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The Origin of Compulsory Drug Prescriptions

Peter Temin

Before 1938, the only drugs for which prescriptions were needed were certain narcotics specified in the Harrison Anti-Narcotics Act of 1914.¹ Any other drug could be obtained by walking into a pharmacy and buying it. If a person wished to see a doctor and get a prescription, he could. But any non-narcotic drug he could buy with a prescription could also be bought without one, and any prescription could be used as many different times and for as many different people as desired.

This state of affairs ended in 1938 when two different categories of non-narcotic drugs--prescription and over-the-counter--were created. Although the Federal Food, Drug, and Cosmetic Act was passed in 1938, this distinction was not spelled out in that law. In fact, it seems clear that the legislative intent of that law was violated by this distinction. This paper recounts the story of how a new category of non-narcotic prescription drugs was created in 1938 and how it was finally written into law in 1951. The story is told in three parts. The first part recounts the organizational and legislative history of the 1938 law. The second part shows how the FDA's regulations extended the law to create the distinction between prescription and over-the-counter drugs. The third part describes the subsequent history of this regulation in the Supreme Court and Congress. A final section summarizes the argument.

I

Sales of medicinal drugs increased greatly between the passage of the 1906 Pure Food and Drug Act and the Great Depression, increasing by a factor of six in the twenty years or so that separated them. But patent medicines still accounted for half of all drug sales in 1929. Drug regulation under the 1906 Act had not succeeded in directing consumer expenditure away from patent medicines by the start of the Great Depression.²

This "failure," if it be one, may have created a desire for more legislation in the minds of people, both within and outside the government, but it did not lead directly to new laws. The initial impetus for a revision of the 1906 Pure Food Act came in the early days of the New Deal, even though the Federal Food, Drug and Cosmetic Act that resulted from this impetus did not pass Congress until 1938, and it came out of quite different concerns. The FDA was still part of the Agriculture Department, and the idea of rewriting the food and drug law came from an interchange in the spring of 1933 between W. G. Campbell, the chief of the FDA, and Rexford G. Tugwell, the newly-appointed Assistant Secretary of Agriculture.

The precipitating factor was a routine letter from the Department of Agriculture, written by the FDA and sent to Tugwell for his signature. The letter explained the FDA's policy toward spray insecticides, which was a compromise between the FDA's opposition to their use and support for the farmers coming from the rest of the Department of Agriculture. The letter said that the FDA was acting "in the interest of public health

and the welfare of the fruit and vegetable industry." Tugwell turned the letter back to the FDA, asking why the insecticide in question was not simply banned as a poison. After an initial burst of irritation that Tugwell would ask them why they hadn't done something they had been trying to do for years, the leadership of the FDA realized that Tugwell was attempting to support them, not to attack them. Campbell explained the situation to Tugwell and then took the opportunity to recommend amending the Food and Drug Act. Tugwell said he would discuss this idea with the President and called Campbell back the same day to report White House approval. Dunbar, Campbell's assistant and successor as chief of the FDA as well as the author of an account of this interchange, reacted by saying: "Why not write an entirely new law?"³

The new law, however, was to be written by old people. Reform was coming from within the FDA and therefore could be expected to strengthen the FDA, rather than to change the administration of the law. Even though the impetus for revision came from a question about the FDA's relationship to its institutional home, the Department of Agriculture, this was not the subject of the proposed reform. The impulse for the reform, such as it was, was unrelated to the content of reform that emerged.

In fact, the committee that drafted the new law was instructed to propose revisions that did not affect the administrative framework through which the law was enforced. The alternative, as the committee envisaged it, was to strengthen the law by creating a more powerful agency that could license producers and enforce its own decisions without operating through the Department of Justice. But other alternatives might have occurred in

a looser discussion. Product liability legislation on the model of more recent laws might have been explored. But one member of the committee reflected after the passage of the bill that the difficulty of getting the bill that was actually written through Congress shows that the committee could not have successfully proposed more radical reform.

