In 1982, the FDA proposed a rule that would allow individuals to import unapproved drugs intended for their personal use. Paul J. Sage, a compliance officer with a special interest in quackery, believed that such a policy would greatly weaken public protection against products that were ineffective and/or dangerous. He also said that if the FDA wanted to do more to protect the public against quackery, it should consider the suggestions in this document.

Docket 82N-0293
Comment of Paul J. Sage
December 15, 1982

QUACKERY - A REVIEW AND APPRAISAL

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QUACKERY: REVIEW AND APPRAISAL

INTRODUCTION

Enactment of the Kefauver-Harris drug amendments in 1962 led many hopeful people to believe we would soon see the demise of quackery. The law's effectiveness provisions put the burden of proof on the proponents of unproven remedies. This change removed from the Food and Drug Administration (FDA) the heavy and complex burden of proving negatives. It was no longer necessary to show that quack remedies did not work; it was enough to establish the products were not recognized as effective by properly qualified experts.

In view of the high hopes it seems ironic that quackery today is flourishing as rarely before. It has grown into a profitable, multi-focal industry that offers the public a beguiling and often risky alternative to quality in health care. It has spread from the passing curiosity of a one-wagon road show into every neighborhood in the land. It reaches out from the mailbox, from "health food" stores where traditions of folk medicine and self-care are often distorted for the sake of profit\(^\ast\), and from various and sundry unqualified healers who employ quack remedies. They all fleece and sometimes harm the public. They may, indeed, kill people who place their trust in them.

Quackery turns on an axis that runs between pretension and desperation. It is easy to recognize but hard to define. It is certainly not a binary function. Rather, a sliding scale exists upon which the functionality of any prescription may vary from typically effective to absurd, ineffective, and dangerous. Although no two definitions of quackery are precisely the same, it is not hard to recognize "hard-core" quackery, the forms that are blatant, that tend to victimize, or that are directly or indirectly fraught with potential for harm to the public. This paper focuses mainly on these kinds of quackery.

BACKGROUND

One way to view the history of drug regulation over the past seventy-five years is a saga of the transformation, by voluntary and regulatory means, of an ancient armamentarium of simple remedies, largely devoid of therapeutic value and sometimes frankly harmful, into a battery of pharmacologically active prescription and OTC drugs whose discovery has introduced complex new

\(^{\ast}\) Professor James Harvey Young of Emory University has observed that today's interest in health is easily twisted into unhealthy buying:

Taking charge of one's own health gets distorted into handing that health over into the custody of a knave or a fool, and paying for the deception.\(^1\)
problems of risk/benefit assessment, problems which are of unprecedented public health importance. Many of FDA's early drug regulatory efforts were aimed at problems we would describe today as quackery. The agency developed a tradition of enforcement-through-litigation which continued into the early 1960's. That tradition was the source of many profoundly important legal precedents. It also served to limit considerably the more blatant and potentially harmful forms of quackery. Upon it FDA built an honorable tradition which became the pride of the agency. Unfortunately, however, enforcement-through-litigation was neither an efficient nor an appropriate way of guiding the ethical mainstream of the drug industry toward compliance with the new requirements of the 1962 drug amendments. In the years following the enactment of these amendments the agency's attention and resources turned to legitimate industry. The intensified drug inspection program, the DESI review, and the OTC Drug review were the fruits of that important labor. These projects guaranteed that the facilities and controls used to make pharmaceutical products were up-to-date and reliable and that the drugs themselves could be relied upon to be effective for the uses for which they were labeled.

As the agency moved into new waters and developed new procedures for regulating products by class, and witnessed extensive voluntary compliance, it realized significant accomplishments which are the source of much pride and satisfaction today. Back at the pier, however, unnoticed and relatively unimportant at first, there remained its old nemesis, quackery, free at last from the regulatory bonds that had once held it in check.

CURRENT SITUATION

Today, a major industry has grown up to serve the market generated by demand for quack remedies. In an article entitled "Nutrition as Therapy" Consumer Reports estimated its size as between one and a half and two billion dollars a year. This is certainly an overstatement of the size of the "hard-core" quackery business. Nevertheless, the serious forms of quackery involve large amounts of money. For example, McGraw-Hill publishes a paperback book, The Nutrition Almanac, which is a compendium of misinformation about health. It has been used in many health food stores to promote sale of vitamins, minerals, and other products for serious diseases that cannot be managed safely except under the supervision of a physician. These diseases range from hypertension to diabetes, cancer, cirrhosis of the liver, and tuberculosis. In 1978 McGraw-Hill had sold 600,000 copies of the almanac. Its retail price was then $5.95. Its value in terms of misbranded products it was used to sell must have been many, many times its considerable value to the publisher.
In describing a case of a patient with hypertension which went out of control when treated with a regimen similar to that recommended in the almanac, Kirkendall et al reported in JAMA that the patient was taking 18 different types of tablets with a total intake of 61 tablets daily. A supply of the tablets cost more than $83.92. The authors estimated the annual cost of the worthless, dangerous regimen amounted to about $1,000.00.3

Major corporations have become involved in serious forms of quackery. General Nutrition Corporation controls a chain of some 700 GNC Nutrition Centers at shopping malls all over the country. The Nutrition Almanac is a commonly used promotional aid in these stores where it has been used illegally to promote various products for use in attempted self treatment of serious diseases, much as Kirkendall, et al have described. GNC recently went public. Its initial offering of one million shares at $15.00 a share was quickly sold out.

Promoters of seriously violative quack remedies employ expensive means of creating and building their market. It is not hard to find full page advertisements, sometimes in color, in the trade press. Some promoters use paperback books to promote use of their products for purposes for which they are not safe. One such book is over 200 pages in length and is illustrated with color plates. Individual promoters of these products obviously have access to very substantial resources.

One of the noteworthy characteristics of the quackery business is the ease with which anyone can get started. It takes no plant, no equipment, and only a very modest investment compared to the potential for profit and the slight risk of criminal prosecution, even for blatant and serious violations.** Many private formulators will prepare and package tablets, capsules, or packets of most any mixture of natural ingredients a promoter may wish to peddle as long as the promoter handles the promotion and assumes the presently slight risk of being held accountable for it. This does not require formal agreements or even the manufacturer's actual knowledge of the promoter's intentions. All one needs to know is what questions not to ask to avoid becoming involved in a definite conspiracy.

** It was ever thus. The following refers to the period around 1850 and is quoted by Professor Young in The Toadstool Millionaires (p. 41):

"Any idle mechanic" as an Ohio editor pointed out, could do it. He "by chance gets a dispensatory, or some old receipt book, and pouring over it, or having it read to him...he finds that mercury is good for the itch, and old ulcers; that opium will give ease; and that a glass of antimony will vomit. Down goes the hammer, or saw, razor, awl, or shuttle -- and away to make electuaries, tinctures, elixirs, pills, plasters, and poultices."4
While it is true that some very large corporations deal in quack products, it is by no means the case that all or even a substantial part of the products handled by these firms are seriously violative. GNC's involvement in serious quackery is almost certainly due to its profitability and to the absence of significant enforcement efforts, rather than to a need to depend on income from that business for profitability or survival.

