CONSUMER SAFETY ACT OF 1972

HEARINGS

BEFORE THE

SUBCOMMITTEE ON EXECUTIVE REORGANIZATION AND GOVERNMENT RESEARCH

OF THE

COMMITTEE ON GOVERNMENT OPERATIONS UNITED STATES SENATE

NINETY-SECOND CONGRESS

SECOND SESSION

ON

TITLES I AND II OF

S. 3419

APRIL 20, 21; AND MAY 3, 4, 1972

Printed for the use of the
Committee on Government Operations

U.S. GOVERNMENT PRINTING OFFICE
77-615 WASHINGTON : 1972

You see, the Division of Biologic Standards assume this public posture, that anyone can come to them with data and they do not stimulate independent investigators. Actually, that is not true. Vaccine studies are funded by drug companies, by the National Institutes of Health, by the Vaccine Development Board, by the Center for Disease Control in Atlanta. And you can imagine the position of a drug manufacturer. He does not want to invest large amounts of money and time to develop vaccines the DBS is not at all interested in, or likely to license. The Vaccine Development Board, itself, abruptly stopped funding on studies for rubella vaccine once the DBS strains were licensed.

It is true the adviser to the Vaccine Development Board on matters of rubella vaccine was one of the DBS scientists, who had developed the DBS strain.

Once again, it simply became an uncomfortable situation. I should point out, since we are talking about conflict of interest, I have had nothing to do with the development of RA 27/3. I have no personal stake in whether it is used or licensed. However, I do feel because of the peculiar nature of rubella, that in the public interest this vaccine should be extensively explored further and be an active candidate for licensure.

In terms of recommendations, to be perfectly consistent, as a scientist I cannot make detailed organizational suggestions. Almost everyone in this room is probably more qualified than I am. However, it would seem to me, on a scientific basis, that first it would be well to spell out in very clear and vivid detail the requirements for any given product, for its revocation of license, and that this should be automatic and should not be influenced by extraneous factors of dubious validity at times.

It would seem appropriate the DBS, along with the FDA, be merged in the proposed independent consumer safety agency.

Also, I believe there should be great mechanism for scientific review of any actions that any regulatory activity or agency takes, and I think there are easy mechanisms to establish this.

Finally, I believe there should be more long term studies of vaccine efficacy and these could be logically designated on an agency such as the Center for Disease Control which already has existing expertise. However, if this would blur lines of authority, it should be developed in whatever new organizational structure is outlined.

So that, then, in summary, is what I have developed.

(See exhibit 24, p. 374.)

Senator PERCY. Doctor, right at the outset of your testimony, you make reference to the General Accounting Office report, that 32 vaccines of no known value, and some possible harm, have continued to be licensed.

WORTHLESS VACCINES

I have never seen a figure as to what the total dollar value of those vaccines would be. What was the cost of the vaccines, which were either of little value or perhaps even harmful, and which were administered to people who felt they were being protected?

Dr. ISACSON. Well, I think it must be astronomical. I do not think I could give you an actual figure. Since some of these appear from the investigation to have been on the market for 20 years, certainly it must add up.

I should probably point out a lot of those were not products used routinely. That is, rubella, or measle vaccine, is going to be given to every child in this country eventually. I think many on the list of 32 were more or less special circumstances, so in that sense, the cost may not have been as high as if it were infectious or dangerous measles or polio vaccine we are talking about.

Senator PERCY. But we are talking about a cost investment of hundreds of millions of dollars, maybe. Certainly I think that incident very dramatically indicated something was wrong.

Taking your recommendations on page 13 into account, which of these recommendations would have prevented such an occurrence taking place, if they had been implemented prior to? We are locking the barn now after the horse has gone out, but which of these would have made such an incident impossible or less likely?

Dr. ISAACSON. Well, particularly recommendations 2 and 3, I would imagine would influence those regarding the clearly detailed guidelines and the outside panels.

Once again, unlike many other branches of the Government, the DBS apparently makes more in-house decisions and as a matter of natural course, if you are going to subject your decision to outside scrutiny, it tends to be a little more careful.

I also think No. 1 would affect us indirectly.

Senator PERCY. Members of this subcommittee, including Senator Ribicoff, as chairman, and Senator Javits and myself, made strong suggestions that the transfer of regulatory functions of DBS be made to FDA. Secretary Richardson announced yesterday that this would be accomplished.

