7. The Role of Federal Policy

GENERAL OVERVIEW

Federal policies affect the development, manufacture, distribution, and use of contact lenses through various paths and in varying degrees, ranging from minor to large.

Direct Federal in-house activities and external funding for vision-care research play only a slight role in the operation of the contact lens industry, one of whose main benefits to consumers lies in the cosmetic qualities of contact lenses. Similarly, tax policy may have an important effect on the industry but not in any way that is distinct from other industries. Features of the tax laws, particularly provisions for accelerated depreciation, investment credits, favorable treatment for retained corporate earnings, and restrictions on corporate divestitures favor larger corporations relative to smaller ones, but the inherent features of the contact lens industry are compatible with small firms, and their position is not seriously threatened by any advantages provided their larger rivals through these tax provisions.

Foreign trade policy does not appear to adversely affect the contact lens industry. The tariff on imported contact lenses is low, 8.5 percent of value (5.6 percent for those coming from countries with preferential treatment), much less than for almost all other components of the tariff category "optical goods, " yet imports account for only a small share (7 percent in 1980) of total domestic purchases (56). (Many of the imported contact lenses, of course, may come from the foreign-owned enterprises of U.S. producers.)

Direct government procurement, an influential economic force in many other industries, is minimal for contact lenses, and Federal third-party payment mechanisms, mainly Medicare and Medicaid, pay for contact lenses only as a therapeutic item for aphakia and a few other ophthalmic conditions. This adds to the use of lenses for these conditions, and probably spurs some research and development along related lines, but has little effect on the much *larger* general market.

However, not all Federal policies are so easily discounted as factors influencing the contact lens industry. Three, in particular, warrant closer examination. In ascending order of impact, they are: 1) patent policy; 2) policies toward the enforcement and maintenance of competition within markets; and 3) regulatory policies that require government approval prior to the general marketing and use of products such as drugs and medical devices, including contact lenses.

PATENTS

For the most part, patents neither pose problems nor exert special influence on the contact lens industry. They seem to offer an acceptable balance between the sometimes conflicting goals of stimulating innovation and keeping market competition viable. On the one hand, they provide incentives and rewards for new product and process developments; on the other hand, they do not appear to create formidable barriers to entry. The record of innovation is a good one, covering a wide range of lens materials, many lens designs for similar applications, and a variety of manufacturing processes. Further, the majority of these developments are accessible to any lens producer. Other evidence shows that entry barriers from patents are not high: upwards of three dozen firms produce soft lenses and over 50 make hard lenses. Although relatively few firms manufacture and sell gas-permeable lenses, the market barrier in this case (and in some others) is not the unavail-

ability of materials or techniques because of patents, but premarket approval by the Food and Drug Administration (FDA), which will be examined later in this chapter.

Patents may still be important in the contact lens industry, however, because they can reserve superior materials, designs, and processes for one or a few firms to the disadvantage of others.

Among the more important patents are those deriving from Wichterle's original work on soft lenses in Czechoslovakia, for which the National Patent Development Corp. (NPD) obtained certain rights, which were then sublicensed to Bausch & Lomb. The headstart provided by the NPD patents on hydrogel material and the spin-casting method for making soft contact lenses enabled Bausch & Lomb to enter the market first (1971) and remain as the sole seller of soft lenses until 1975. The subsequent development of other hydrophilic polymer plastics allowed many rivals to get around the NPD-Wichterle product patent, and vigorous price competition has been one of the results. However, the economical spin-casting manufacturing process has continued to work to the advantage of Bausch & Lomb, enabling it to operate profitably in the face of large price declines.

However, neither of the original patents successfully blocked entry by others; the product patent was quite easy to invent around and the process patent, although very advantageous and durable, covers but one of several manufacturing methods. The resulting entry of other firms has brought lens prices down by a considerable amount since 1975, as shown in table 7 (soft lens wholesale prices were **$68.70** in **1975,** but only $30 in 1982). Accordingly, patents seem to be a rather noncontroversial element in the contact lens industry. However, to remain so, they should continue to be carefully defined, affording only the reasonable minimum degree of exclusivity warranted by the particular discovery or invention.

THE MAINTENANCE OF MARKET COMPETITION

Policies to protect competition in the markets of the U.S. economy are administered at the Federal level by the Department of Justice and the Federal Trade Commission (FTC). The two agencies enforce the Federal antimonopoly laws and in other ways also seek to maintain, restore, or create competition in society's interest.

