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DISPENSING '82

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I would propose to you that the USP has been a mirror to the practice of Pharmacy in this country. To understand the dispensing of medicines in 1982, therefore, we need to understand USP and its relation to Pharmacy and Medicine, industry, and FDA.

So I turned to the Good Book (and you will notice that I am using the Revised Standard Version, USP XX-NF XV wherein both the USP testament and the NF testament are combined into one volume) — I turned to the Good Book and found it was written that,

. . . in the beginning, physicians created the drugs. The plant and animal substances were without dosage form and void; and darkness was upon their value.

And the spirit of the physicians moved upon their medicinal usage. and the physicians said, Let there be standards: and there were standards.

And the physicians saw the standards, that it was good; that they divided good from bad, the light from the darkness. And the physicians called the good, USP; and the bad they called non-official. And the January meeting and the December publication were the first year of the USP, 1820.

And the physicians said, let there be future revision of this work, to improve upon it; and let it further differentiate among the substances available. and there was a second edition of USP in New York and a second edition in Philadelphia, an ungodly by human miscommunication in 1830 and 1831.

And the physicians said let us choose drugs the utility of which is most fully established and best understood and form from them preparations and compositions in which their powers may be exerted to the greatest advantage, fully bioavailable, fully reproducible, fully predictable, the herb yielding seed after its kind; and the tree yielding fruit, whose seed was in itself, after its kind; and the physicians saw that it was good.

And the physicians said let the liquids of drugs be gathered together in the USP, and let the solids appear also; and it was so.

And the physicians called the solids extracts, powders, confections, and pills; and the waters they called decoctions, infusions, solutions, syrups, spirits, tinctures, vinegars, wines and waters; and they saw that it was good and published the third edition of the Pharmacopeia in 1840.

And the physicians said, Let there be specialists in the firmament of the heaven to divide the day from the night, to select the good drugs from the bad. And there were formed two great lights, the greater light to select the drugs by day, and the lesser to make the drugs by night; and the homeopathic stars were formed also. And in 1850 the fourth edition of the Pharmacopeia was published with the help of the pharmacy specialists.

And the physicians said, let the drugs spring forth abundantly, every type and size of dosage form, each after its own kind, reproducible, of content uniform; and at that time there was founded the American Pharmaceutical Association to teach, show and tell the pharmacy specialists how to. And in 1860 the fifth edition of the Pharmacopeia was published.

*The author is indebted to the writers of Genesis (anon.), the Preface to USP, 1820 (Jacob Bigelow, M.D.), and Revelations (St. John the Divine) whose words have been plagiarized everywhere possible.

And the physicians said let us make pharmacists in our own image, after our likeness; and let them have dominion over the extracts of the plants, the pills of the tile; the unguents of the slab, the fluidextracts of the percolator and over every dosage form that rolleth down the gullet or spreadeth upon the epidermis.

So the physicians created the pharmacists in their own image, with their own knowledge of dosage form preparation, created they them; male and, later, female ad lib, ad rib.

And the physicians blessed them, and said unto them, Be fruitful, and multiply, and replenish our drug supply, and subdue it; and have dominion over the fluidextracts of the percolator and the pills of the tile and over every dosage form that we might prescribeth.

And the physicians said, Behold, I have selected for you every herb-bearing seed, and every beast of the earth, and every fowl of the air, and every thing that creepeth upon the earth wherein there is safety and efficacy;

And the physicians saw everything that they had made, and behold, it was very good. And they published the sixth edition of the Pharmacopeia in 1870, with the pharmacists doing most of the standards-setting work.

Thus the division of the work of the physicians and the pharmacists was established and in the seventh edition of the Pharmacopeia in 1880 the physicians ended the work of drug preparation which they had started, and rested from all that work which they had made.

But later, the physicians said, It is not good that the pharmacists should be alone, we shall make them an helpmate for them.

And out of their richness the physicians formed pharmaceutical manufacturing companies and brought their drugs to the pharmacists to see what they would call them; and whatsoever the pharmacists called them, that was the name thereof. Scientific creationism? Big bang? Certainly, big bucks. And the Pharmacopeia of 1890 was the largest yet.

And the whole earth was of one language, and of one speech: generic Latin.

And there endeth the allegory. For in 1906, the physicians and pharmacists did not hide themselves amongst the trees of the garden from the presence of the lord government when it first came down with a federal Food and Drug law. Rather, they stood up to the lord government and said.

> do not set up your own standards, but instead enforce the standards of strength, and quality, and purity of the drugs that we have written in the USP.

And they were persuasive, in large measure because the sons of the lord government (i.e., the state governments) had already recognized and were using the USP and NF in their work, and there were state boards of pharmacy and there was a National Association of Boards of Pharmacy.