What do you believe should be the most important point on the agenda of the new agency?

Dr. ISAACSON. Absolutely clearing lines of authority first, so there is no question of who is responsible for what and what they are capable of doing. This apparently has been one of the problems before in that there is some doubt as to who was responsible for what and when. I think that would be absolutely essential.

Then, I believe it should be very important to establish some rigidity in guidelines. This will help remove all sorts of outside influences or financial or matters of simply dubious judgment.

This is one of the instances in which there has to be an automatic removal of licensure. There can be nothing else interfering with this decision.

I think, also, that adequate funds and staff need be made available. It is a tough job. I am sure part of the DBS failure is not so much the attitude as really lack of wherewithal. After all, they were organized after many of these products were already on the market. It is going to take an extensive effort to investigate all of it. They will need support, whatever agency handles this.

Senator PERCY. You have certainly made it clear that you believe vaccine regulation should be handled within an independent regulatory agency. Do you believe this function could also be performed within HEW, if it is just moved over as a part of the present structure and confined at a fairly low organizational level, or do you think it could be adequately performed within HEW if raised in stature, authority and power?

Dr. ISACSON. Yes, I believe it could be adequate.

Senator PERCY. The latter, but not the former?

Dr. ISACSON. Yes.

Senator PERCY. Do you feel that the concerns you have outlined here represent the major problems of immunization we face in the country?

Dr. ISACSON. I believe they are very important issues and they certainly need all of the effort that is being put into them.

INEQUITY IN VACCINE DISTRIBUTION

As a matter of fact, there is one even more overriding problem we have in this country, and it is really an inequity in vaccine distribution. We have always taught medical students from immemorial that measles is no respecter of social class and it has not been, everybody got it. Now it is primarily a disease of the urban ghetto. We worked very hard on vaccines, technically and biologically. We agonize over them and run trials. After all of this we find out we do not seem to have the social will to distribute it.

Polio, we should have wiped off the face of the country. It still pops up in Mexican American inborder areas. Diphtheria is a disease of the poor now, and it is an important one.

Now, if things follow true to form, we know that vaccines protect against disease: we know, secondly, that vaccine utilization follows a very precise socioeconomic gradient and that starts in the suburbs and gradually filters through the rest. So take rubella. We know if it strikes in the next few years, as predicted, what is going to happen? Birth defects, again is going to be mainly a problem of the ghettos. And it is not a matter of our scientific ability. It seems to be more a matter of our social will.

In a sense I think this is more of a problem in this country than some of the other details.

Senator PERCY. What should the priority be if DBS vaccine research remains in NIH?

Dr. ISACSON. I do believe more effort on long term surveillance. You see, we did have this incidence where literally millions of children were innoculated with a vaccine shown later to contain an animal tumor virus. It turns out, apparently, none of the children have been harmed.

We have a measles vaccine that was dangerous. We did not find out about it until 4 years after it was approved.

The point is, there is a lot we do not know and there has been a rather unfortunate tendency by DBS, once a vaccine is licensed, to pretend it has no further problems. It is really hard to explain, I think, to the public that you are going to license something for use, but yet you are going to continue long term studies on possible safety.

In a way it does not make sense, but yet it is something I think we have to face, and I do not think they are facing this adequately. That would be of primary concern.

I will support strengthening, certainly, their researchability in the valuation of safety, whether short term of long term. I think this ought to be done, provided we can make it clear that research on development of new vaccines is removed from this regulatory system.

March 30: 1972.
Senator Abe Ribicoff speaking:

In addition, the report reveals that for at least three years, from 1966 to 1968, the DBS was releasing diluted influenza vaccine that did not come close to meeting the announced standard for potency, even according to the manufacturers' own tests. During that period, DBS did not reject a single lot of influenza vaccine, though some were less than 1% of the required strength. According to the DBS influenza vaccine control officer, the vaccine manufacturers "would sell water if they could get away with it."

The report also states that there is substantial scientific doubt whether influenza vaccine is effective at all, even when it is used full strength. Senator Ribicoff said he is asking HEW Secretary Richardson to review the question of the effectiveness of influenza vaccine.