Two facets of the contact lens industry's activities relate to these laws and enforcement agencies. The first of these is the considerable merger activity that has occurred up to the present time, including the acquisition of smaller firms by larger ones within the industry, and of larger firms by external industrial corporations. Under the Clayton Act, mergers that may substantially lessen competition are prohibited, and thus an examination of these mergers in the context of the Clayton Act is instructive.

The second link between the contact lens industry and the antitrust enforcement agencies is found in the distributional mechanism by which lenses reach the consumer, particularly the presence or absence of competition, and the forms it takes, among dispensers. In recent years the FTC has addressed two restraints on distribution competition: State limitations on the competitive opportunities for opticians, and State approval of professional prohibitions on price competition by lens prescribers and fitters.

Mergers

Many of the numerous mergers that have occurred in the contact lens industry are identified in appendix B. Since none of these involved the acquisition of one major producer by another (generally illegal under the Clayton Act), the observed degrees of market concentration, if some what higher than had these mergers not occurred are mostly explainable in other terms, mainly the early phases of the typical industry life cycle.

But concentration levels are not the only basis for judging the effect of mergers. The absorption

of smaller firms by larger ones threatens a major source of innovation. The history of the industry is replete with the achievements of individual scientists and small firms. For example, key contributions in the development of the soft lens sector include those of the then-small NPD in the origination of the product, and the later research contributions of such smaller firms as Milton-Roy (since acquired by Bausch& Lomb), Calcon Laboratories, Polymer Optics, Salvatori Ophthalmic (these last two recently have been acquired by Syntex), Rynco Scientific, Danker Laboratories, and others, none of which rank among the major firms.

State Commercial Practice Restraints

Regulation of the commercial practices of eye-care professionals occurs at the State level and has an especially strong impact on the prices consumers ultimately pay for their contact lenses.

The acquisition cost of contact lenses includes, in addition to the lenses, a refraction test and lens prescription, post-refraction corneal measurement, trial lens fitting, and followup examinations and care. Competition among lens manufacturers has brought the price of lenses down substantially, but lens prices are not the major component of the total cost of obtaining contact lenses, at least from ophthalmologists and optometrists. The predominant component is the professional services required to examine the eye and to choose and fit the lenses with satisfactory results. Thus the potential gains from competition, including price, in these services considerably outweigh those from competition among lens manufacturers. In fact, competition in the service component of contact lens acquisition costs has been the main contributor to the price declines observed for all major lens types.

State laws covering eye-care professionals vary from one class of practitioner to another, and vary sharply from State to State for optometrists and opticians. Ophthalmologists, as medical specialists, are governed by medical practices acts, which are essentially uniform from State to State. Optometrists and opticians, however, are subject to other specific regulations such as those issued by State optometry boards. Generally, the regulations on these two classes of practitioners cover professional qualifications for licensure; restrictions on employment activities and optometric and optician outlet locations, including branching; and limitations on doing business under a trade name. Optometrists are usually more restricted than ophthalmologists and less restricted than opticians in their provision of eye-care services ***(55).***

The greatest State-to-State variation in permissible activities is in the case of opticians. These variations, shown as they relate to the provision of contact lenses, are given in table 17. In no State can opticians prescribe corrective lenses. In the five States comprising group I, they are "expressly

Table 17.-Contact Lens Fitting by Opticians: Survey of State Limitations (including District of Columbia)

1.	States where opticians are expressly permitted to fit contact lenses:	
	Arizona	North Carolina
	Connecticut	Ohio
	Massachusetts	
II.	States where opticians are expressly forbidden to fit contact lenses:	
	Kansas	New Mexico
	Missouri	Vermont
	New Jersey	
III	States where opticians may fit contact lenses on the direction of or under the supervision of an ophthalmologist or optometrist:	
	Alaska	Mississippi
	California	Nevada
	Colorado	New York
	Delaware	Oregon
	Florida	South Carolina
	Hawaii	Tennessee
	Illinois	Texas
	Kentucky	Virginia
IV	States where opticians may dispense contact lenses on a fully written "prescription: "	
	Alabama	Florida
	District of Columbia	Wyoming
V.	States where law on the question is ambiguous or nonexistent:	
	Arkansas	Nebraska
	Georgia	New Hampshire
	Idaho	North Dakota
	Indiana	Oklahoma
	Iowa	Pennsylvania
	Louisiana	Rhode Island
	Maine	South Dakota
	Maryland	Utah
	Michigan	Washington
	Minnesota	West Virginia
	Montana	Wisconsin