The FDA was the successor to Harvey W. Wiley's Bureau of Chemistry. The 1906 Act said that the regulation necessary for the enforcement of the Act should be made by the secretaries of the Treasury, Agriculture, and Commerce and Labor, while examinations of specimens should be made in the Bureau of Chemistry of the Department of Agriculture or under its direction. The Secretary of Agriculture was charged with the responsibility of following up any suspected violations of the Act found by the Bureau of Chemistry.^{4a} Given Wiley's proselytizing energy and his role in securing passage of the Act, these provisions came to mean that the Bureau of Chemistry administered the Act, subject to the constraints imposed by having to work through the secretary of Agriculture and the Department of Justice, in the case of prosecutions.

The regulatory functions of the Bureau of Chemistry were separated from the myriad other functions of the Bureau in 1927. The regulators went into the newly formed Food, Drug, and Insecticide Administration, renamed the Food and Drug Administration in 1931, while the remainder of the Bureau joined the old Bureau of Soils to make a new Bureau of Chemistry and Soils. The personnel of the FDA was the same as in the old Bureau of Chemistry, and its leadership was drawn almost exclusively from the Bureau. At the beginning of 1937, the chief (Campbell) assistant chief (Dunbar), five division chiefs, and nine field chiefs had all begun work in the Bureau of Chemistry before the start of 1908.⁵ It is only

logical to assume that their view of food and drug regulation had been formed within the context of the 1906 law.

The new bill was introduced to Congress in 1933, but failed to pass in that session. Neither congressional nor presidential support was strong and Roosevelt assented when Congress wanted to adjourn its special session without action on this bill. The bill stayed before Congress for five years before it was finally passed in 1938. In Tugwell's words: "The legislation existed in a kind of limbo from 1933 to 1938, periodically being used as an illustration of the New Deal's socialistic tendencies but actually never being pushed by any political sponsor."⁶ The bill finally passed on the heels of a drug disaster, much as the 1906 act was passed in the wake of The Jungle's appearance.

The bill that passed was neither a simple response to the drug disaster nor the same bill that had been introduced in 1933. It had been watered down during its long legislative history, and the disaster resulted in new provisions being added to the bill rather than previous provisions being restored. Tugwell's opinion was that:

The Food Drug and Cosmetic Bill as it passed in 1938 was a discredit to everyone concerned with it. What had started out in 1933 on a tide of consumer approval to be a new charter of honesty and fair dealing in the manufacture and sale of products in everyday use had ended up as a renewed permission to exploit the public. . . . Consumers, so far as could be seen had no votes. At least they had no voices.⁷

The legislative history of the 1938 Act has many similarities to the history of the 1906 Act. The congressional debate lasted several years before leading to congressional passage. The President-- a Roosevelt in both cases--sent a message to Congress supporting the bill, but does not seem to have worked actively on its behalf.⁸ And the law finally passed in response to a burst of adverse publicity about a health hazard.

The Massengill Company, a respected drug firm since 1897, wanted to sell a liquid form of sulfanilamide, the first of the new sulfa drugs. It already sold Sulfanilamide in tablets and capsules, and it set about to find a solvent for the drug. It found that sulfanilamide would dissolve in diethylene glycol and that the resultant solution had reasonable appearance and taste. This solution was labelled "Elixir Sulfanilamide" and went on the market in September 1937.

Alas, the Massengill Company had not tested diethylene glycol for toxicity, and it turned out to be toxic indeed. Just over one hundred people died a painful death from taking Elixir Sulfanilamide. The FDA seized as much of the Elixir as it could find once it was alerted to the situation, retrieving all but six of the two-hundred forty gallons made. But the FDA could not prosecute Massengill for causing the deaths of one hundred people. Under the 1906 law, it could only prosecute Massengill for mislabelling its product. "Elixir" was a term used to describe an alcohol solution, and it was misapplied to diethylene glycol. Massengill paid a fine of \$26,100 for its mislabelling. It was the largest fine ever paid for mislabelling, but is still small when compared to over one hundred deaths.⁹

The Elixir Sulfanilamide disaster led to the introduction in the House of a bill banning interstate commerce in harmful substances. It was included in the committee version of the Food, Drug, and Cosmetic Act, where it formed the new-drug approval part of the law. New drugs could not be introduced until the FDA certified their safety.¹⁰ The momentum given to the whole bill by this addition was enough to carry all the other provisions except those on advertising through Congress. As with The Jungle in 1906, the public concern over a particular medical disaster or public health problem dragged a substantial amount of only tangentially related legislation through Congress in its wake.