At the present time it is easy to document blatant violations with serious potential for harm. These violations occur at all levels in the marketing pattern from manufacturers, to wholesalers and distributors, to retail merchants. In the November 7, 1980, issue of JAMA, Stoffer et al warned of the health hazard inherent in diverting patients from proper therapy by "nutritionists" at health food stores. They described the case of a patient of theirs who was advised to substitute kelp and vitamin supplements for digoxin, a diuretic, and levothyroxine sodium. They then surveyed ten health food distributors by having one of their employees visit the stores and talk to their manager or the resident "nutritionist." In each case the employee said that their physician was treating them with thyroid hormone for goiter and asked if the store had anything to help. All ten stores had something to offer. Two advised against taking the thyroid that had been prescribed by the patient's physician. A prosecution case against the responsible persons at the latter two stores would be easy to make, easy to prove, and, if publicized, it would discourage this kind of dangerous, reprehensible misconduct.

The situation is no less atrocious at the level of manufacturers, jobbers, and wholesale distributors. Wholesalers and commercial distributors are promoting concoctions such as wheat germ, sunflower seeds, lecithin, and whatnot as an effective treatment for such serious and manageable diseases as glaucoma. Herbs are being promoted and sold as remedies for serious infections, heart disease, high blood pressure, and other serious afflictions. Even though homeopathy has largely faded from the scene, recent years have seen the emergence of a new breed of "homeopathic" remedies which are sold to the public or to practitioners who are not homeopathic physicians and who are not qualified by training and experience to manage the serious conditions for which the drugs are promoted.

All of the practices outlined above involve violations of the Federal Food, Drug, and Cosmetic Act that are easy to document and easy to prove. In some cases firms have grown so large and their line of violative products has become so diverse that the biggest problem in attempting to deal with them is cutting the investigation and any planned regulatory action down to a manageable size.
An explosion of misinformation about health has occurred coincident with the
deregulation of quackery. Popular magazines such as Prevention and Let's Live
combine sense and nonsense in an appealing way to invite unfounded belief in
the therapeutic value of natural substances. The books of Adele Davis are an
example of the many popular publications which contain misinformation about
health care. Use of products as recommended in her books has reportedly
resulted in one documented death and one serious injury, both infants.⁵

Promoters of quack remedies appear and peddle their wares at conventions which
attract large audiences. Local newspapers sometimes carry "public service"
announcements which publicize the conventions! The themes of the quack are
often heard on radio talk shows and T.V. programs. Promoters of quackery have
gained access to the public through a variety of media. They no longer need
depend on their own promotion, advertising, or labeling to get their message
across, although in today's risk-free environment, many still do. A flood
tide of misinformation about health has overwhelmed our capacity to
effectively respond to it. Other voices that were once prominent and highly
respected are similarly lost.

Public skepticism about the integrity of government has increased greatly in
recent years. Quacks have taken advantage of this attitude in ways that are
most effective. Honored American traditions such as freedom to choose and
reverence for nature are turned to the benefit of promoters of dangerous forms
of quackery. Quacks have discovered that FDA is a human institution,
sensitive to criticism, and that regulatory activity can seemingly be stopped
before it is initiated by maintaining a barrage of criticism. It is a
remarkable fact that the amount, kind, and intensity of criticism is quite
unrelated to any current, identifiable regulatory actions. Deregulation of
quackery has seen the agency acquire the image of an active and ruthless
tyrant!

DISCUSSION

One must start from the premise that quackery has been with us since the dawn
of time and will never go away (neither will dangerously defective products,
dirty warehouses, or other problems FDA is responsible for regulating). Lewis
Thomas has given a delightful account of the origin and prognosis of quackery
in his essay, "On Magic in Medicine".⁷ We are not so far removed from the
medicine of the dark ages as we might wish to believe.

A second truth is that FDA does not have and cannot expect to obtain resources
in the future that would be needed to secure compliance through acting against
all or even a significant percentage of violators at once. Under these
circumstances, it is appropriate to consider how the agency can best combine
its regulatory activities with educational efforts to discourage serious forms
of quackery.
REGULATION

FDA's policy establishing priorities for quackery is contained in FDA's Compliance Policy Guide 7150.12. This guide stratifies problems in four categories according to known or potential risk and economic impact. Only problems that present potentially serious risks or major economic frauds are candidates for agency attention. The Compliance Policy Guide generally requires that all available legal sanctions be considered in developing regulatory actions involving quackery. The guide provides little direction as to how to choose among the various sanctions (formal warning, seizure, injunction, and prosecution) except that prosecution is identified as the remedy of choice for harmless major economic violations.

In recent years promoters of seriously violative quack remedies have become adept at moving from product to product and promotional scheme to promotional scheme, easily keeping their distance from the relatively small number of time and resource consuming civil actions that have been employed in efforts to regulate violations. These promoters do not much care what product serves as a vehicle for their business. What they are really seeking is something to sell and as little difficulty with FDA as possible. For this reason, a regulatory approach that aims at particular products and civil remedies is not likely to be, and has not been, a very effective way of discouraging even blatant, serious violations.

In view of the nature of the business and constraints resulting from a lack of enough resources to reach all violators at once, it would seem that FDA's approach to discouraging blatant, serious forms of quackery should be similar to that employed by the IRS to promote compliance with the tax laws: employ selective prosecution to deter violations. The agency should look for and take advantage of opportunities to make simple, small, timely, and manageable cases that document serious violations. It should prosecute violators, and publicize results. Use of civil sanctions should usually be limited to circumstances where the lower burden of proof or other benefits are of special importance. For example, in highly controversial situations where regulatory action is warranted, civil litigation may be the only appropriate approach. It may also be the fairest and best approach when an untested theory of law is first applied. Otherwise, the Food, Drug, and Cosmetic Act is the strongest federal criminal statute available to discourage health fraud. It alone offers a means of regulating fraud without proving fraud or intent to defraud.

FDA has prosecuted only one firm for drug-related quackery in the past decade. Injunctions and seizures have been the agency's typical regulatory tools. It has become obvious to those in the business that they have relatively little to fear from FDA's use of these measures. At worst, after
promoters have made fortunes from promotion and sale of illegal products, the government has been able to seize some small fraction of their production or get a court order to make them stop. Sometimes successful civil actions have resulted in victories that are actually so narrow as to seem almost Pyrrhic. By making seemingly trivial changes in products, marketing practices, or both, it has been possible for some firms to continue to do business despite the "success" of FDA regulatory efforts.

Unsatisfactory results sometimes flow from the frequently intense pressure to settle civil cases by compromises that involve reformulation or relabeling of violative products. Quacks have everything to gain and nothing to lose by negotiating labeling agreements that permit them to trade on an illegally won false reputation. It is a curious fact that, of all humans, judges hate most to be forced to decide disputed issues. So the pressure to settle becomes quite intense and very slight achievements can acquire an appearance of being eminently reasonable. FDA and the agency's attorneys must often negotiate with the Department of Justice and the offices of the local U. S. attorneys concerned. Settlement in civil cases invites complex negotiations that may leave in place products with labeling that is perhaps more sophisticated but still quite capable of leaving promoters of quack remedies in a business that is actually protected by the outcome of the negotiations.