Senator Ribicoff's Subcommittee on Executive Reorganization and Government Research has been investigating federal regulation of vaccines, blood banks, and drugs for several years. Hearings on the role and performance of DBS will be held within the next two months, during the Subcommittee's consideration of S. 3419, a bill which would combine DBS with FDA and move both into an independent regulatory agency.

Senator Ribicoff is sponsoring S. 1177, a bill to establish an independent consumer advocate. In his statement on the Senate floor, Ribicoff declared that "if there had been an independent consumer advocate, I doubt that an agency such as DBS could have continued to allow millions of doses of diluted influenza vaccine to be released for public use year after year * * * or that worthless vaccines would have remained licensed for decades * * * or that the kind of timid regulation we have discovered at DBS would have for so long gone unnoticed."

Attached is Senator Ribicoff's speech in the Senate this afternoon. Copies of the GAO report are available from the Subcommittee in room 162 of the Old Senate Office Building.

MARCH 31, 1972.

Following is the text of a speech Senator Ribicoff will make in the Senate Thursday afternoon, March 30, 1972, regarding a GAO report on the effectiveness of vaccines.

I am today releasing a report prepared at my request by the General Accounting Office concerning the regulation of vaccines by the Division of Biologics Standards in the Department of Health, Education and Welfare. This report focuses on two major problems: the Division's apparent policy, pursued until 1969, to allow the release of subpotent influenza vaccine and its failure to require that vaccines sold to the public be effective.

Specifically, the report indicates that there are thirty-two bilogic drugs or vaccines on the market today that are ineffective. All of those drugs have been on the market for at least ten years; some have been sold for decades. DMS has allowed all of them to remain on the market, even though many of them can cause serious side effects.

With respect to influenza vaccine, the report reveals that for a period of at least three years, from 1966 through 1968, DBS allowed manufacturers to sell influenza vaccine that did not come close to meeting the announced standard for vaccine potency according to the manufacturers' own tests. A majority of the lots of influenza vaccine submitted for release during this period failed to meet the standards. Nevertheless, the DBS did not reject a single influenza vaccine lot submitted to it during that period. According to statistics of the Center for Disease Control, over 20 million doses of influenza vaccine are sold each year in the United States.

BACKGROUND OF THE REPORT

The report I am releasing today has been in preparation for over eight months. Last summer, after discussions with Dr. J. Anthony Morris, a microbiologist with the DBS, and James Turner, a consumer advocate with expertise in food and drugs, I asked the GAO to look into the performance of the DBS in a number of important areas. This is the first of GAO's reports in response to that request; a later report will deal with the Division's regulation of adenovirus and pertussis. On October 15, 1971, and again on December 8, I called upon HEW to conduct a full review of the performance of DBS. On those occasions, I released papers prepared by Dr. Morris and Mr. Turner which raised a number of disturbing questions about the quality of our vaccines and the policies of DBS.

Since last summer, impartial GAO investigators have been at work examining the records and documents of the DBS, and talking to the people who have been responsible for vaccine regulation. The entire GAO report is based upon the DBS's own official documents and records, not upon charges made by anyone inside or outside the agency. It was compiled from the recorded, day-to-day observations of those who actually conducted the control operations for the DBS.

The report is an appalling chronicle of omission and bureaucratic failure. It is deeply unsettling that the government's efforts to protect the health and safety of the public could remain ineffective for so long.

EFFECTIVENESS OF VACCINES

Let me now turn to the substance of the GAO report. With respect to the effectiveness of vaccines, the GAO report reveals that 75 out of 263 biologic products licensed by DBS were not recognized as being effective by most of the medical profession, according to a memorandum by the Director of the DBS. The GAO concluded that "DBS has not required biological products to be effective as a condition of licensing and has not removed ineffective vaccines from interstate commerce."

There are at least 32 vaccines currently on the market that are "generally regarded as ineffective by the medical profession," according to the DBS Director. I am releasing a list of these ineffective products. All of these drugs have been on the market for more than ten years, some of them for decades. Some of them can cause serious side effects. For example, one such drug, licensed in 1956 for the treatment of "upper respiratory infections, bronchitis, infectious asthma, sinusitis, and throat infections," contains six ineffective organisms. According to the circular on the package, there have been, associated with the use of the drug, "reports of children getting systemic reactions: fever, rash, abdominal cramps, and diarrhea four to eight hours after injection." All this from an ineffective drug.