II

The labelling provisions of the Federal Food, Drug, and Cosmetic Act of 1938 need to be described in some detail to make their later history comprehensible. Drug labels--which could not be "false or misleading in any particular--had to contain much more information than required by the 1906 law. All ingredients had to be identified and the quantity of each identified. Directions for the use of the drug and warnings about its danger had to be included also. This entirely new labelling requirement is one of the most important parts of the law and worth quoting in full:

Sec. 502. A drug or device shall be deemed to be misbranded-- . . . (f) Unless its labelling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: Provided, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.¹¹

Finally, a drug was deemed mislabelled if it was dangerous to health when used in the dosage recommended on the label as required by Section 502 (f).

Another section of the law listed exemptions to the labelling requirements of Section 502. A drug or device did not have to be labelled in accordance with the law if it was to be repacked or reprocessed before being sold to consumers. And a drug was exempt from some labelling requirements if it was dispensed on the written prescription of a licensed physician, dentist, or veterinarian. It was not automatically exempted from Section 502 (f) if it was sold by prescription.

The 1938 law restricted the range of drugs that could be offered on the market and mandated that information about them had to be supplied to the consumer. But it appeared to leave the eventual choice of drugs--among those available, to be sure--to the consumer himself. This was stated publicly to be the aim of the FDA in proposing and supporting the legislation. Self-medication was to be improved and facilitated, nor hampered. Campbell, then chief of the FDA, said forcibly in Senate hearings at the start of the legislative process: "There is no issue, as I have told you previously, from the standpoint of the enforcement of the Food and Drugs Act about self-medication. This bill does not contemplate its prevention at all. If it did a single short section in the measure could have been drawn up to that effect. But what is desired. . . is to make self-medication safe."¹²

He reemphasized the point in the same forum in the following year:

"All of the provisions dealing with drugs. . . are directed toward safeguarding the consumer who is attempting to administer to himself."¹³

And the House Report on the bill that eventually became law explicitly adopted Campbell's point of view: "The bill is not intended to restrict in any way the availability of drugs for self-medication. On the contrary, it is intended to make self-medication safer and more effective."¹⁴

Despite these assurances from the chief of the FDA, the FDA moved within six months of the bill's passage to sharply curtail self-medication and used a substantial and increasing proportion of its drug resources to enforce its imposed limitations thereafter. It is this story that is of central concern here.

Most drugs, it is well to remember, were sold without the intervention of a doctor before the Great Depression. The distinction between doctors and pharmacists was quite complete by 1929; consumers got less than five percent of their drugs directly from doctors. But pharmacists still operated quite independently of doctors. Even though most drugs ordered by prescription--like most other drugs--were purchased through drug stores, prescriptions were not needed to buy any non-narcotic drug. Only about one quarter of the drug sales from drugstores were ordered by prescription. Drugstores sold many more patent medicines and approximately as many home remedies as drugs ordered by prescription. Mirroring the independence of pharmacists from the control of physicians--and contrasting sharply with conditions today--less than five percent of drug advertising was directed at doctors. Almost all drug advertising at the end of the 1920s consisted of newspaper and magazine ads directed at the public.¹⁵

The Federal Food, Drug, and Cosmetic Act was signed by the President in June 1938. The FDA promulgated regulations to enforce the Act before the end of 1938. And among these regulations were those making clear the scope of the exemption from labelling requirements set forth in Section 502 (f) of the Act. This section said that a drug's label had to include directions for use and warnings about possible dangers arising from use of the drug. The FDA said a shipment or delivery of a drug or device was exempt from these requirements:

If the label of such drug or device bears the statement "Caution: To be used only by or on the prescription of a ----" (the blank to be filled in by the word "Physician," "Dentist," or "Veterinarian," or any combination of such words), and all representations or suggestions contained in the labelling thereof with respect to the conditions for which such drug or device is to be used appear only in such medical terms as are not likely to be understood by the ordinary individual, and if such shipment or delivery is made for use exclusively by, or on the prescription of, physicians, dentists, or veterinarians licensed by law to administer or apply such drug or device; but such exemption shall expire when such shipment or delivery, or any part thereof, is offered or sold or otherwise disposed of for any use other than by or on the prescription of such a physician, dentist, or veterinarian.¹⁶