More than 50 years ago Dr. Lyman Kebler, FDA's first drug expert, offered these views on the subject of revising literature:

A strenuous, continued plea was made by a lawyer, the son of a physician, to be allowed to revise his literature to bring it within the truth and then to continue the business. The (government) solicitor's heart was touched and he finally agreed to a revision on condition it be submitted to his office for final review. The issuing of a fraud order was stalled. A wholly unsatisfactory revision came in due time. In the meantime this attorney published the stuff he submitted and continued his business. One had been put over on us. He became more brazen and five years later was compelled to close out all his fraudulent mail-order business or be debarred from the mails. He was an excellent candidate for a fraud order at the outset but misplaced sympathy spared him. At a second hearing the alleged revision proved very troublesome.

Things have not changed much in the past fifty years.

One example will serve to illustrate how meager the accomplishments of negotiated settlements in civil litigation may be. Several years ago FDA brought an injunction case against a major distributor of a mixture of diisopropylamine dichloroacetate (DIPA) and calcium gluconate which had been falsely labeled as "calcium pangamate," the bogus "Vitamin" B-15. A consent decree, negotiated under pressure from the court, required that the firm stop marketing "DIPA-based" "calcium pangamate" but failed to prohibit the firm from marketing in its place a product in which dimethylglycine (DMG) was substituted for DIPA and, again, falsely labeled as "calcium pangamate."
It seems very doubtful that distributors would label their products falsely if they did not perceive a lack of FDA interest in using criminal sanctions to deter violations.

Medical World News described FDA's response to the marketing of the so-called "vitamin" B-15 products as a "Slow moving" crackdown. 2 It did indeed move slowly. All of these products are simple hoaxes. None contain panganic acid or its salts. Rather they consist of other chemicals such as DIPA or DMG. It is an easy matter to show that such products are misbranded and adulterated. Yet as the vitamin B-15 fad grew to enormous proportions, FDA approved only a few civil cases. These actions were successful but they required use of considerable resources over an extended period of time and they were quite ineffective in regulating the illegal marketing of the products. In the meantime there have been reports that chemicals in commonly marketed "B-15" products are mutagenic when tested by the Ames test.10, 11 Whether these results are reproduced or not, they clearly point to the importance of establishing a more credible deterrent to discourage marketing of inadequately tested products. Unregulated, faddism bears the seeds of a national disaster that will make the Jonestown tragedy look like a picnic. Nobody knows whether the grim specter will manifest itself as excessive concentrations of heavy metals or marine toxins in tablets of dried Green-lipped mussels (the subject of a current fad as an arthritis cure), as unexpectedly toxic effects of some naturally occurring component of an exotic, dried, powdered blue green algae product, or as some completely unexpected consequence of some other bizarre chemical cocktail. It seems clear, however, that the time for prophylaxis is now.

Litigation of civil cases inevitably involves the conduct of discovery under the rules of civil procedure. Discovery in civil cases is much broader than in criminal cases and, in recent years, it has sometimes become debilitating. This is not a problem unique to FDA's cases. Our entire legal system is strained to the point of breaking by increasingly burdensome problems connected with civil discovery.

People once felt that the immediacy of civil seizures or TRO's offered important advantages and good reasons to use these measures to deal with problems having serious potential for harm. However, criminal law enforcement procedures can afford swift means of controlling distribution of illegal products through seizure pursuant to regular criminal search warrants. Supplies of illegal products can be seized as instrumentalities of crime under authority of these warrants. This is an appropriate use of the criminal search warrant as long as the agency's bona fide intention is to prosecute violators.
Use of criminal investigative and enforcement procedures is an obvious alternative to employing civil remedies. Equally obvious are certain benefits offered by employing criminal provisions of the law. First, criminal convictions offer superior deterrent potential. This potential is increased by the statutory scheme which makes a second violation of the Food, Drug, and Cosmetic Act a felony. The evidence needed to establish a criminal violation is identical to that needed to prove a civil violation. So while the burden of proof is higher the elements of proof are the same. Naturally evidence of personal responsibility must be presented in any action aimed at an individual. This is true of both civil and criminal litigation.

Even though negotiation is as common in criminal cases as in civil litigation, the nature of the negotiation, its thrust and direction, is different. In criminal cases the number of counts may be reduced, or an individual defendant may be dropped, but neither the content of labeling nor the continued marketability of the product is ordinarily involved. Pressure to settle is much less likely to result in tacit approval of any future marketing plan.

The reason most often given for not prosecuting more quackery cases is that they require too much of FDA's resources. It is certainly true that quackery cases once required an almost superhuman commitment of resources. That was when it was necessary to prove claims were objectively false. A marvelous account of complexities FDA no longer needs to face may be found in James Harvey Young's account, from The Medical Messiahs (pp. 104-112), of FDA's second case against B & M. More recently, the Krebiozen case was at trial for some nine months and litigation went on for more than ten years with The Diapulse Corporation over charges that many claims made for its pulsed diathermy machine were false and misleading.

In today's environment, with blatant violations so common, it is possible to design cases that are really quite easy to prove. It is no longer necessary to prove that claims are objectively false or misleading. The agency can use new drug charges, charges that products are prescription drugs, or charges that a product's labeling fails to bear adequate directions for use to establish violations. It is not hard to prove that any substance when promoted for use in treating cancer, diabetes, hepatitis, heart disease, or other similar conditions is not safe for use except under the supervision of a physician. Any such product is misbranded within the meaning of Section 503(b)(4) of the Act unless its label bears the prescription legend. Products promoted and marketed to meet demand for quack remedies rarely bear the prescription legend. In the absence of a body of scientific evidence to provide a foundation for a drug's labeling it is also impossible to prepare adequate directions for its use, so it is also easy to prove misbranding under Section 502(f)(1) of the Act which declares that drugs are misbranded unless their labeling bears adequate directions for use.
Discovery in criminal cases is much more limited in its scope than in civil litigation. Therefore, it is easier to estimate and manage resources needed for simple criminal cases of the type described above. This kind of case calls for a fairly discrete resource commitment. The Speedy Trial Act promises reasonably swift justice. Trials should be scheduled within 180 days of the filing of an information or indictment. Simple, easily proved cases are very difficult to defend. It is not unreasonable to expect many cases of this kind to be resolved by guilty pleas. Even losses in criminal cases differ from losses in civil litigation. The latter set precedent. The results of a "not guilty" verdict is that and nothing more. Criminal cases ordinarily set precedent only when convictions are obtained and reviewed by a higher court. For all these reasons more frequent use of criminal prosecution has considerable appeal.

One objection to more routine use of criminal prosecution to deal with quackery violations is a firm belief among some responsible people at FDA that before use of criminal sanctions is justified there must be either evidence of intent to defraud or a civil judgment which erases doubt about the illegal nature of the conduct. FDA does not apply this standard in the case of all serious violations. For example, decisions to recommend prosecution of major pharmaceutical manufacturers for adverse reaction reporting violations have been based on evidence of flagrantly irresponsible conduct. Quackery violations that involve significant direct or indirect health hazards are inherently flagrant. The principle of requiring a judicial determination or evidence of intent has no place in regulating serious kinds of quackery. Promoters of quack remedies know very well that they make their way at the margin of legal conduct and they often go beyond it. When they do these facile, astute, and preying entrepreneurs are not entitled to the same kind of consideration as middle of the road, ethical business people. There is no likelihood of effectively regulating quackery if major promoters and distributors of quack remedies are given this kind of consideration.