SOURCE: U.S. Federal Trade Commission, Bureau of Consumer Protection, *State Restrictions on Vision Care Providers: The Effects on Consumers ("Eyeglasses II"),* **Washington, DC, 1980.**

permitted" to do post-prescription corneal measurements, select appropriate lenses, and complete the fitting procedure. In the five States in group II, they are expressly forbidden to perform any of these procedures. In the 16 States in group III, they may perform the post-prescription procedures "on the direction or under the supervision" of a prescribing ophthalmologist or optometrist. The four jurisdictions in group IV permit opticians to select and fit lenses for a patient with a "fully written" prescription (containing both refraction test information and post-refractive eye measurements) from an optometrist or ophthalmologist, and in the 22 States in group V the law is "ambiguous or nonexistent."

An analysis of restrictions on opticians' activities raises the question of the extent to which they are warranted as consumer protections and the extent to which they are intended to constrain the competition posed by opticians against ophthalmologists and optometrists. The FTC has examined these questions and has come to view many of the restraints to be both unnecessary in terms of protecting the consumer and undesirable from a competitive point of view. (These conclusions have been strongly challenged by both ophthalmologic and optometric professional groups.) Accordingly, in the proposed "Eyeglasses II rule, " the FTC staff recommended making contact lens fitting by opticians more accessible to consumers. The FTC staff did not suggest that a broad Federal law supplant the individual State laws (although Federal law can do so) so the effects of the proposed rule would occur only in States where opticians can fit or dispense contact lenses. The ruling would require the initial examiner (ophthalmologist or optometrist), initial fitter (ophthalmologist, optometrist, or optician) and any subsequent fitter to provide patients with complete and fillable copies of their contact lens prescriptions so they could have the original or subsequent lenses fit by opticians, if they so choose and where the State law allows. At the end of **1983,** this proposal was "on hold, " awaiting the FTC's decision whether or not to take action. It may not be adopted, it may be adopted as is, or it may be adopted in expanded form **(29).**

Although not suggested by FTC staff, the FTC ruling could supersede all State laws, widely broadening the rules on opticians' practices to make them fully competitive with optometrists and more so with ophthalmologists. This type of action could increase competition in the marketplace while allowing for due assurance of quality. The less sweeping Eyeglass II rule would achieve these results in lesser degree.

Last, the FTC has been a participant in a successful attempt to expand competition—specifically, price competition—in the fitting of contact lenses. State laws directly or indirectly prohibiting price advertising by professionals have been severely narrowed on two grounds. First, limitations and sanctions imposed by professional groups against price advertisers invite challenge under the antitrust laws as price-fixing agreements. Second, this type of restriction on advertising and direct statutory prohibitions is of doubtful enforceability because of their apparent conflict with the rights of free speech granted by the first amendment to the Constitution. The Supreme Court has ruled that truthful advertising falls within these rights (3a, 39). Accordingly, price advertising by optical outlets has become common and has generated an increased awareness of prices by consumers. As a result, optical outlets have priced their services at the lower end of the price range and have pulled down prices charged by other contact lens providers. Among outlets, the large optical chain has been an especially vigorous price competitor, providing soft lens fittings for an average price close to **$100.** Thus, Federal policy, through the FTC, has contributed to price competition among lens care providers and has the potential, through the presently shelved Eyeglasses II rule, to create more market alternatives and further price competition, possibly in every State.

FDA REGULATORY POLICY

Of all the aspects of Federal policy that bear on the operation of the contact lens industry, none is more controversial or perhaps as influential as the requirement that soft and gas-permeable lenses be approved by the FDA for safety and efficacy prior to general marketing. Such a requirement generates both benefits and costs for society. The benefits stem from the greater knowledge and experience acquired in the proapproval laboratory and clinical studies, which may lead to more effective and safe products and their wiser use. The costs are broader in variety, including the resources expended in any proapproval studies that otherwise might not be conducted, the impacts on consumers from delayed or denied approval of new contact lenses, and any anticompetitive impacts of the regulatory barrier. Ideally, premarketing approval would impose only those costs that are outweighed by the resulting benefits, but for soft and gas-permeable lenses this may not be the case. Controversy exists because the regulatory process places* a high benefit on problems averted by cautious premarket testing. Producers, on the other hand, since they bear much of the costs directly, are especially sensitive to this side of the equation relative to the benefits. Accordingly, it may be inevitable that regulators and the regulated, with different perceptions of the weights to give benefits and costs, are in conflict over the appropriate extent of regulation. In the case of contact lenses, FDA's policies have remained unchanged, due largely to the complexity of the law in effecting a lower level of regulation, and, to a lesser extent, the opposition of some firms that have gained marketing approval for their products under the current high standards.