And likewise, in 1938, the physicians and the pharmacists persuaded the lord government to recognize in the Food, Drug and Cosmetic Act the USP requirements for packaging and labeling also.

And again, after the Kefauver-Harris Amendments of 1962, the physicians and pharmacists persuaded the lord government to recognize the United States Adopted Name as the "established name" of the drug substance.

At that same time, however, the physicians and pharmacists did fail to provide a comprehensive system of prescribers' information, so the lord government forced

the drug manufacturers to do it for them; thus the package insert is negotiated between each company and the government, rather than written by physicians and pharmacists in cooperation with the manufacturers and the government.

And also at that same time, 1962, the lord government decreed that each batch of antibiotics must be baptized even unto the 50th successful generation before the antibiotics makers's genius and genuineness can be accepted as unimpeachable, or so it would appear. There exists in our generation a concern over the necessity of this confirmation exercise and its ritual expenses. Very recently, the prince of the government's agency advocated a return to USP of antibiotics responsibility and the control of antibiotics in the same manner as other drugs.

The lord giveth, the lord taketh away, and the lord giveth again. Sometimes.

And finally, at that same time, 1962, the lord government threw down the whole book and we find there at the end the revelation: I am alpha and omega, the beginning and the ending, which is, which was, and which is to come: the NDA. Blessed are they that follow the NDA, that they may have right to life in the market square, and may enter in through the gates into the city. For without, are dogs and copycats, and sorcerers and quacks, and whoremongers and (censored), and idolaters and look-alikes.

But in our time, since November '80, we see a new heaven and a new earth: for the first heaven and the first earth were budgeted away; and there was no more sea-Med.

And I see the new USP, the new compendium, coming down from the Committee of Revision, adorned with monographs for every drug and general notices for every issue.

And the USP shall have monographs promptly after a drug is first marketed, and shall wipe away all tears from FDA eyes; and there shall be no more death of quality, neither sorrow, nor crying by manufacturers, neither shall there be any more duplication of USP tests by NDA's, and the drug makers that are athirst of the market fountain shall read **Pharmacopeial Forum** freely. And physicians and pharmacists will no longer have to read the **Federal Register,** an apocryphal text to the professions.

And there shall in no wise enter into the USP any thing that defileth, neither whatsoever worketh abomination, or maketh a lie: but they which are written in the book of standards shall be the best that the industry, the FDA, and the professions can devise.

Finally, in our time we have seen the lord government adopt by FDA regulation a program for patient package inserts to be prepared by the manufacturers for dispensing by pharmacists, PPI negotiated by the lawyers of each company with the bureaucrats of the FDA, without input from physicians and pharmacists — or patients either. And physicians and pharmacists did voice such objection that now the lord government proposes to revoke its regulations, specifically citing the Good Books of USP.

But search as I might this old crystal ball
I can not ascertain,
I can not see,
Whether the future contains
USP DI
or PPI
Again.

So I'll lay down the Good Book and my crystal ball and examine the idea to which Pharmacy and Medicine seem so adverse.

The situation is this.

FDA has on the books (i.e., in the **Federal Register**) a final regulation covering patient package inserts for practically all drugs. It establishes the content and format of the patient inserts. It states the requirements for providing them. Each manufacturer has to estimate the number of new prescriptions to be dispensed from each drug container he sells and shall supply sufficient PPI for those new prescriptions plus any that may be requested on refills. He must have Spanish translations available on request. The manufacturer may supply the PPI with the container itself, or he may send them separately. The wholesaler, in turn, may send them together or separately to the dispenser. The dispenser must provide a PPI to the patient on each new prescription, unless the prescriber directs him not to; even so, he has to give it to any patient who asks for it. The dispenser has no discretion: he has to provide it, or not provide it, depending on the wishes of the physician, overriden by the wishes of the patient.

One other point: if the dispenser chooses to prepare his own PPI, he may do so adhering of course, to the FDA regulation guidelines for content and format. If he prepares it to cover all brands of the drug, he may therefore discard the separate inventorying of competing PPI and throw them in the trash along with the physician's package insert.

As I said, this is a final regulation. It was put on the books over a year ago by the Carter Administration and FDA Commissioner Goyan.

FDA proposed to start by implementing it for ten drugs/drug classes. All implementation was stayed by the new Reagan Administration, however. And now, FDA Commissioner Hayes has proposed to rescind the regulation itself. Comments on the **proposal** to rescind were due at FDA last Tuesday.

USP has spoken in opposition to FDA regulating a PPI program since the St. John's pharmacy Congress in 1976.

Our view of the FDA 1980 final regulation is that it has the wrong people writing the words, the wrong people responsible for distributing them, the wrong people responsible for regulation of the system, and the wrong emphasis on the written word. Lest you think I have left something out and that there was something right with the proposed FDA program, let me quickly disabuse you of that heresy.