It is certainly true that FDA's relationship with the broad cross section of regulated industries should be based on a presumption of good faith and ethical endeavor to meet common goals in both government and industry. This philosophy cannot be applied to regulating quackery. Promoters of quack remedies may be deterred by concern about enforcement but they will not otherwise be guided or led voluntarily into honorable or ethical endeavor. Thus, for this small segment of the regulated industry, it seems appropriate to resume use of the once traditional sanction of prosecuting violators. The agency's objective here should be to create deterence through fear of punishment. There is no other potentially effective means of regulating quackery. Even this will not reach all quacks. But it should have a meaningful impact on serious quackery at the industrial and commercial level.
At one time search warrants had an almost symbolic aura within the agency as a heavy-handed sort of law enforcement measure. While it is true that search warrants are rarely necessary when dealing with the ethical businesses FDA regulates, within a program of creating deterrence to quackery through use of prosecution -- where their use is chiefly to control distribution of seriously violative products; or to obtain evidence that has been refused -- using search warrants is in no sense extreme. They are a perfectly legitimate law enforcement tool. In the public's eye a seizure is a seizure. Whether it is made pursuant to a warrant or as a civil seizure under Section 304 of the Act is a distinction that is quite meaningless to the average person. It is meaningful to lawyers who understand how the discovery permitted under civil rules can be used to keep their clients in business while they litigate, or who appreciate how civil discovery can be used to stall, enervate, and compromise a prosecution case.

Another impediment to more routine use of prosecution for serious quackery violations has resulted from FDA's selection process, its procedures, and its well-intentioned goal of securing a maximum impact on quackery with a minimal use of resources. In the absence of a program to precipitate action, this goal can transform efforts to regulate quackery into an endless quest for the perfect case, the ideal defendants, and the most favorable jurisdiction. Carried too far the effort to maximize achievements can produce complete waste. Investigations become endless and payoffs are never realized. This, in turn, results in a sense of regulatory lassitude which is itself a powerful and pervasive deterrent to developing enforcement actions. If FDA is to improve its ability to deal with quackery, it must abandon the quest for ultimates and be satisfied with achievements one can expect to realize. An overly ambitious quest for a maximum return on a minimum investment can lead not to "the most bang for the buck", or even to a whimper, but to the desolate, consumptive nothingness of a black hole in empty space.

Prodded by sincere concerns, memories of FDA's once proud tradition for combatting health fraud, and by recognition that many responsible public and professional friends of the agency still regard it as a champion of vigilant enforcement, the agency has continued to devote a considerable amount of high level management attention to the problem of quackery. This attention has seen the appearance of committees and of plans intended to help cope with the problem.

Unfortunately, all too often, the attention given quackery has served as a means of doing something without accomplishing a great deal. For example, several years ago FDA conducted a nationwide survey pursuant to a program that took many months to develop and implement. The ostensible purpose of the
program was to systematically identify worthwhile candidates for prosecution on a district by district basis. (FDA has 21 district offices in the United States and Puerto Rico.). It turned out that the program actually served as a gigantic turn-down mechanism through which a number of potentially worthwhile targets were reduced to one. Like the proverbial product of committee work, the selected target has the head of a goat, the mid-section of a monkey, and the tail of a guinea pig.*** Each creature is, in its own way, marvelous, but as anyone who's ever worked on a committee knows, you can't win 'em all!

Turn-down mechanisms are wasteful procedural devices that save a bureaucracy from having to grapple with problems on a substantive basis. Identifying and eliminating them is an enterprise rich with potential for public service. Another device that has served as a turn-down mechanism affecting quackery cases is the "lead bureau" concept. This concept was developed to keep the Bureau of Drugs out of regulatory matters that common sense would direct to the Bureau of Foods unless that bureau needed the support of drug charges to implement its own regulatory policy. Health claims for fiber added to whole wheat bread are an example of a problem to which this concept is properly applied. Misapplied, the "lead bureau" concept directs to the Bureau of Foods regulatory questions concerning serious disease claims for drugs that are also foods or components of foods. This kind of application of the concept should be repudiated. Except in the most unusual circumstances the rule should be that the nature of the violation(s) and the ease of proving impressive charges should determine which bureau handles a case. Formal coordination should be required only when equally serious violations are found or when one bureau wishes to employ charges for which another is ordinarily responsible.

One approach that has been suggested for improving FDA's ability to deal with regulation of quackery has been to create a strike force for the purpose in the Office of the Commissioner. The term, "strike force," itself has an undeniable appeal. However, one must carefully consider whether such a reorganization would be step toward greater effectiveness or another way of doing something.

To make a case for a strike force it should be necessary to show at least that there are complex problems around in the field of quackery that FDA's bureaus are unable to handle, that it wants to regulate, and that it cannot or does not want to simplify. For example, one might argue that the best way to deal with Laetrile would be to try to prove in court that claims that it is effective are false in fact, and that its promoters know it. Implicit in this approach is the kind of extraordinary resource commitment that went into the

*** As the reader may know, the guinea pig's tail is vestigial (if it exists at all).
prosecution of the Krebiozen case. Today, it would probably also be necessary for FDA to sponsor impressive, controlled clinical trials. Careful investigation of all claimed cures would be needed. An intensive effort to seek evidence of actual fraud would be required. This would be a perfectly honorable kind of endeavor, but nobody seriously wants to tackle it; if it were tackled it seems most unlikely that proof of actual fraud would be found, or that a successful effort would materially affect the proliferation of modern day quackery. Because quackery has become a multifocal problem involving a diverse variety of promoters and products, its successful regulation will depend upon FDA's ability to bring a relatively diverse array of basically simple prosecution cases with relatively small and discrete, rather than large, indeterminate resource commitments.

Proponents of a strike force have referred to a 1950's era task force that has been justly praised as a powerful deterrent to quackery. The unit was not actually a task force. It was a cadre of seasoned regulatory managers, under the leadership of the late Gil Goldhammer, that comprised the Division of Regulatory Management in the Bureau of Enforcement. These regulatory managers handled all contested litigation, developed cases of first impression, and managed particularly difficult investigations not only in quackery but also in such diverse areas as deliberate adulteration of olive oil and orange juice, other fraud investigations, complex filth cases, cases involving illegal sale of dangerous drugs, and cases that were precursors of today's CMP cases. Today, in the Bureau of Drugs, these functions are among the duties of the Litigation and Recall Staff. That is where they should remain unless and until the agency is ready to reestablish a Bureau of Enforcement.

This comment, from the pen of a former senior FDA official, supports the proposition that there has been more interest at high levels in limiting than in promoting measures to effectively discourage criminal conduct involving quackery:

I don't believe we should program resources for fraud, except as a control over spending too much time on this. *** I am very reluctant to program even one man year for fraud work. *** being a realist, we can't say do no fraud work, ***. I would put a limit of five man years on such activities.