Or consider the possible side effects noted on a package circular for another ineffective vaccine used for treatment of infections and inflammations of the eye: "febrile reactions, preceded by chill * * * temperature of 101–104. Fever subsides in a few hours and the patient may be left with muscular pains; chilly sensations and malaise may be expected * * *. The patient should be kept under close observation through the period of increased temperature, and if excessive fever occurs, it should be combated vigorously." There are many other examples.

And yet, in all these years, DBS never moved to take a single one of those ineffective drugs off the market, or even to inform the public or the medical profession of their ineffectiveness. In light of this kind of adverse reaction data, it is incredible that DBS could license such biologics as "safe." Since the agency believed that there was no corresponding benefit from the harm suffered by patients, it could have moved to take these drugs off the market under its undoubted authority and responsibility to withhold licenses for drugs which are unsafe. Instead, the DBS maintained that it had no authority to regulate biologics for effectiveness and simply washed its hands of the problem.

LEGAL AUTHORITY TO REGULATE EFFECTIVENESS

According to the DBS, its failure to move against ineffective vaccines was caused by a belief that HEW did not have statutory authority to require that vaccines be effective in use. HEW's General Counsel believed that authority had existed since the Kefauver drug amendments of 1962. Thus, while HEW argued that it had the authority and wanted to delegate it to the DBS for enforcement, DBS argued there was no such authority to delegate and recommended that additional legislation be sought before moving against ineffective biologic drugs.

An exchange of memos within HEW in 1969 illustrates the nature of the regulatory impasse. On February 28, 1969, the HEW General Counsel sent a memorandum to the DBS taking the position that HEW had responsibility to assure that all drugs—including biologics licensed by DBS—were effective and that HEW was prepared to delegate this authority to DBS. On July 30, 1969, the Director of DBS replied, stating that he opposed such a delegation and again urging the Department to seek additional legislation. The Director's opposition to a simple administrative solution was especially perplexing since he knew that there were 75 licensed biologics that were ineffective. In addition, his stated reasons for opposing a simple delegation of existing regulatory authority are disturbing. He wrote:

"In view of the continuing undercurrent recommending the combining of the DBS with Food and Drug, we are quite reluctant to request such a delegation (of authority to require biologics to be effective) since it would offer an excellent opportunity of such proponents to renew their efforts in creating one central agency."

In fairness to the DBS, it should be pointed out that it did seek to persuade HEW to seek new legislative authority to regulate biologics for effectiveness. However, the Division refused to initiate or even cooperate in developing any alternative course of action to deal with a serious public health problem. Even worse is the implication of the Director's memorandum of July 30, 1969, that he felt it more important to foreclose any real or imagined infringement on the separateness of his domain than to take the most direct means at hand to protect the public from ineffective, sometimes harmful vaccines.

For ten years, beginning in 1962, while memos were quietly exchanged within the bureaucracy, nothing was done to protect the public against drugs that were ineffective. The drugs stayed on the market; people continued to get adverse reactions from them. Those drugs are on the market today, ten years after HEW was given authority to do something about them.

Thirty-nine days after I raised the issue on the floor of the Senate, HEW took its first steps toward a responsible position. A memorandum from HEW General Counsel Wilmot Hastings concluded that the Department did have authority to regulate all vaccines for effectiveness. Furthermore, he stated that the Department's authority would soon be delegated to DBS.

Several months passed. On February 7 high officials of HEW and the National Institutes of Health were shown a draft of the GAO report and were made aware that the information concerning ineffective vaccines would be made public. In announcements in the Federal Register on February 25 and March 15, HEW declared that vaccine manufacturers would finally have to present evidence of the effectiveness of their vaccines or lose their licenses. To date, however, only manufacturers of biological vaccines have been required to come forward with proof of efficacy. No such requirement has apparently been laid down for manufacturers of virus vaccines. I shall continue to monitor the new program closely to assure that hopeful public announcements are followed by decisive regulatory action. The public will benefit from the new policy only if it is rigorously enforced with respect to all vaccines.