It seems simple enough. The law said that the FDA could exempt drugs or devices from the requirement to include recommended usages and the dangers of misuses when these regulations were "not necessary for the protection of the public health." The FDA interpreted this to mean that--among other conditions--the usage and dangers labels were not needed for drugs sold by prescription. To insure that drugs without these labels would in fact be sold by prescription, the FDA required that they have a warning on the label, that any instructions be unintelligible

to the layman, and that they be shipped for this exclusive purpose. The FDA said further that the exemption expired if the drug or device was sold without a prescription, making the seller immediately guilty of misbranding the drug or device in question. It all seems simple and logical--until its implications are understood.

The Act said elsewhere (Section 503) that drugs sold by prescription were exempt from some labelling requirements, but it did not say which drugs were to be sold by prescription or that there were any drugs that could not be sold without a prescription. This regulation is different. It says that drugs with certain kinds of labels--"Warning. . ."--can only be sold by prescription. It allows the drug companies to create a class of drugs that cannot legally be sold without a prescription by putting the appropriate label on them.

This is a stunning change in the way drugs were to be sold. Before this regulation took effect, consumers could get any non-narcotic drug they desired without going to see a doctor. If they wanted, they could, of course, consult a doctor and get a prescription. But they were under no obligation to do so. If they chose not to, they could go directly to a druggist and buy the drug of their choice. After this regulation became effective, the consumer could no longer buy some drugs without seeing a doctor first and getting his approval. Which drugs were now beyond the consumer's reach? The drug companies would decide, although the FDA could sue them for mislabelling if it disagreed with their choices. The consumers became passive recipients of this decision.

Far from encouraging self-medication, as Campbell had said the

1938 Act would do, this provision sharply curtailed it. Previously, the consumer was allowed to judge for himself whether he wanted to take any drug on the market. Now the drug manufacturers and the FDA would decide for him which drugs he could select on his own. He was no longer considered capable of selecting his own drugs. And his inadequacy was to be emphasized and increased by writing the labels for prescription drugs "in such medical terms as are not likely to be understood by the ordinary individual." The FDA had appointed doctors as the consumer's agents in selecting drugs.

The 1938 law reduced the scope of competition by making it harder to introduce new drugs into the market. The government rather than the market was to protect consumers. The FDA went further along this road in its administrative regulation. Even though the government undertook to guarantee the safety of all available drugs, consumers were not to be allowed to choose freely among them. Some--to be selected by an unspecified process--were obtainable only under professional guidance. Congress assumed that people could not understand the implications of a list of ingredients; the FDA assumed that they could not or would not follow directions for the use of drugs.

The FDA's assumptions were new to the drug market. Had they arisen from a change in the technology of producing drugs, from the availability of many new and complex drugs? The answer is no. The drug revolution came after 1938. The discovery of the first sulfa drugs, Prontosil and sulfanilamide, had been announced in 1935, but there was little in the few years following those announcements to suggest that this was not simply the identification of another isolated therapeutic agent, like Salversan or insulin.¹⁷ The regulation grew out of conditions existing

before the revolution in drug therapy produced by the wonder drugs of the 1940s. The dangerous component of Elixir Sulfanilamide was the solvent, not the sulfa drug.

Second, what else could have produced the FDA's regulation? We do not know with any certainty, but there are one or two suggestive clues. The FDA's Annual Report for 1939 identifies the regulation as the result of "an administrative conclusion of some moment." The conclusion resulted from a conflict the FDA saw within the new law. On the one hand, the law said that all drugs must be labelled adequately, adding that any drug that was dangerous to health when used as the label suggested was automatically misbranded. On the other hand, the report asserted, "Many drugs of great value to the physician are dangerous in the hands of those unskilled in the uses of drugs. The statute obviously was not intended to deprive the medical profession of potent but valuable medicants."¹⁸

The conflict was created by the assumption underlying the first of the two sentences quoted. The FDA assumed that adequate directions for self-medication could not be written for some drugs. The reasons for this assumption are not given. There were no new drugs with complicated modes of administration that only a doctor could understand. There was very little knowledge of drug interaction even among professionals. Insulin, which had been commercially available for well over a decade, surely was as dangerous and as complex to administer as any other drug, but there is no mention of it. Instead, aminopyrine, cinchophen, neocinchophen, and sulfanilamide are listed as dangerous. Is the danger that the full potential of the drugs will not be used by consumers acting alone?