Like the grin of the Cheshire Cat, interest in limiting potentially useful regulatory measures lingers and manifests itself first in one way, then another. Indeed, in a bureaucracy, careers can be built upon the elaboration and embellishment of increasingly sophisticated turn down mechanisms. What is needed at this time, however, is to bell the cat itself. FDA should set a new course to promote effective use of its limited resources. It would surely be a
disappointment to see interest in limiting regulatory efforts more highly prized than interest in regulating increasingly blatant violations. After all, the latter is what the agency is expected to do by even the most conservative of its responsible critics. The Heritage Foundation, for example, identified regulating health frauds as a legitimate function of the agency. FDA should avoid taking steps that would lead to further centralization. Some decentralization is what is needed at the present time.

FDA should adopt a regulatory plan that provides some reasonable amount of resources and that will permit conventional law enforcement measures to be employed and good simple cases to be brought easily, swiftly, surely, and without involving, in every particular case, the entire management of the agency, up to and including the staff of the commissioner's office. This is the way to show industry that the risk of enforcement action is real.

Easily developed, easily proved, essentially simple quackery cases, which involve significant direct or indirect hazards have suffered from delays inherent in the review process and from a lack of agreement about basic regulatory approach. Cases that are created stale lack regulatory appeal. FDA's case review system has evolved in response to the agency's need to be able to handle sophisticated regulatory questions which often involve subtle scientific and medical issues. It may be in need of a general overhaul but it is certainly much too lengthy and complex for many simple quackery cases. The system has not led to selection of regulatory options with strong potential for deterrence. It should not be difficult to establish an efficient, effective, and serviceable regulatory program for quackery involving drugs to permit simple cases which meet predetermined agency policy standards to be developed by the district offices in consultation with the Bureau of Drugs and the Office of General Counsel with the cooperation of local U. S. prosecutors. Such a program has been developed and named a "Direct Reference" prosecution program although, as is explained below, it provides for an appropriate amount of headquarters' supervision to permit good operational management.

A final difficulty in establishing a credible regulatory deterrent for serious violations involving quackery results from the fact that no time has been programmed for use by FDA's district offices in dealing with quackery. This is a necessary consequence of the fact that there is no program. Allocating some definite amount of resources to serious quackery problems is the best way to solve the vexing problem of managing resources. Failure to have a program and to program time for quackery violations also means that FDA's managers get no credit for time spent on quackery or for their accomplishments. Under these circumstances, it is not surprising to see industrial quackery flourishing.
DIRECT REFERENCE PROSECUTION

KEY REQUIREMENTS

The key requirements for establishing a "Direct Reference" prosecution program include setting standards for developing small, simple criminal cases, aimed at serious problems that reflect community concerns, decentralizing decision-making concerning the selection of cases that meet those standards, permitting the use of resources of interested local federal prosecutors when the agency's Office of General Counsel actually has none, and managing FDA's own resource problem through allocating a definite amount of the agency's annual resources to it. Any program must give attention to case selection and development, decision-making in quackery cases, and to resources and rules applicable to the operation of the program.

CASE DEVELOPMENT

The various phases of case development in the field of quackery and the logic which guides them are outlined below:

```
ACQUISITION
  ↓
SCREENING
  ↓
INVESTIGATION
  ↑  ↓
  EVALUATION
  ↓
DECISION
```

This scheme is essentially the same as that described by DeVita, et al for selecting potential chemotherapeutic agents for clinical trial at the National Cancer Institute. 13

Case development begins with the acquisition of leads or complaints. These may enter the program by means of professional, trade, or consumer complaints, reports of apparent violations discovered from surveillance during inspections, from reviews of advertising or promotional activities, or by way of complaints transmitted for investigation by headquarters' units.
The second stage of case development involves screening or preliminary evaluation of enforcement potential. At this point an estimate is made of how serious an apparent violation may be, whether resources are available to investigate it, how difficult proof of the violation appears to be, how large the violative business appears to be, and whether there is any reason to rule out an investigation.

If a case passes the second phase of development an investigation is initiated. This is a critical step in case development. Investigation is the process by which facts are collected, observations made, and opinions obtained to afford a basis for evaluation of the case and ultimately for a decision.

The process of evaluation begins as the investigation progresses. It serves two purposes: guiding the investigation and managing investigative resources by establishing an endpoint which is the final phase in the process: Decision. It is obvious upon inspection that the feedback between investigation and evaluation can become a resource sink. Waste of resources can be avoided by timely and proper execution of the decision-making function.

**Decision-Making in the Prosecution of Quackery Cases**

This is a decision table for criminal prosecution cases in the field of quackery:

- **Technical question**
- **Ethical question**

(can we?)

(should we?)

**Diagram:**

- Is there a violation?
  - Yes → Will prosecution serve a sufficient public interest?
    - Yes → Prosecute
    - No → Drop case
  - No → Drop case
In every case both the technical and the ethical question must be independently evaluated. If one is confused with the other, decisions will be inconsistent and sometimes unsound. Note that there are twice as many grounds for dropping a case as for bringing it. That is, every case must pass both the technical and ethical test. Sometimes evaluating the ethical issues will suggest the need for further investigations to develop additional factual evidence, i.e., to make it possible to prove the case with fewer resources or to demonstrate that the violations are more serious.

Evidence and the law are the basic elements that must be considered in deciding whether or not any case is technically sound. Evidence is trustworthy information. It may be in the nature of an observation, a measurement, a thing (i.e., a document, sample, photo, etc.) or a reliable opinion. The program presumes a solid foundation in technical evaluation among investigators and compliance officers responsible for its operation. FDA's investigators and compliance personnel are generally well trained and well qualified in the technical aspects of case development.

In the area of quackery the ethical question may be more difficult than the technical question. It requires that three elements be weighed instead of two: EFFECTS, RESOURCES, and OUTCOMES. Also, unlike law and evidence, the factors that need to be analyzed to decide the ethical question are more intangible. It is helpful to reduce them to very simple terms to avoid confusion. It thus becomes clear that making the ethical test is an entirely manageable problem.

The question of the EFFECTS of quackery, insofar as the individual is concerned, can be diagrammed as follows:

```
beneficent       benign      harmful
```

Ethical considerations permit a breakpoint (decision to drop case) to be inserted anywhere on the above diagram. They require a breakpoint when the violation documented appears to be beneficent.
What is a beneficent form of quackery? Here is an example:

*Herpes simplex* is a virus capable of producing fewer blisters and other infections that can be extremely painful, sometimes to the point of being incapacitating. The infections are self-limiting and recurrent. No drug is known to be effective in treating them, or in preventing recurrence. There is a remarkably strong placebo effect associated with the use of any therapeutic maneuver in treating *Herpes* infections. Such maneuvers afford significant relief to victims of the disease. Lysine is an innocuous amino acid. Inadequately controlled research has resulted in reports that the substance is remarkably effective in *Herpes* infections. Controlled studies suggest these reports are probably pretentious. Nevertheless, lysine tablets are being promoted as an effective treatment.

If we assume the claims of effectiveness are entirely pretentious, this would be a form of quackery that is, nevertheless, beneficent in its effect. The drug affords the patient a way of caring that is often effective and, as far as we know, harmless. FDA should not interfere with its marketing. Even though it is illegal, the activity fails to exploit or victimize. It is not worth regulating.