INFLUENZA VACCINE POTENCY

One vaccine that should be subjected to close scrutiny in this program is influenza vaccine, the other major subject of the GAO report. The report deals with both the efficacy and potency of influenza vaccine. Efficacy refers to a vaccine's ability to cure, combat, or prevent a disorder. Potency refers to a vaccine's ability to produce a certain result in laboratory tests, to show that it contains the proper amounts of antigens. A vaccine may be potent—that is, contain the prescribed amount of antigens—and still not be effective if, for example, the antigens it contains do not protect against disease.

Both the efficacy and the potency of influenza vaccine have been, and continue to be, subject to substantial question. For an extended period prior to 1969, the potency of influenza vaccine went virtually unregulated. The GAO report tells a shocking story about the DBS's abdication of a clear responsibility. The DBS control official for influenza vaccine has stated that, in his opinion, if manufacturers could get away with it, they would sell water as vaccine. The GAO report indicates that, between 1966 and 1968, with respect to influenza vaccines, manufacturers were being allowed to do very nearly that.

The first influenza vaccine was licensed in 1945. As of December 1971, there were outstanding eight licenses to manufacture influenza vaccine, and six companies were actually manufacturing it. In 1970, over 20 million doses of influenza vaccine were sold, making it one of the largest selling vaccines produced in this country.

As interpreted by the Department of Health, Education, and Welfare, the law requires every licensed vaccine to be safe, pure, potent, and effective. In order to determine potency, DBS prepares a reference vaccine containing—according to a prescribed test—a given amount of antigens. Manufacturers must then apply the same test to vaccine lots they submit for release, and their results must show the vaccines to meet a level of antigen content equal to, or at a certain percentage of, the DBS reference vaccine. By regulation (42 CFR 73), a licensed vaccine cannot

be released unless the manufacturer's tests show the vaccine to be safe, pure, and potent. The GAO report shows that, with respect to influenza vaccine—at least between 1966 and 1968—this rule was utterly ignored.

In addition to the manufacturer's tests, which are required, DBS may itself require a manufacturer to submit—prior to the release of vaccine to the public—samples of the product lots and the protocols containing the results of the manufacturer's tests. DBS reviews these protocols and may conduct its own tests. DBS may then either release the lots of reject them.

On September 18, 1962, however, in an extraordinary memorandum, DBS severely circumscribed the scope of its own independent testing of influenza vaccine. According to the memorandum, the decision to release a vaccine lot was to be based only on the manufacturer's test results, not upon the DBS test results, even if the two were inconsistent. As explained by DBS officials in 1971, "lots were released on the basis of satisfactory information furnished by the manufacturers and tests by DBS were a mechanism to be sure that manufacturers could perform the tests and that results were reliable. As if this abstention from responsibility were not enough, DBS then began to release many lots of influenza vaccine that were subpotent even according to the manufacturer's own test results.

In the years 1966, 1967, and 1968, manufacturers submitted 221 lots of influenza vaccine to DBS for release. According to the manufacturers' own test results, 115 of these 221 lots were subpotent and should have been rejected, even under the standard of the 1962 memorandum. And yet DBS allowed the release of every single one of the 221 lots, including all 115 which even the manufacturers' tests clearly showed to be subpotent.

Not only was subpotent influenza vaccine being released indiscriminately, but in many cases the subpotent vaccine lots which were supposed to be as potent as the DBS reference vaccine fell short by enormous margins. In some cases, influenza vaccine was released that had less than 1% of the potency required. In addition, a number of the 106 lots which were potent according to the manufacturer's test were shown to be subpotent by subsequent DBS testing. For example, one manufacturer submitted a lot containing three separate strains of influenza vaccine. According to the manufacturer's test results, the strains were, respectively, 100%, 171% and 149% as potent as the DBS reference vaccine. DBS tests, conducted on September 13, 1967, showed their respective values to be .8%, 15%, and 12%. Incredibly, even this lot was released for sale to the public.

In another instance, the DBS control officer asked one manufacturer to perform tests first on a vaccine known to be that of the manufacturer, and later on a series of unlabeled vaccines, one of which was the same as vaccine that had been tested previously. When the manufacturer knew he was testing his own vaccine, the test results were markedly higher than when the same vaccine was tested as an unknown. Thus there is substantial doubt about how many of the 106 vaccine lots shown to be potent according to the manufacturer's tests did, in fact, meet the unenforced standards.