Is the danger that they will be used indiscriminately? The phrase "potent but dangerous" in the FDA's Annual Report suggests a perceived problem along these lines; the detailed reasoning behind this critical regulation is not known.¹⁹

III

The 1938 regulation does not seem to have aroused much discussion at the time, and its effect on the function of prescriptions was never tested in the courts. The case usually cited as its court test, U.S. v. Sullivan, was concerned with other aspects of the law, and the distinction between prescription and "over-the-counter" drugs was simply accepted.

The FDA began to prosecute pharmacists for violations of this regulation shortly after it was promulgated. The enforcement of the distinction between prescription and over-the-counter drugs was at the expense of pharmacists, not manufacturers. There was one termination in 1943, two more in 1945, and more in each subsequent year. Among the drugs involved, sulfathiazole--a relatively early sulfa drug no longer in use--and two barbituate sedatives--nembutal and seconal--reappear again and again.²⁰

Among the early cases was one brought against Sullivan's Pharmacy in Columbus, Georgia. Sulfathiazole tablets were shipped to the pharmacy in bottles of one thousand with adequate labels of the "Warning. . ." variety. On two separate occasions, a dozen sulfathiazole tablets were removed from the bottles, put into pill boxes, and sold to customers without the warnings from the bottles. They were also sold without prescriptions,

as the District Court record makes clear.

The case was taken up through the courts until it was decided by the Supreme Court in 1948. The issues before the Court, as expressed in the opinions of the Court, were two. First, did the Act cover the resale of a drug within a state after the drug had passed through interstate commerce? The majority argued that it did, and the dissent was silent. This aspect of the decision was written into the law in the Miller Amendment of 1948. Second, was repackaging a drug included in the list of proscribed activities listed in the law? According to the law, alteration, mutilation, destruction, obliteration, and removal of labels was prohibited, as well as any other act that resulted in a drug being misbranded. The majority of the Court argued that this prohibition included repackaging drugs without recopying the label; Frankfurter argued from the vagueness of the prohibition that it did not.

There is no mention in the Supreme Court's opinion whether the drugs were sold by prescription or not. Even though the record of the lower court was clear on this question, it was not an issue in the final decision. The legal distinction between prescription and over-the-counter sales introduced by the regulation was not controversial. The intervention of the government into a local drug sale was.²¹

By the end of 1948, the extension of the law to cover the final sale of drugs and the ability of the FDA to sustain its prosecutions were clear, but the legality of requiring prescriptions was still unsettled. The FDA had been moved from the Department of Agriculture to the Federal Security Agency in 1940, and Ewing, the head of that agency, described the situation clearly to Congress in 1951:

While some lawyers have disagreed, I believe that authority for our present regulation and for its proposed revision is found in the present statute-- though it is contained in one four-line proviso. At least in its general pattern, the regulation was held valid by the Supreme Court of the United States in United States v. Sullivan.²²

The "four-line proviso" is the last part of Section 502 (f) quoted above. And Ewing acknowledged that the decision in U.S. v. Sullivan was not as explicit as he would have liked.

Ewing was speaking before Congress because Congress was considering an amendment to the Federal Food, Drug, and Cosmetic Act that would clarify the legal status of prescriptions. The discussion of the amendment centered on the way in which the line was to be drawn between prescription and over-the-counter drugs, but the amendment itself also clarified other ambiguous areas. Telephone prescriptions and prescription refills, among other practices, were not recognized in the law, and the amendment included them in its restatement of the rules on prescriptions. The amendment had been proposed to clarify a variety of controversial or ambiguous FDA rules on prescription.²³

The House considered the amendment first. The committee report noted that the existing unamended law allowed the manufacturer to decide whether a drug was to be sold by prescription only or over the counter. The result was that, "Lack of uniformity. . .has led to great confusion." The

same drug could be classified as a prescription drug by one manufacturer and as an over-the-counter drug by another. It could even be labelled differently in separate shipments by the same manufacturer. If a druggist sold a prescription drug over the counter, that is, without a prescription, the druggist could be prosecuted for misbranding, but if the Federal Security Agency, the FDA parent agency, disagreed with the manufacturer's designation of a drug, it had to sue the manufacturer. Given the relative size of drugstores and drug manufacturing firms around 1950, it was far easier to enforce adherence to the drug companies' labelling than to affect the labelling itself.

