the 10-digit NDC. These barcodes *always* contain the GS1 GTIN because there is no way to encode the NDC by itself into a standardized barcode (linear or 2D). This has been common practice in the industry, predating the 2006 Linear Barcode Rule by nearly two decades on a voluntary basis.

- **The 14-digit GS1 GTIN that is used by drug manufacturers to meet the Drug Supply Chain Security Act 2D barcode requirement**
  With the passage of the DSCSA, manufacturers are including a 14-digit GTIN in the *2D barcode* to fulfill the "NDC-in-datamatrix-barcode" requirement. This 14-digit GTIN is now usually printed in 14-digit human readable form next to the 2D barcode. GS1 may tell you that the 12-digit GTIN and the 14-digit GTIN on a given package are "the same", but clearly a 12-digit number cannot be equal to a 14-digit number. To patients, healthcare professionals and anyone not an expert in GS1 arcana, these two identifiers are different, and they also do not equal the 10-digit NDC or the 11-digit NDC-based reimbursement code.
- **the 11-digit NDC-based reimbursement code used by dispensers, payers and others**
  This number is never printed on the drug package itself but, as you know, is used by these entities to refer to a given drug in their inventory, billing and payment systems.

Four different identifiers for every type of drug package is a serious problem when healthcare provider reaction time is critical and lives are at stake. Which identifier do you need for the system you are working with now? If it needs the 10- or 11-digit NDC, your application had better convert it for you when you scan either the linear barcode or the 2D barcode. If you type it in, the application had better accept any of the four possible codes and convert them to whatever it needs. Today, few, if any applications do all of those conversions. The vast majority require you to know in advance which format they require so you can scan or enter it that way, or it simply won't recognize your number.

The need for an entirely new, enlarged NDC format is the perfect opportunity to fix this serious deficiency. In the interest of reducing confusion, reducing errors, increasing supply chain efficiency and healthcare provider efficiency, and most importantly, in the interest of *patient safety*, the FDA must decide from the start that we will end up with *a single identifier* that all members of the supply chain, healthcare providers and payers will use to identify a given type of drug package. This requirement should be firmly established before you even look at alternative solutions because this requirement should outweigh all others. It is the requirement that all potential solutions should be measured against. Solutions that do not end up with a single identifier going forward should be rejected immediately as insufficient.

Possible ways of achieving a single identifier for pharmaceuticals

The only reason I have included this section is to assure you that there are one or more potential solutions that will end up with a single identifier for each type of drug package. That is, that requirement will not result in an impossible task. In fact, the FDA has already gone through a similar process with medical devices, and for a similar reason. Prior to the implementation of the Unique Device Identification (UDI) final rule, the identifier for any given device was not necessarily unique to that device. In fact, hospitals and other buyers of devices might need many identifiers for a given device configuration. UDI was intended to ensure that a single identifier would describe a single manufacturer's device configuration.

The implementation of UDI was more complex than is absolutely necessary for prescription drugs, but some of the same basic concepts could be followed, with GS1 being the sole "number issuing agency",

since the vast majority (perhaps all) drugs are identified today with GS1 GTINs. There would be no need to establish alternate agencies. In this case, rather than the FDA issuing a Labeler Code to each drug manufacturer, these manufacturers would be required to obtain a GS1 Global Company Prefix (GCP) and register it with the FDA. They could then assign and register each NDC for each of the drug packages, which would be in the form of a fully compliant 14-digit GTIN.

The beauty of this approach is that all existing NDCs could simply be "upgraded" to their corresponding 14-digit GTIN—the one that is already on their product today within the DSCSA 2D barcode. They would need to change the pure NDC printed on the front of their labels from the obsolete 10-digit NDC to the new 14-digit version. The linear barcode should go away when this conversion takes place, but if you decide to keep it, the only change necessary would be to use a different type of linear barcode on each package. The existing UPC symbology cannot accommodate a larger GTIN and therefore cannot accommodate an expanded NDC.

One very important benefit of this approach is that the new NDCs in their native form can finally be encoded into linear and 2D barcodes, without padding or other adjustments. That's because GS1 barcodes are designed for GS1 GTINs.

Again, this exercise is just to show that there is at least one possible solution that meets the single identifier requirement, and this one actually has other benefits as well. Others could certainly come up with other solutions that meet that requirement in a different way, once FDA establishes that the solutions must result in a single identifier for use by all users.

The timing of your actions

Whatever solution you arrive at, you need to settle on it soon. I would say by the end of 2019 ideally, but at least by the end of 2020 as a *worst-case* scenario. I know you are aware that the changes necessary across the supply chain will be huge, no matter which approach you take. I recommend that the FDA not choose an approach based on the fact that it minimizes the changes for one industry segment over the others. You should choose the approach that best meets the requirements, period (that's why the requirements must be established and prioritized *first*).

Once the approach is established and documented, FDA must set fixed dates for the *start* and *end* of a transition period that accomplishes the complete switch to the new approach at the manufacturers *before* the supply of 5-digit Labeler Codes are exhausted. All companies throughout the supply chain, the healthcare provider networks and payer networks must have systems that can understand and make use of the new NDC format/approach on the *start* date. Manufacturers must *not* begin using the new format/approach on their drug packages until that *start* date. And manufacturers must be fully using that new format/approach on all of the products they ship by the *end* date of the transition. All entities must continue to understand and accept both the new and the old format/approach NDCs for many years after the official transition ends. In effect, there can be no official end to the recognition and acceptance of the *old* format NDCs because it could take many years before the last product using the old format is either dispensed or destroyed.

Also related to timing, I strongly recommend that you set the end of the linear barcode requirement on drug packages to correspond with the *start* of the transition period. That is, drug manufacturers could eliminate the linear barcodes from their packages as soon as they begin introducing product with the new NDC format/approach. That will work because on that date all users of the NDC would have new

software that would make use of the new NDC format and that should include making use of the 2D barcode on packages. It will not add significantly to the complexity of software changes that enable the new NDC. Perpetuating the linear barcode beyond that time would be counterproductive because the 2D barcode already contains the NDC, plus a wealth of other information that will enable even greater patient safety uses. FDA should take the lead in firmly guiding the industry toward achieving these benefits for all by eliminating the linear barcode when the new NDC format is on a package. Since this timeframe will probably be 9 to 10 years out, companies should be expected to purchase install 2D barcode readers by then with that much notice. The argument against eliminating the linear barcode will never go away. People are going to complain no matter how much time you give them, so it is better to do that transition logically. Participation in the modern healthcare system should require companies to invest in 2D barcode readers 10 years from now. Patients will benefit well beyond the cost of the new readers where they don't already exit.

Thank you again for allowing us to submit ideas for your consideration.

Sincerely,
Dirk Rodgers
630-839-9177