The GAO report shows that for at least three years absolutely anything a manufacturer submitted would be released. Responsibility for this frivolous policy extends to the highest levels of the DBS hierarchy. The ultimate decision to release a vaccine lot is made at a policy-making level, and there is no indication that policy makers were unaware of what they were doing. The fact that vaccine lots had failed manufacturers' tests appeared clearly on the documents on which their decision was supposed to have been based.

DBS has indicated that the reason for its lax attitude toward the results of potency tests was its lack of faith in the potency test used at the time. Some changes have been made since 1968 and manufacturers have stopped submitting vaccine for release that is subpotent according to manufacturers' tests. However, as Morris and Turner have demonstrated, criticism of the inadequate test and efforts by DBS scientists to find improved ways of testing were strongly discouraged by the DBS leadership throughout the 1960's. Even today, doubts remain about the validity of the DBS potency test.

EFFICACY OF INFLUENZA VACCINE

In addition to problems of subpotent influenza vaccine, there remain substantial questions about the vaccine's efficacy. As early as 1962, the Public Health Service's Center for Disease Control estimated that the vaccine was

only 20–25% effective, a level far below that of any other major vaccine. A 1969 study published in the Bulletin of the World Health Organization (vol. 41, pp. 531–535) concluded that "optimally constituted influenza vaccines at standard dosage level have little if any effectiveness and that even larger doses of vaccine do not approach the high degrees of effectiveness that have been achieved with other virus vaccines."

The current recommendation by the Public Health Service Advisory Committee on Immunization Practices is that only people who are chronically afflicted with certain diseases should receive the vaccine. Indiscriminate distribution of the vaccine is not only unnecessary, but may make matters worse for the small category of persons whom the vaccine could conceivably help. According to the DBS Director, during the influenza epidemic of 1967–68, "persons who really didn't need the vaccines were getting them, while persons who did were ignored." DBS should finally address the problems raised by the influenza vaccine. I am writing to Secretary Richardson to ask specifically that the efficacy of influenza vaccine should be closely examined under the newly announced efficacy program and that alternative methods of preventing influenza be seriously considered. I also look forward to receiving from the Department of Health, Education, and Welfare a copy of the report on DBS Management prepared for the National Institutes of Health by a committee headed by Dr. James Schriver.

VACCINE REGULATION AND CONSUMER PROTECTION

The problems raised by this report, however, have broad implications. The release of this report represents a continuation of efforts of my Subcommittee to assure better federal regulation of foods and drugs. In addition to the investigation of vaccine regulation, my Subcommittee on Executive Reorganization and Government Research, in conjunction with the GAO, is investigating federal regulation of blood banks and blood products. My Subcommittee has worked with the GAO in the preparation of four reports on the Department of Agriculture's inspection of meat and poultry. These reports were critical of the Department's performance in assuring wholesome meat to American consumers. Through the Subcommittee, I released a GAO study of the federal government's regulation of the tuberculosis control drug, isoniazid. That report found that FDA had ignored its own regulations concerning the experimental use of investigational new drugs on human subjects. In 1971, the Subcommittee held hearings on chemical additives in our food supply. Witnesses warned about the danger of chemical food additives and residues of drugs such as DES in the food supply. A Committee Print concerning federal regulation of chemical food additives will soon be published.

All these investigations and reports have established the need for comprehensive legislation to protect American consumers. Two bills now pending in my Subcommittee would have a major effect on the problems we are continuing to discover in our regulatory agencies. One bill is S. 1177, which I am sponsoring, to establish an independent Consumer Protection Agency. This bill would create an advocate for the interests of consumers who would argue on behalf of consumers at all levels of federal agency activities. If there had been an independent consumer advocate, I doubt that an agency such as DBS could have continued to allow millions of doses of watered influenza vaccine to be released for public use year after year. I do not believe that worthless vaccines would have remained licensed for decades. I doubt that the kind of timid regulation we have discovered at DBS would have for so long gone unnoticed; or that filthy conditions would be allowed to prevail year after year in our meat and poultry plants, or that chemicals which add little or nothing to the nutritional quality or safety of food would be allowed to remain in the food supply. An independent consumer advocate would have an enormous impact on the way federal agencies deal with the interests of consumers. My Subcommittee will soon report out S. 1177 and I intend to see the bill become law.