The House committee consequently recommended that the responsibility for designating a drug to be sold over the counter or by prescription only be given to the FDA. The House bill reworded the FDA's regulation to require a prescription for a drug if "its toxicity or other potentiality for harmful effect. . .has been determined by the Federal Security Administrator, on the basis of opinions generally held among experts. . . to be safe and efficacious for use only after professional diagnosis. . . ." The FDA's regulation had acquired a paragraph explaining why certain drugs needed prescriptions, and the House's references to "toxicity or other potentiality for harmful effect" and to drugs that were "safe and efficacious for use" were taken from the regulation. The House kept the FDA's reference to efficacy and added the requirement that the FSA decide which drugs were to be sold by prescription.

The National Association of Retail Druggists favored giving the FSA this power; the Association of Pharmaceutical Manufacturers, the American Drug Manufacturers Association, the American Pharmaceutical

Association (APhA), and the Proprietary Association opposed it. A minority report joined the drug manufacturers in opposing this grant of power. The minority report said, ironically in view of its acceptance of the distinction between prescription and over-the-counter drugs, the "the bill as reported jeopardizes the traditional right of self medication and choice of remedies." It in fact jeopardizes the rights of manufacturers, not consumers. "The bill," the minority continued, "could very well become a handmaiden of socialized medicine." It would raise the costs of drugs and increase agitation for government relief.²⁴

The Senate Committee reported the controversy over the House proposal to grant new power to the FSA. It reported further that the FDA and FSA had agreed to remove this provision from the amendment and that the manufacturers' associations had been satisfied with this concession. It concluded that "the subcommittee was assured by the FDA and the FSA that the bill, while not in their view the best solution, would be workable in the form proposed under the agreement." The drug manufacturers had enough muscle to prevent the FDA from interfering with their right to designate the terms of sale to their drugs. Instead of an administrative decision, which the drug companies could appeal, the FDA would have to sue the companies for misbranding if it disliked their decisions.

The Senate Committee said that its definition of dangerous drugs, that is, drugs requiring prescriptions, was "substantially the same" as the one in the FDA regulation. But a careful look at the Senate version

of the bill, which became the Durham-Humphrey Amendment, shows that the reference to "efficacy" had been removed. The law was to deal only with safety under the new amendment, as it did under the 1938 provisions for new drugs.²⁵

Several aspects of the story about origin and passage of the Durham-Humphrey Amendment are of interest. Some are of interest because they were not controversial, while others are of interest because they were. In the first group, the most important paradox of the discussion was the apparent absence of controversy on the heart of the matter, the FDA's division of medicinal drugs into two categories. The FDA had decided--in contrast to the long tradition of legislation in this area--that the consumer was unable to choose some drugs for himself, even if furnished full information. In fact, the position of the FDA assumed that adequate directions for laymen could not be written for some drugs. It followed that any directions written for laymen were misleading and that any drug labelled for laymen was misbranded. The only way to label such a drug properly was to provide a prescription-only label. Instructions should be available, but not on the label, according to this argument.²⁶

Before 1938, the function of drug legislation was to prevent fraud. Since consumers did not have the ability to analyze drugs chemically or access to the technical medical literature, drug labels were to inform the consumer about the chemical and known therapeutic properties of drugs. The function of government was to assure that the labels were adequate and correct. The government did not undertake to limit the choice of consumers, only to increase the information available to them.

(The exception to this rule, narcotics, shows by its restricted scope how broad the domain of consumer choice was to be.)

The Federal Food, Drug and Cosmetic Act of 1938 added to that function the assurance of safety. The government undertook to assure the public that any drug on the market could be taken in reasonable quantities without harm. The government thereby restricted the range of consumer choice by taking harmful substances off the market. But the layman was still free to choose his own drugs from among all non-harmful, non-narcotic drugs. He could consult a doctor if he wished, but he was under no obligation to do so.