The Origins, Development, and Scope of FDA Authority Over Contact Lenses

An understanding of the economic effects and current issues in the regulation of contact lenses requires an understanding of the law itself, including a look at its origins and present features.

Prior to 1968, when only hard contact lenses were available, there was little, if any, regulation. However, in 1968, formal regulation of contact lenses began as a result of two factors. These were the development of hydrophilic soft lens material, and two court cases (1,42) that established FDA's authority to regulate contact lenses, nylon sutures, and several other "devices" as drugs, and to subject them to premarket approval requirements comparable to those for new drugs. A medical devices group was set up to handle this responsibility, and some guidelines for contact lenses were established in 1969. (The first approval under these guidelines for soft lenses was granted to Bausch & Lomb in 1971.) In the 1976 Medical Devices Amendments to the Federal Food, Drug, and Cosmetic Act, contact lenses were specifically defined as medical devices.

The 1976 law established three classes for all medical devices according to the degrees of risk associated with their uses. Class I devices are not used for sustaining human life and do not pose significant risks to human health. Devices so classified must be made in accordance with good manufacturing practices (GMPs), which include keeping a device master file that contains design specifications, production and quality assurance data, control numbers and dates of manufacture, distribution information, and complaint records.

Devices placed in Class II are (somewhat unclearly) defined as those for which the "general controls" of Class I offer insufficient assurance of safety and effectiveness, and information exists for establishing "performance standards." Class II devices must meet the Class I standard of good manufacturing practices, as well as the Class II performance standards; but no Class II performance standards have been formulated, so Class II devices are, in effect, treated as Class I devices.

Class III was established for those devices for which Class I controls offer inadequate protection, Class II performance standards do not exist due to the absence of sufficient information, and the device "supports life, prevents health impairment, or presents a potentially unreasonable risk of illness or injury." All medical devices produced after 1976 that are not "substantially equivalent" in intended use, safety, and effectiveness to de-

vices marketed prior to 1976 are automatically placed in Class III and require FDA "premarket approval" prior to their general distribution and use, unless they are reclassified to a lower class. They must also meet the general controls requirements for Class I and Class II devices.

Contact lenses were originally placed in Class 111, except for hard (PMMA) lenses, which were placed in Class II. At the end of 1983, all lenses with 95 percent or more PMMA were in Class II (6), and the FDA was engaged in a lengthy procedure to reclassify daily-wear spherical soft lenses and rigid gas-permeable lenses to Class I (or perhaps Class II). The reclassification of rigid gas-permeable lenses was denied by FDA in December 1983 because of inadequate, publicly available data on safety and effectiveness (43).

The route for obtaining premarket approval for new Class III devices is the Investigational Device Exemption (IDE) process, which allows a producer to market a device on a limited scale, under controlled conditions, to obtain the information necessary for FDA evaluation. IDE guidelines are established by the FDA, and the study protocols set forth by manufacturer must conform to these guidelines.

Typically, only the large contact lens manufacturers have performed full IDE studies from testing the effects of the polymer on corneal tissue all the way through the actual clinical trials of the finished lenses (28). Studies of this scope usually cost $1 million or more (40). Smaller makers of contact lenses, who usually purchase the polymer "buttons" from another source, leave tissue testing and other related studies to the polymer manufacturer and just sponsor the clinical trials. These trials usually take from 6 to 12 months and cost between $250,000 and $350,000 (28,40).

The Effects of the Present System of Regulation

Regulation has had several effects on the structures of contact lens markets, and the higher classification for soft and gas-permeable lenses has created larger effects on them than on hard lenses. The negligible regulation of hard lens market entry before 1969 and the modest regulation since then have kept the barriers to entry low, explaining in large part why this industry sector is characterized by many firms, mostly small, competing in price, innovation, and service, usually on a local basis.