While it is clear that cases involving beneficent forms of quackery are contraproducive, it is important to recognize that FDA can decline cases where the potential for harm is beyond dispute. When the problem is local, impact small, population at risk few, likelihood of success slight, and resources required great, it cannot afford to prosecute even if there is good evidence of ability to harm consumers.

The question of RESOURCES can also be visualized by use of a diagram.

```
   many
resources

    substantial
resources

    few
resources
```

Prosecution cases in the field of quackery should be designed to employ resources efficiently. This is another achievable objective if the techniques involved are understood. With quackery becoming increasingly widespread, a common problem is to discover a firm with 40 products, all of which may be illegal. How can this kind of business be regulated without an unreasonable strain on FDA's investigative, expert, administrative, and financial resources? The answer
contemplated by the program is to pick one or two, or perhaps three products, the easiest opportunities, and prosecute. If violations continue or the first effort fails, another product or two can be selected, resources permitting, and the process repeated. This approach keeps resource commitments discrete and manageable, in a setting where success will promote a maximum of deterrence since all convictions after the first are felonies.

It is helpful to consider the size of the enterprise in evaluating how much, if any, resources should be devoted to it. Size may also be represented as follows:

<table>
<thead>
<tr>
<th>large business</th>
<th>intermediate</th>
<th>small</th>
</tr>
</thead>
<tbody>
<tr>
<td>nationwide impact</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Obviously, it will be more productive to work on large businesses than small ones. However, the program need not exclude businesses of reasonable size involved in relatively serious kinds of quackery which can be prosecuted with few resources in a favorable environment.

The other issue that must be considered in deciding whether to prosecute is the probable OUTCOME. Winability can also be diagrammed:

<table>
<thead>
<tr>
<th>highly winable</th>
<th>reasonable prospect for success</th>
<th>slight chance of winning</th>
</tr>
</thead>
</table>

Everyone wants to win. An objective of the program is to win some quackery cases. However, the trip to the bar of justice is an experience that can instill awe in both the traveler and those who watch the trip. Therefore, high winability is not an essential requirement for cases that are carefully investigated, well supported, involve problems that are serious in nature or large in scale, and that can be presented without excessive resource commitments.
One can take the four diagrams presented above, add a fifth to represent audacity, and score them arbitrarily as follows:

Effect:

<table>
<thead>
<tr>
<th></th>
<th>harmful</th>
<th>benign</th>
<th>beneficial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Size:

<table>
<thead>
<tr>
<th></th>
<th>large</th>
<th>intermediate</th>
<th>small</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Resources:

<table>
<thead>
<tr>
<th></th>
<th>few</th>
<th>intermediate</th>
<th>many</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Likely Outcome:

<table>
<thead>
<tr>
<th></th>
<th>good</th>
<th>fair</th>
<th>poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Audacity:

<table>
<thead>
<tr>
<th></th>
<th>extremely</th>
<th>pretentious</th>
<th>unfounded</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score</td>
<td>2</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Certainly, unless there is some special problem which militates against prosecution we can say that any technically adequate case that scores ten is one the agency should bring. It passes the ethical test. No one would want to bring a case that scored zero or nearly so. But we must avoid the hazard of attempting to reach a decision by averaging, or by numbers alone. There is more than one way to reach five or nine, and they do not necessarily point to the same decision. The program is not intended to authorize direct reference to the U.S. attorney of prosecution cases involving pretentious, harmful violations of small size that would require many resources to produce a good outcome. A protective feature of the program is the "Special Problems List" which is used to rule out actions involving issues so volatile as to be unsuitable as vehicles for prosecution cases at the present time.
RESOURCES AND RULES

The Direct Reference prosecution program contemplates that FDA's districts would have and use such sources of advice and guidance as they require, within and outside of the agency, to develop their cases. They are authorized and advised to contact the professional staff of the agency, the Office of General Counsel, other agencies, and, when appropriate, independent experts for advice and guidance. They are encouraged to seek advice on tactics, strategy, and sources of support. The program requires that quackery cases be investigated under the active supervision of seasoned investigators and compliance officers in consultation with a Trial Attorney Contact appointed by FDA's General Counsel or a federal prosecuting attorney and the Bureau of Drugs' Compliance Officer monitoring them. It also requires that any case brought to a U.S. attorney be approved first by the District Director and have the support of at least one nationally recognized expert on each medical and scientific issue in the case, as well as that of a well qualified local expert who would be willing to testify if asked to do so. Cases developed under the program must be small in size and violations must be easy to prove. "Health-food" products are eligible for action under this program only if their labeling, advertising, or promotion shows that they are intended for use in the management of serious diseases that can be treated effectively under the supervision of a physician. The program includes a bureau level veto feature which may be exercised at any time. It provides for disputes to be resolved by negotiation. Issues that cannot be decided in this manner are appealable to the Commissioner's Office.

CHARGES:

The program limits the charges which the districts may employ to focus on violations that may be proved easily. When evidence is available to support them the program would permit use of charges that products do not bear adequate directions for use (502(f)(1) violations), that they are prescription drugs which are misbranded because they do not bear the prescription legend (503(b)(4)) violations), or that they are unapproved new drugs (505 violations).

Other charges may be employed, but only with concurrence of the Bureau of Drugs or the General Counsel's Trial Attorney Contact. Because they may be exceptionally difficult to prove, false and misleading labeling charges that raise ultimate questions about a product's effectiveness will not ordinarily be employed. When 502(f)(1) charges are employed the district must be able to assure availability of expert medical testimony to show there is no evidentiary foundation to prepare adequate directions for use. When 503(b)(4) charges are
employed the district must be able to assure availability of expert medical testimony to establish that the collateral measures necessary to use of the product in the disease for which it is recommended are such that it cannot be used safely except under the supervision of a licensed physician. When 505 charges are brought, the district must have evidence of representations in labeling (not merely in advertising or oral representations) of a lack of general recognition of safety and/or effectiveness. Of course, 502(f)(1) charges may be predicated on the absence of any directions in labeling for uses for which the product is promoted or advertised. However, such charges must also be supported by expert medical testimony that there is no evidentiary foundation for preparing adequate directions, and that the product is not recognized as effective for such purposes.

EVIDENCE

The program requires that special care be given to assuring that prosecution cases in the field of quackery are supported by expert testimony that is appropriate in both KIND and QUALITY.

KIND

It is instructive to consider a decision that was lost for failure to secure the right kind of expert support. The case involved a vitamin/mineral preparation that was promoted as a cure for impotency. In this case the government relied on the testimony of an expert in nutrition to attempt to prove that the claims made for the product were false. The effort failed because nutritionists are not qualified to treat impotency and the government's expert could not provide the kind of support necessary to sustain its position. An expert in the field would have been able to testify that successful treatment depends on overcoming fear of failure to perform and that no drug is known to be effective for this purpose. While a nutritionist's testimony could have been used effectively to supplement and support that of a physician who was experienced in the management of the disorder, it was not an adequate substitute for an expert physician's testimony.