I'll elaborate.

1. **Wrong people writing the words.** Physicians, dentists, pharmacists, and nurses have to communicate with patients about drugs; patients have to communicate with their practitioners about drugs. Respectively, they know the circumstances under which they give and receive drug use information. They are the ones who should develop the formats and write the words; not the advertising department or the legal department of the drug company; or even the medical department, for that matter, because the manufacturer's medical people are not in the ordinary day to day practice of the profession dealing with ordinary day to day patients, practitioners, and drugs. USP, of course, has all those groups working together writing the patient information section of USP DI. And during the years everybody was arguing with FDA about doing it for ten drugs, USP has done it for practically all drugs.
2. **Wrong people responsible for distributing the words.** FDA put the burden on the manufacturer. Why? The prescriber and the dispenser see the patient; the manufacturer does not. Why start the patient labeling process an extra step back in the system, thus adding a whole new layer of cost to it? Why? Because FDA can control manufacturers more certainly than it can physicians and pharmacists. Furthermore, application of the PPI requirement to a drug gives the FDA control over every manufacturer and every package of that drug, whether

it is a new drug or a not-new drug; post '62, post '38, or pre ' 38; single-source or multiple-source; USP or nonofficial. It gives FDA the best net it has to cover the market place for all brands and packages of a drug or class of drugs.

3. **Wrong people responsible for regulating the system.** I've just described how the FDA PPI system would extend its control over manufacturers. The point is, however, that the FDA would have to extend its coverage to the pharmacists who are supposed to dispense the PPI — and to the physicians who administer the drug in their office and thus must give the PPI, too. Physicians and pharmacists don't even read the **Federal Register** to find out what would be happening to them. No, the practices of medicine and pharmacy and nursing are regulated at the state level and that is where the PPI system should be implemented. The fact that no state has ever felt impelled to require a PPI for even one drug ought to suggest something about the prematurity of the regulation.
4. **Wrong emphasis on the written word.** The FDA regulation makes the piece of paper, the PPI, the be-all and end-all of patient communication. In its required cost justification of the PPI program, the previous Administration calculated that nobody in the pharmacy but a clerk would have to handle the PPI. They did not include the cost of any pharmacist involvement in making certain that the right PPI went with the prescription. No pharmacist involvement in talking to the patient about anything the PPI might say, or might not say.

That is the antithesis of the USP system where the whole emphasis is on getting the practitioner and patient talking together and the written drug use information becomes simply, although importantly, a take-home reminder. One-third of the USP Dispensing Information book is in patient language, to help the practitioner counsel the patient; two-thirds of USP DI is backup information for the practitioner. To the charge that it's no use, that practitioners don't talk to patients, and patients are too afraid or too ignorant to talk to practitioners about drugs, I say that was sometimes to be expected when neither had the basic tools for communication. USP DI gives both practitioners and patients the basic tools — right now — and for practically all drugs. Of course, it takes a while to learn to use a new tool, and some never get the hang of it. A new tool can change the way an entire occupation or profession works — can even wipe it out. Have you talked to any buggy makers lately? Any Pullman car porters? Any iron lung repairmen? Any soda jerks?

It remains to be seen whether the cacophonous opposition to PPI of the last couple of years can be resolved into a positive, harmonious alternative. The health professions and their organizations are as competitive amongst each other as the industrial companies are. It is psychologically as difficult for them, apparently, to use patient information prepared by another group as it is for a manufacturer to distribute a drug produced by another firm.

USP's view is that the writing of the words is done and that the system to keep them up to date is working. The big task, then, is to get them into the hands of the practitioners and their patients, modifying the USP words where necessary to fit the practice situations and the limitations of the logistical systems ofgthe particular practices.

Basically, USP offers to be your editor in adapting our words to your needs, since the words are all on an electronic typesetting computer system in the USP office. So far, we have prepared leaflets for a state diabetes association, a booklet containing all of the antihypertensive drugs in a cooperative venture with the National High Blood Pressure Education Program, and 3x5 cards for the Canadian Pharmaceutical Association. The Canadian Health Protection branch is cooperating in the CPhA project; otherwise, no Federal government agency seems to be ready to do anything. No company has approached us. The American Medical Association has announced that it will be working with USP DI in producing its Patient Medication Instructions (PMI). The American Society of Internal Medicine and the American

Academy of Family Physicians have contracted to distribute the Advice to the Patient book for use in the offices of their physician member. Apparently, the national American pharmacy organizations are so busy watching each other, or are so jealous of USP, that they're letting Medicine take the lead.