By the end of 1938, the FDA had announced that the government would sharply curtail this freedom of choice. Consumers, the FDA said, were not competent to make their own drug choices. The manufacturers would decide by their labelling practices which drugs were safe for the consumers and which were not. And licensed physicians and dentists would select among those drugs that the manufacturers thought were dangerous the ones that the consumer could use. The government had delegated the consumers' choice to manufacturers and doctors. And nobody commented.

Almost nobody. A law review article in 1947 argued that the Congress had not intended the labelling rules of the 1938 law to be used to restrict sales of some drugs to prescription. The author reviewed the history just presented and argued that the clear legislative intent of Congress was to aid self-medication, not to restrict it. He questioned the legality of the FDA rule quoted above, but predicted that the courts would uphold it. He predicted that the courts would not examine the rule

carefully, but instead would presume that the FDA was expert and informed in its special area. His predictions were confirmed the following year by the decision and opinions in U.S. v. Sullivan.²⁷

This change in the underlying assumptions of drug legislation came about through internal FDA processes. The shift from assuming a capable consumer to assuming an incompetent consumer was made within the FDA within six months of the Federal Food, Drug, and Cosmetic Act's passage. Not only was the shift in assumptions not controversial, the method by which it was accomplished occasioned no comment as well. The decisions of the FDA were ratified by the courts and enacted into statute by the Congress. Neither branch of the government undertook to question the FDA's assumptions.

IV

The FDA had abandoned the assumption that people behaved rationally in their choice of medicines and replaced it with the assumption that they behaved customarily. The evaluation of drugs became significantly more complex in the years following World War Two, and a change in assumptions in the 1950s might have been explained by changes in the range of available drugs. But a change in the 1930s cannot be explained by this variable. Most drugs existing before World War Two--with a few prominent exceptions--had as their goal the relief of symptoms. Consumers experiencing these symptoms were capable of evaluating the extent to which different drugs relieved their symptoms and making reasoned choices among non-addicting drugs. They still retained this capacity in 1938.

The change came from outside the market for drugs. It was the government's perception that changed, not the behavior of individuals. As a result of the Depression, policy makers in the federal government lost faith in the ability of the market economy to protect individuals from a variety of economic and non-economic ills. The New Deal moved in to substitute regulatory protection for the protection afforded by the market. And the FDA's regulation, like the Federal Food, Drug, and Cosmetic Act itself, was simply a logical extension of this view. The attitude toward drug purchases could be justified after the fact by the changes taking place at the time of the post-war Durham-Humphrey Amendment, but it had been imposed on the drug market from outside in the 1930s.

Notes

¹ 38 Stat. 785 (1914).

² C. Rufus Rorem and Robert P. Fischelis, The Costs of Medicines: Committee on the Cost of Medical Care Publication no. 14 ^{at} 18, 102 (1932)

³Paul B. Dunbar, Memories of Early Days of Federal Food and Drug Enforcement, 14 Food, Drug and Cosmetic Law Journal (1959). See Stephen Wilson, Food and Drug Regulation 78-9 (1942), Fred B. Linten, Leaders in Food and Drug Law, Part Five, 5 Food, Drug and Cosmetic Law Journal (1950), and Bernard Sternsher, Rexford Tugwell and the New Deal 225 (1964), for slightly different accounts. Dunbar claims the idea of revision arose within the FDA; others claim it came from Tugwell. Tugwell's biographer notes that he had listed the reorganization of the FDA as a major problem a month before his conversation with Campbell.

⁴David F. Cavers, The Food, Drug, and Cosmetic Act of 1938: Its Legislative History and Its Substantive Provisions, 6 Law and Contemporary Problems (1939); Charles O. Jackson, Food and Drug Legislation in the New Deal 26-7 (1970).

^{4a}₃₄ Stat. 768-69 (1906).

⁵ Dunbar, supra note 2 ^{at} 125; Henry Welch and Felix Marti-Ibanez, eds., The Impact of the Food and Drug Administration on Our Society 13 (1956).

⁶Rexford Tugwell, The Democratic Roosevelt 466 (1957).

⁷Tugwell, supra note 6 at 464.

⁸Roosevelt sent a special message to Congress supporting the revision of the food and drug laws. Wilson, supra note 3 at 113.