QUALITY

The ethical question presented by the example described above involving Herpes simplex and lysine was easy enough to resolve once reliable information was available. Quackery cases require that special care and attention be given to obtaining reliable information. This becomes clear when we look at the context in which the lysine question arose. It was identified as a possible problem by one of FDA's medical officers. The medical officer indicated that use of the drug could expose persons with liver disease to the risk of death from a remedy that is essentially worthless. A second medical officer confirmed the judgment that the drug
has not been proven effective, and identified a nationally recognized expert on treatment of Herpes. The expert shared the agency's doubts about the drug's effectiveness, but regarded it as safe and beneficent because of the placebo effect. He could not speak authoritatively on the issue of liver disease. With the aid of experts at National Institutes of Health, an expert on amino acids and the liver was identified. He had studied the relationship between lysine and liver disease and had found no evidence it affects the disease. He viewed the risk as theoretical and most improbable. One must know the medical advice upon which quackery cases rest reflects the kind of clinical experience and specialized knowledge only an expert on the subject matter can provide. One can obtain advice from any well qualified secondary source but for reliance it is necessary to have full blown, expert support. Evaluating the lysine problem took less than a day's work, spread over a week. But it took some literature research and half a dozen phone calls, all steps which must surely be taken in evaluating every case involving quackery. Of course it is not necessary to take every step in every case. Once a matter has been established, there is no need to remake the wheel.

EVALUATION

The "Direct Reference" approach to prosecution is appealing for many reasons. Cases developed in the community, in cooperation with local U.S Attorneys, articulate community concerns. This is the way cases of this type should be developed. By involving local prosecutors and, as necessary, the grand juries they routinely employ, the approach will tend to defuse complaints about bureaucrats in Washington dictating action that can better be resolved within the community. Because of their superior investigative authority, in some cases grand juries may be better able than FDA is to ferret out evidence of serious negligence or actual intent to defraud or mislead consumers. The approach is apt to produce cases that are fresh and relevant to defendants' immediate past conduct.

Adopting a program of this kind would not be without some risks and drawbacks. In criminal cases there is a higher burden of proof. Some cases may be handled poorly. Some cases may be chosen that would not be selected at headquarters. However, even if a case that was selected as an indirect health hazard problem under the program (Category 2 under CPG 7150.12) turned out to be a harmless patent fraud, prosecution would remain the remedy of choice under Category 3 the Compliance Policy Guide. The mistake would be essentially harmless and consonant with FDA's established policy. As long as cases are kept small and simple, as the program requires, and enjoy the support of local federal prosecutors, few of FDA's resources should be wasted even if a few mistakes are made. The drawbacks associated with this plan seem to be risks worth taking. In addition, the risks should diminish with experience.
The benefits of this kind of program extend beyond promoting development of more small, easily proved prosecution cases. The program should also improve FDA's effectiveness in developing criminal cases, build morale and expertise in the field, give the investigators and compliance officers who participate in the program experience and training in identifying and resolving not only technical problems but also ethical issues that are somewhat more complex than those usually encountered at the operational level, sharpen judgement and encourage the development of ability in decision-making, afford some discretion to senior field managers for use of their resources, and better discharge the agency's legal responsibility for prosecuting violations involving quackery, as well involving local U.S. attorneys in worthwhile efforts to represent important consumer interests without unnecessary strain on FDA's resources.

The regulatory program is not a plan to unleash Prometheus. It limits the new authority in several ways to provide for good management. First, it authorizes use of no sanction except criminal prosecution. By offering a single sanction, one that is serious, and one that demands a high burden of proof, the proposal guards against trivial or inappropriate cases. United States Attorneys are, for their own good reasons, not likely to select poor cases or permit harrassment. Second, by programming a fixed amount of time for the work it is possible to assure the program will not run away with the agency's resources. Ideally the program would be scheduled for twenty person years of FDA's field work time annually. Third, the program's rules focus attention on serious violations that can be proved easily. Finally, a reporting and veto system allows for careful monitoring and such control of the program as may be necessary. The reporting requirements and the experimental nature of the program allows individual cases, particular districts, or the experiment as a whole, to be dropped if it does not appear to be working. The approach allows for as much involvement and participation by FDA's attorneys as the General Counsel's Office wishes.

There are three good reasons why FDA should strive to improve the effectiveness of its efforts to regulate quackery. First, it is the agency's legal duty. Congress could have placed law enforcement relating to quackery involving drugs with the FBI or elsewhere in the federal government. In fact, this task was given to FDA and FDA must meet its measure. Second, through direct and indirect means quackery is often a significant hazard to the public health. Having some credible regulatory program obviously serves a broad public health interest. Finally, quackery harms the public through degradation of the overall quality of health care. Elderly Americans and the sick are harmed more than most by quack remedies. Quackery touches the life, the health, and the pocketbook of millions of Americans every year. That is why a law was enacted to regulate it. Those who administer that law, whether they view quackery as a burden, a challenge, or both, must continue to work toward realization of approaches to enforcement that stand a chance of succeeding. The "Direct Reference" prosecution program is such an approach.
EDUCATION

In the past several years there has been increased interest in developing a much improved and expanded FDA-sponsored educational program. Actually the agency's public education efforts have been very worthwhile and they have had considerable support. Moreover, one must be very careful about transferring the agency's resources from fighting crime to printing posters.

It is certainly true that quack claims interest the public, and proponents of quackery have established and employed means of communication that are far more effective than anything FDA can hope to create with its own resources. FDA's public education material serves many valuable purposes. It is a reliable source of health related information and a resource for everyone who is concerned about health and patent fraud. It provides efficient, effective ways of responding to inquiries from consumers, health professionals, writers, and members of Congress. But one cannot expect it to carry the day by significantly influencing the public as a whole or those in the business of marketing seriously violative quack products. At the retail level, FDA's condemnation may actually serve as an endorsement. The agency's educational material cannot, and never will match the clout and volume of propaganda that promotes quackery. Unreliable information reaches millions of consumers, month after month, year after year. It comes from numerous sources, via many routes, none of which are "tainted" by a connection with "Big Brother."

If FDA relies chiefly on its own resources, it will never compete successfully with the promotional efforts of industrial quackery. No matter how catchy and colorful the presentation, how clear and non-patronizing the message, and how broadly circulated FDA's material may be (and it should be all these things) FDA will lose hands down if it relies on its resources, its say so, and the material it produces to educate the public.

NATIONAL COUNCIL ON HEALTH FRAUD

There is a better way. To be fully credible and effective, public health information about quackery should be sponsored by a respected authority, independent of government, in a setting devoid of confrontation. We need to promote the establishment of a National Council on Health Fraud. The American Cancer Society's Committee on Unproven Methods of Cancer Management could serve as a model. By bringing together medical experts, public educators, regulatory authorities, publishers, attorneys, and others concerned about cancer quackery this committee serves as a valuable and respected source of information. Of course, there is no need to duplicate the committee. But a similar organization, organized under the auspices of a respected authority, would be a valuable ally in the broader campaign against quackery.
One organization that is doing an exemplary job and that enjoys great public respect in this area is Consumer's Union. Consumer Reports has published articles on Laetrile, Fluoridation, and "Nutrition As Therapy" which are good illustrations of the really high quality, influential, and informative work of Consumer's Union. This kind of material needs to be reproduced by the millions and given the widest possible circulation. Consumer's Union should be encouraged to greatly expand its program. It could be considered a candidate for organizing a National Council on Consumer Fraud. Certainly, if it is willing to participate, it should be represented on such a council.