Ay! There's a crack in the mirror! Pharmacy — you — are not looking to USP; Pharmacy — you — are not demanding of USP; Pharmacy — you — are not using USP to help the profession in its service to the public in providing drug use information. Why? Has Pharmacy — you — got anything better? Or is Pharmacy — you — going to lose our patient consultation responsibility, so loudly proclaimed by Pharmacy leaders — you, before our practioners get down off their count-and-pour pedestals?

The announced intention of the American Medical Association in launching its PMI program is to be sure that physicians are in charge of telling patients what they should know about drugs. USP, of course, believes that the physician is the first person who should tell the patient about the drug he is prescribing and we will do everything we can to help AMA spread our good words on their PMI. But as a biprofessional organization, USP sees the opportunity for pharmacists, and others involved with followup patient care, to reinforce the message initiated by the prescriber and to fill in the gaps in the initial consultation.

Is the crack in our mirror going to expand? After over a century of Pharmacy control of this biprofessional organization, is interest and control going to shift back to Medicine? Or will it go to Industry? Or Government?

When USP stopped being a recipe book, it reflected the fact that pharmacists were no longer making drugs. At that time USP could have become a manufacturers' handbook on how to make drugs in large batches. Instead, because it was controlled by pharmacists, not by manufacturers, it mirrored the pharmacists' new responsibility; it became the pharmacists' guide for testing the drugs the manufacturers made. But pharmacists did not test drugs to the degree of assurance that the public needed, and the federal government established an agency to enforce the USP requirements. USP medical and pharmaceutical scientists still write the requirements, and physicians and pharmacists still control the USP organization, but another crack in our mirror is fast forming. It is due to the disinterest of practicing pharmacists nowadays in even reading and understanding the standards and tests of quality of pharmaceuticals — disinterest to the point where officials of the American Pharmaceutical Association have entreated the Food and Drug Administration to require the New Drug Application number to be printed on the label of the container. The fact that a manufacturer once upon a time applied to FDA for an NDA would be, presumably, the seal of approval that would obviate a pharmacist having to be knowledgeable of quality — whether the particular batch on hand was of USP quality; and whether he, the pharmacist, had done anything to impair the quality that the manufacturer had built into it.

No longer a drug maker, no longer a drug tester, no longer knowledgeable of drug quality standards, what is a pharmacist going to do? A good materials management person taught in a college of engineering or a college of business can control an inventory and distribution system for packaged drugs — and PPI — as well as for any other commodity. The only thing he could not do is counsel each patient in the depth the patient needs concerning the use of the drug, the depth readily achievable by the pharmacist using USP DI. Or by the physician or nurse using USP DI.

Some of you may think that I should not be standing up here today and promoting USP this way, that I have abused Rho Chi in its Lecture Award by my advocacy of the USP DI system.

But I am not USP. You all are USP. You should all be advocating USP!

USP is the organizational system created by Pharmacy and Medicine to provide the official communications between the two professions. USP is the hundreds of physicians and pharmacists and dentists and nurses and veterinarians and allied scientists and consumers who serve on the advisory panels to the 85 members of the USP Committee of Revision — those 85 physicians, pharmacists and allied scientists that the delegates of your schools and associations elected to the Committee of Revision — the volunteers who make all of the decisions that go into the books.

I am just a hired hand holding up the mirror to you, the leaders of Pharmacy. From where I stand, you need USP and particularly its dispensing information system. If you're a teacher, start teaching it. If you're a practitioner, start using it. If you're a patient, start demanding it.

If you see nothing in our mirror, it will not be because it has shattered into rubble; it will be because there is no profession of Pharmacy to reflect. USP will still be there, used by other health professions, and industry, and government.

But let us conclude on the up-side of the prospects seen in looking at Dispensing in 1982. It is entirely fitting for a person from the Pharmacopeia (derived from the Greek *pharmakon* medicine + *poiein* to make) speaking before Rho Chi, a Greek letter society, to refer to an ancient epistle to Corinth for a look at the future of Pharmacy as a consulting, communications profession. So I turn once again to the Good Book and find that it is written:

Though I speak with the tongues of men and of angels, and have not reliable drug information, I am become as sounding brass or a tinkling cymbal. And though I have good drugs to dispense, and understand all their mysteries, and all knowledge, and though I have all the books in my pharmacy, so that I can answer any question, and have not communication skills, I am nothing. And though I dispense all my drugs to cure the sick and work 24 hours a day, it profiteth me nothing.

Communicators suffereth long, and are kind; communicators envieth not; communicators vaunteth not themselves, are not puffed up, doth not behave themselves unseemly, seekest not their own glory, are not easily provoked, thinkest not that medicines are evil; rejoiceth not in side effects, but rejoiceth in the truth, in reliable drug use information, in USP DI.