

Toward a Standardized ID System for Drugs

In his writings, and particularly in 1984—the well-known novel predicting the totality of government bureaucratic involvement in society and our private lives—George Orwell forecast that numbers would gradually replace names as the common means of identifying virtually everyone and everything.

We are now only a couple of years away from that fateful date, and already we see that much of what Orwell predicted has come to pass. For example, it seems more important today for a person to have a Social Security number than it is to have a name. Just try filing your income tax, or getting a driver's license, or registering in college, or opening an interest-bearing account, or cashing a check, or filing a health insurance claim form, and so on *ad infinitum*, without giving a Social Security number. One quickly finds that, if not impossible, it is very difficult at best. But yet, none of these activities has even a remote bearing on Social Security or the intended purpose in issuing Social Security numbers.

Numerous other examples—from the universal price codes appearing on packaged food products, to long-distance direct dial telephone numbers, to nine-digit zip codes, to personal charge account numbers—can be cited from everyday life that also illustrate how numbers and numeric codes have virtually taken over how we now operate in daily living.

All this is happening because, whether we like it or not, these systems generally work. They provide fast access, ready location, foolproof identification, ease of information storage, and similar advantages. As we move closer to the computerized age, such benefits will continue to grow in both kind and degree.

But one area has somehow remained outside of, or at most on the fringes of, our otherwise successful efforts to manage various affairs and activities by developing and applying useful and logical numbering systems.

That area is drug identification. True, we do have a "National Drug Code," and NDC numbers do appear in drug company catalogs, on product labels, and in a few other places. But NDC numbers are not in wide use and it is clearly evident that they are not now—and never will become—an adequate and useful substitute for the drug or drug product name in a manner comparable to Social Security numbers as identifiers for people.

Why is this?

Even a cursory familiarity with the NDC system makes the answer clearly evident. Namely, the NDC numbering system has virtually no consistency or standardization.

Each NDC number is comprised of three segments: the first segment is unique to the manufacturer, and that portion is reasonably satisfactory (although such things as company mergers have created some room for improvement even there); the second segment is used to identify the drug entity; and the third segment identifies the dosage form. It is in these latter two portions of the NDC numbering system that there is absolutely no consistency or standardization.

Each individual drug company is completely free to use

whatever number it wishes to identify the drug and the dosage form. The result, of course, is that there is no uniformity because everyone uses a different number to identify both the same drug moiety and the same dosage form.

How much better it would be if the system were standardized so that a single, uniform number was applied to tetracycline, and similarly that another single, uniform number was used to designate 250-mg capsules. The composite NDC number then would be light years more useful as a means of drug identification, of simplifying such public health measures as poison prevention and treatment, of inventorying and stocking pharmacy shelves, of processing drug reimbursement claims, of more rational drug prescribing, and so on.

Washington rumors are that federal budgetary squeezes may cause the Food and Drug Administration to close down its office that runs the NDC system, thereby abandoning the system itself. Undoubtedly, had the present NDC numbering system been more effective, it would have enjoyed much greater use, thereby making its elimination less attractive to the budget-cutters.

In a concurrent development, the National Association of Pharmaceutical Manufacturers—the so-called "generic manufacturers association"—recently recommended to FDA that a set of uniform drug identification numbers based on the active ingredients be established at the federal level. This proposal was primarily prompted by legislation or regulations being adopted at the state level concerning drug product identification. The NAPM even went a step further with its suggestion by generating a proposed alpha numeric "ID list" covering over 600 drug entities in specific dosage forms.

Based upon our review, the NAPM identification scheme itself is not as useful as it would be if drug entity and dosage form were two separate components of the composite ID number, and if each of these two elements were standardized separately.

However, that really is only a detail of implementation. The key point is the recommendation that *the system itself be standardized*. In that, they have our wholehearted support.

Critics will claim that the NAPM has its self-interest reasons for urging the adoption of such a standardized system. That is true; just as it is also true that the brand name segment of the drug industry had its self-interest motives for opposing a standardized approach years ago when the NDC system was originally developed.

The important consideration now is the broader picture of all that can be done using today's and tomorrow's computer technology if only there were a compatible drug numbering system. It is ironic that the industry that was so far-sighted as to pioneer in the use of the metric system on a commercial level is now the laggard in permitting full adaptation to a standardized drug numbering system, with its associated technological benefits.

Clearly, it is a time for statesmanship in the board rooms of the nation's major drug companies.

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