A case might be made against a center organized by Consumer's Union alone. First, some might say it tends to be just a bit too anti-business. Second, if the program is to involve health issues broadly, there would perhaps be a role for other organizations in its management and direction. Possibly groups like the American Public Health Association, the AAAS, and others could be interested in joining as sponsors for the project.

EVALUATION

Ideally, a council would be self-sustaining and enjoy support from broad cross sections of the public and private sectors. An important objective of an effort to create a council would be to develop independent means of support. Independent support would probably be essential to mounting a continuing, broad based, multimedia educational program. Hopefully, the council would be able to sponsor or find sponsorship for a TV program similar in format to Wall Street Week to present information about quackery in programs that address issues of broad public interest in the field of health. The production and distribution of Wall Street Week costs something on the order of $100,000 per program. Obviously, a very broad base of financial support would be needed to sustain such an enterprise; FDA could never finance it alone. On the other hand, it seems reasonable to suppose that FDA might provide some seed money to encourage the formation of a council, support it for a few years while it seeks its own sources of sustenance, and encourage others to support it.

The State of California operates a Cancer Advisory Council of fourteen members and four consultants. All serve without compensation except for travel and expenses. They meet about twice a year. Their administrative support requirements include about 0.8 person years of professional time, and 0.5 years of skilled secretarial support. All in all, the annual cost of that enterprise is probably between seventy-five and one hundred thousand dollars. Providing similar administrative support for a National Council would probably cost more than the California program.

Based on FDA's experience with the National Coordinating Committee for Large Volume Parenterals, it seems reasonable to assume that the cost of financing contracts to provide basic administrative expenses, per diem, travel, report creation (exclusive of production and distribution costs) for the first three
years of its existence and to provide for efforts to establish a continuing means of support would not exceed a total of $600,000. The National Coordinating Committee was running on a budget of about $150,000 a year. Spending half a million dollars to support a National Council On Health Fraud would be a worthwhile investment. This is a very small sum compared to the size of the market for quack remedies.

Aside from the resources needed to create it, a successful council would have few drawbacks; the effort should actually enjoy broad support. If it is successful, each of its members and the public as a whole will stand to benefit from its work. Even if it does not achieve a self-sustaining basis, it should leave in place valuable work products prepared while it enjoys FDA's support. It is possible that the council would disagree with FDA on a particular enforcement matter or even an issue of public policy. However, open discussion of such issues would be healthy developments that would keep the public behind FDA's overall mission and enhance the credibility of all concerned.

There is perhaps some risk in promoting creation of an independent authority on health fraud. It could look FDA squarely in the eye and ask, with all its authority, "Wherefore, FDA? Why don't you regulate these violations?" The question is a tough one in today's environment with blatant and audacious violations so common and so rarely regulated. It would be less difficult if FDA's regulatory efforts were designed to produce more effective deterrence.

POLITICS

No discussion of quackery can be regarded as complete without considering its politics. The promoters of quack remedies have found sympathetic allies among such single issue political coalitions as the anti-fluoridationists, the Laetrile lobby, the vitamin group, and other similar entities. Actually these groups functionally merge with each other. Sometimes the merger appears to blend into well structured conservative organizations such as the John Birch Society. Sometimes it runs into more mysterious right-wing organizations of sovereign citizens, such as the Sheriff's Possee Comitatatus.

Promoters of unproven remedies support conventions, bowling teams, issue publications, distribute flags, bumper strickers, and banners, and generally weave their way into the warp and woof of people's lives in a much more intimate and intrusive way than government could ever do. Any visible action by FDA, indeed even the distorted image of the agency itself which these groups generate, serves as a vehicle for the ongoing political attack on FDA and the law. It would be a perfect example of the post hoc fallacy to suppose that this kind of political activity can be defused by FDA through the kinds of actions chosen to deal with the problem of quackery.
To the extent that FDA's regulatory actions have tended to be few and to be product oriented, the agency has actually served up single issue situations which are themselves disadvantageous. A case against someone who was selling Laetrile for use contrary to medical advice in attempted self-treatment of a manageable kind of cancer would probably be much more acceptable politically in the context of a program that also prosecuted a few cases involving a diverse variety of other kinds of health fraud.

FDA should defend the law by maintaining a responsible enforcement effort. It need not be overly large; it need not be complex but it should be visible and large enough to instill just a little fear into the hearts of manufacturers, wholesalers, and retailers of a variety of seriously violative products. This, combined with a good communications program, is FDA's best bet for keeping the respect of those influential people whose support is needed to save the agency, and the public, from a return to the predatory days of the Toadstool Millionaires. This should also be enough. FDA should stop treating quackery as an endlessly frustrating problem with an inexhaustible potential for consuming resources. Quackery would be a perfectly manageable problem if FDA would allocate resources to it and bring an end to the practices and procedures that have so often frustrated high hopes and great expectations within and without the agency.

SUMMARY AND CONCLUSIONS

If the promise of FDA's Diamond Jubilee is to endure the agency must reestablish a link with its long and honorable tradition of enforcement, continue creative educational efforts, and explore the possibility of using other people's money, skills, and reputation to make its efforts more effective.

One thing that FDA is uniquely able to contribute to efforts to control quackery is to prosecute violators. A small credible enforcement effort aimed at prosecuting a diverse assortment of violators for easily proved violations will do two things. It will encourage some of those who are significantly involved in quackery at every important commercial level to avoid the kind of reckless conduct that is rampant today. The tax laws, as administered by the IRS, do the same kind of thing. There is just enough fear in most of our hearts every year to ensure that our basic good character manifests itself on April 15. Adopting a policy of using small, straightforward enforcement actions to create deterrence will also give those who are responsible for and concerned about law enforcement involving quackery the satisfaction of knowing that the agency is pursuing a reasoned and defensible approach to discharging its regulatory responsibilities.
It is important to recognize that anything that makes particular enforcement targets more predictable will make it easier for promoters of quack remedies to keep FDA on the run and keep themselves in business. This problem can be avoided by employing criminal sanctions and criminal investigative procedures much more routinely than has been the case in the past, and by using standards rather than unnecessarily centralized case review or targeting methods for simple cases involving blatant and serious types of health fraud. By allowing districts more latitude to make choices based on conditions prevailing locally one would expect to see a more diverse variety of cases than would be expected from a highly centralized, easily outguessed cumbersome administrative apparatus. Significant cases involving patent fraud could be fed into this program from headquarters as the agency deems appropriate.

In the field of education the need is to turn outside the agency. We need a National Council on Health Fraud with a permanent independent media program. FDA needs to take advantage of the support it enjoys among all responsible Americans who concern themselves with health fraud and quackery. Of course FDA should not unnecessarily abandon or curtail the good efforts of its own consumer, congressional, press, and professional education services. These should continue to flourish and enjoy support in these times when resources are limited. The additional need is to create new means and support new efforts to reach out and bring together concerned, qualified, and independent allies for the benefit of the public we all seek to serve.

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REFERENCES