The other piece of legislation is S. 3419, a bill to establish a single independent agency responsible for regulation of product safety, food, and drugs. The proposed Consumer Safety Agency would perform the functions of HEW's present Food and Drug Administration, but would have a wider range of responsibilities and authorities. One such additional responsibility would be the regulation of vaccines currently performed by the DBS. In holding hearings on S. 3419 my Subcommittee will review the performances of the DBS and seek to determine whether the Divisions' regulatory responsibilities would better be handled in

conjunction with the federal government's regulation of other drugs. In addition, we shall consider whether additional transfers of authority would improve the quality of consumer protection.

The failures cited in the report I am releasing today are major failures in consumer protection. It would be misleading, however, to focus only on these incidents and ignore the larger problems of bureaucratic regulation. These problems are symptoms of a general disorder.

The real problems lie in a regulatory bureaucracy in which authority is apportioned according to irrational distinctions; in which different federal agencies frustrate each other's policies by pursuing conflicting goals; in which questions are decided not on their merits, but in order to preserve or extend an agency's jurisdiction; in which important regulatory authority is buried between layers of bureaucracy, and decision-makers lose their visibility and public accountablity; in which the only day-to-day influence on regulators from outside the government comes from representatives of the regulated industry; in which agencies with regulatory responsibilities also view themselves as advocates for a particular interest group; in which regulators move back and forth between jobs in government and executive positions in regulated industries; in which important decisions are made without input from a variety of affected interests.

All these problems plague our regulatory programs. We have to do better. We cannot solve all the problems of ineffective federal regulation in one piece of legislation. But we do have a responsibility to begin. S. 1177 and S. 3419 are important first steps in the right direction.

(Attached is the list of the 32 vaccines referred to as ineffective by the DBS director and their manufacturers.)

VACCINES REFERRED TO AS INEFFFECTIVE BY THE DBS DIRECTOR AND THEIR MANUFACTURERS

Product listed in report	Brand name of product listed in report	Manufacturer
1. Product A	Bacterial vaccine mixed respiratory	Hollister-Stier Laboratories.
2. Product B	Respiratory UBA	Eli Lilly & Co.
3. Product C	Staphylococcus-streptococcus UBA	Do.
4. Product D	Combined vaccine No. 4 with catarrhalis	Do.
5. Product E	Mixed vaccine No. 4 with H. influenzae	Do.
6. Product F	Staphylococcus vaccine	Do.
7. Product G	Entoral	Do.
8. Product H	Typhoid H. antigen	Do.
9. Product I	Vacagen tablets	Merck, Sharp, & Dohme.
10. Product J	Brucellin antigen	Do.
11. Product K	Staphylo-strepto serobacterin vaccine	Do.
12. Product L	Catarrhalis serobacterin vaccine mixed	Do.
13. Product M	Sensitized bacterial vaccine H. influenzae serobacterin in vaccine mixed.	Do.
14. Product N	Staphage lysate type I	Delmont Laboratories, Inc.
15. Product O	Staphage lysate type III	Do.
16. Product P	Staphage lysate types I and III	Do.
17. Product Q	Catarrhalis combined vaccine	Merrell-National Laboratories (division, Richardson-Merrell).
18. Product R	Strepto-staphylo vatox	Merrell-National Laboratories.
19. Product S	Staphylococcus toxoid-vaccine vatox	Do.
20. Product T	Respiratory vatox	Do.
21. Product U	Respiratory B.A.C	Hoffman Laboratories, Inc.
22. Product V	Gram-negative B.A.C	Do.
23. Product W	Pooled stock B.A.C. No. 1	Do.
24. Product X	Pooled stock B.A.C. No. 2	Do.
25. Product Y	Staphylococcal B.A.C	Do.
26. Product Z	Pooled skin B.A.C	Do.
27. Product AA	Mixed infection phylacogen	Parke, Davis & Co.
28. Product BB	Immunovac oral vaccine	Do.
29. Product CC	Immunovac respiratory vaccine (parenteral)	Do.
30. Product DD	Streptococcus immunogen arthritis	Do.
31. Product EE	N. catarrhalis vaccine (combined)	Do.
32. Product FF	N. catarrhalis vaccine immunogen (combined)	Do.