In contrast, Class III status for other lens types poses a formidable financial barrier for the small firm; as a result, few of them have gained a position in these markets, although a small number have managed to come into specialized sectors. Thus, the soft and gas-permeable lens markets are almost wholly accounted for by large firms, many in the case of soft lenses, only a few in the case of gas-permeable lenses. As both sectors grow relative to hard lenses, the smaller firm may become less prominent in this industry. The number of small producers has declined sharply, and most of the survivors have had to steadily reduce their output and employment levels (22,28).

Paradoxically, regulation also offers a temporary method of survival, which many have grasped. Since their survival depends on being able to market the newer, more popular lens types, but premarket approval is costly, many smaller firms have capitalized on the letter, if not the spirit, of the IDE. They have begun to produce and distribute lenses for supposed "clinical investigation" purposes, but really to gain a toehold in these otherwise foreclosed markets. Since IDEs initially required that clinical investigations contain a minimum level of case studies but specified no ceiling, they provided much more than a modest level of opportunity. But even large sales under an IDE may not be profitable if full case files and reporting systems are maintained, thus creating an incentive, even the necessity, for such costly work to be foregone. The hope of many of these firms seems to have been to market their lenses as investigatory products extensively and indefinitely, with little accountability to the FDA as to results, or that reclassification of soft and gas-permeable lenses would render the whole IDE procedure moot before the time of accountability arrived.

Recent action by the FDA, however, may well close this marketing of lenses. Open-ended investigational periods and data collection can now be halted by mandatory FDA cutoff dates for

these IDEs and other new criteria that firms must follow. In the absence of reclassification, this cut-off policy may render the small firm a minimal factor in the new product markets.

The complex question of reclassification raises two important points. First, standard, proven materials, such as the HEMA polymer used for soft lenses, might be reclassified to Class II or I, while newer materials could remain in Class III. In other words, reclassification could be ongoing and determined more by actual risk and less by possible risk, as time passes, than is presently the case. Reclassification could rely heavily on general experience-in-use of lens materials and types as they become more commonly adopted and thereby become stronger candidates for reclassification.

Second, the professional literature and reporting of problems from lens use is also a contributor to the diminishing role of small firms. Unlike he case of drugs, for which a large body of independent clinical literature is generated by professional sources and can be called on to support premarket approval applications by small market entrants, almost all clinical studies of contact roses are made by the larger manufacturers and, hus, are proprietary information not to be used by other producers in support of their applications without permission. In addition to the redundancy of effort caused by the absence of a common base of available clinical documentation, this "ground zero" approach rewards early entry and creates for those who clear the premarket approval hurdle a vested interest in keeping the barer high for other would-be entrants. Accordingly, independent professional clinical studies of new lens materials, designs, and uses could be encouraged. (Although funding these studies poses practical problem, it is not an insurmountable one. One possibility is an excise tax on lenses, earmarked specifically for clinical research purposes.)

The likely structural effects of the Class III premarket approval requirement in the contact ns field are fewer firms entering at a slower rate. Any entrant will be delayed; many, particularly small firms, may not be able to enter at all. In rn, any effects on structure are likely to be translated into changes in market behavior. Competition among fewer firms often differs from that among many, and competition among large firms takes different forms than that among smaller firms. Consequently, although price competition may be seen in the market for soft and gas-permeable lenses, it may well be less than would occur if smaller firms were also in these markets. The emphasis in rivalry threatens to shift increasingly to promotion and away from price. Vertical ties between manufacturers, prescribers, and outlets are more likely to emerge, narrowing product choice to consumers.

Smaller firms may continue to find ways to survive and to create some market competition, although in narrower roles than the protection of maximum competition calls for. Operating as licensees of other firms, especially those ranking below the leaders in market share, smaller firms can increase the challenge against the dominant firms. By acting in consortia, small firms may even generate a research effort. But neither their price nor research roles are likely to approach the magnitudes that small firms have achieved in the hard lens market and in certain specialty areas of the soft lens market **(28,34).**

Thus, the likely economic effects of FDA regulatory policy toward contact lenses are not the elimination of competition or serious threats of its large-scale curtailment, but a degree of limitation. What is at stake is the rigor of market competition. Consumers of contact lenses maybe less well off if small firms, which history shows to be especially vigorous competitors in contact lens development and pricing, are constrained, because of limited economic resources, from entering the market as effective rivals,

In conclusion, the study of regulatory and other Federal policies toward contact lenses, their manufacturers, dispensers, and users, is instructive both for what it tells us about the effects of these policies on the economic performance of the contact lens industry, and for the broader implications offered about regulation in general. Either way, the objective is wiser and more effective Federal policy determination and administration.