⁹Jackson, supra note 4 chapter 7; James H. Young, *The Medical Messiahs* 186 (1967). A member of the Massengill family published a history of pharmacy and his family's involvement with it in 1943. He did not mention Elixir Sulfanilamide. Samuel Evans Massengill, *A Sketch of Medicine and Pharmacy* (1943).

¹⁰Cavers, supra note 4 at 20, 40.

¹¹52 Stat. 1050-51 (1938).

¹²U.S. Congress, Senate, Hearings of S. 1944 before a subcommittee of the Committee on Commerce, 73rd Cong. 2d Session (1934), reprinted in Charles W. Dunn, *Federal Food, Drug and Cosmetic Act: A Statement of Its Legislative Record* 1083 (1938).

¹³U.S. Congress, Senate, Hearings on S. 2800 before the Committee on Commerce, 73rd Cong. 2d Session (1934), reprinted in Dunn, supra note 12 at 1195, and quoted in Wilson, supra note 3 at 164.

¹⁴U.S. Congress, House, House Report 2139, 75th Cong., 3d Session (1938), reprinted in Dunn, supra note 12 at 822 and quoted in Williams, supra note 3 at 163.

¹⁵Rorem and Fischelis, supra note 2 at 18, 153.

¹⁶₃ Fed. Reg. 3163 (Dec. 28, 1938).

¹⁷Peter Temin, *The Role of Regulation and Technology in the Creation of the Modern Pharmaceutical Firm* (1978).

¹⁸U. S. FDA, Annual Report (1939), reprinted in Food Law Institute, *Federal Food, Drug and Cosmetic Law, Administrative Reports, 1907-49 929* (1951).

¹⁹One spurious justification for the regulation must be noted. It was justified in a law-review article by reference to the wording of the law which allowed exemptions to the labelling requirements when they were "not necessary for the protection of the public health." If a drug was sold by prescription, the argument ran, then the full directions and warning required by law were not necessary for the protection of public health. Dunn, supra note 12 at 856-7. This argument is reasonable, but it misses the point. The regulation does not articulate the conditions of prescription sales; it requires prescription sales. It does not give the implications of a consumer's choice; it eliminates that choice. It does not allow for possible prescription sales; it mandates them.

²⁰U. S. Congress, House, Hearings before the Commission on Interstate and Foreign Commerce on H.R. 3298, A Bill to Amend Section 503 (b) of the FFDC Act. 82nd Cong., 1st Session 97-105 (1951). Two violations were at issue: the selling of drugs over the counter without adequate labelling and the unauthorized refilling of prescriptions, which was the subject of another part of the regulation.

²¹U. S. v. Sullivan, 332 US 689 (1948); 62 Stat. 582 (1948). The District Court opinion said: "This regulation as it affects the present case would require the drug to be sold on a physician's prescription and to bear the direction for use specified in the prescription." The first clause was included for accuracy, but only the second was being litigated. The U. S. brief to the Supreme Court relegates to a footnote the comment that adequate directions for use by laymen of dangerous drugs could not be written. See U. S. Supreme Court Reports 332: Records and Briefs, Transcript of Record, U. S. v. Sullivan (1948).

²²U. S. Congress Hearings, supra note 20 at 16.

²³Young, supra note 9 at 273-4.

²⁴U. S. Congress, House, Amending Section 503 (b) of the Federal Food Drug and Cosmetic Act, House Report 700, 82nd Cong., 1st Session 16-17 (1951).

²⁵U. S. Congress, Senate, Amending Sections 303 (c) and 503 (b) of the Federal Food Drug and Cosmetic Act, Senate Report 946, 82nd Cong., 1st Session 2-4 (1951); 65 Stat. 648 (1951).

²⁶Edward B. Williams, Exemption from the Requirement of Adequate Directions for Use in the Labelling of Drugs, 2 Food, Drug and Cosmetic Law Journal (1947).

²⁷Williams, supra note 26 at 163-72; U. S. v. Sullivan, 332 US 689.

See also Peter Barton Hutt, Regulation of the Practices of Medicine Under the Pure Food and Drug Laws, 33 Association of Food and Drug Officials of the United States (1969), a chief council for the FDA in the early 1970s.

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