of new products, and, as a result, the number of introductions exceeded 3,800 in the decade ending in 1960.[7] Of these, the largest number by far consisted of new combinations of existing drugs and of new dosage forms.[8] The remainder, or 432 in total, were new chemical entities, and these absorbed the largest share of the research effort. It should be noted, however, that this category included salts and other derivatives of known drugs as well as entirely new substances.[9]

The nature of industry research may be inferred to some extent from information on new products. As we might expect, there appears to be a large effort to invent around existing patents, and this has led to the introduction of a considerable number of new drugs whose therapeutic effect is quite similar to that of products already on the market. We should note, however, that rarely do different chemical compounds have perfectly identical therapeutic properties and that small differences may be important for some patients.

To a great extent, industry research activities build upon the scientific achievements of the past. They are concerned, primarily, with the smaller, albeit less uncertain, steps forward. Although these activities may duplicate what has already been done and also frequently may lead to new drugs that represent at best a very minor advance, it is still true that a number of important modifications and variations have been discovered within industry laboratories.

The second major emphasis of industry research concerns the process by which new scientific knowledge is translated into marketable products. Product rivalry is strong, and this has insured that new drugs will not lag far behind advances in scientific knowledge, no matter whether these advances originate in university, government, or foreign laboratories. This is an important area, because in most cases substantial research and development problems remain even after the original discovery has been made. Not only is there frequently a substantial gap between laboratory synthesis and large-scale manufacturing methods, but also considerable analysis and testing is required before a drug may be marketed. And these activities, which may well be more costly than basic research, are undertaken for the most part within industry laboratories.

Whether the impetus for a new drug comes from competitive successes, from basic research carried on within the industry, or from new scientific knowledge arising from non-industry sources, the problems of synthesis and testing remain, and these absorb the major share of industry research expenditiures. Large quantities of the promising compound are normally required before efficient production techniques are available, and large sums are expended for this purpose. It has been estimated, in fact, that approximately one-half of total expenditures on research with the industry goes to support the work of synthesizing, purifying, modifying, and preparing suitable substances for subsequent physiological tests.[10] Once this process is completed, the new substance is subjected to intensive biological investigation. The first concern is to determine the therapeutic properties of the substance this encompasses the major purpose of the drug as well as side effects. In addition, it is necessary to test for toxicity levels and to determine the compound's potency in order to gain knowledge of appropriate dosages. For these purposes, the pharmaceutical industry used in its research facilities some nine million laboratory animals during 1961.[11]

There is, moreover, a great deal of uncertainty concerning the therapeutic properties of new substances. As would be expected, most of those tested in laboratories are found to be without sufficient promise to justify clinical testing on human beings. In 1958, for example, nearly 115,000 substances were subjected to biological tests by pharmaceutical firms, while only 1,900 were considered worth testing clinically.[12] The Food and Drug Administration requires that manufacturers undertake efficacy studies on new drugs and that the results of these tests

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[7] Paul de Haen, "New Product Survey" (New York: privately printed by author, 1960).

[8] Although new chemical substances are not involved in these cases, considerable attention may still be required. E.g., a good deal of work was done in an attempt to combine Glucosamine with certain antibiotics in the hope that this would increase the absorption of the drug into the blood stream (*Administered Price Hearings*, Part XVIII, p. 10257).

[9] During 1959, sixty-three new chemical entities were introduced. Of these, eleven were new salts of old products and twenty-three were derivatives of known drugs. The remainder of twenty-nine were entirely original products (U.S. Senate, *Drug Industry Antitrust Act* [hereinafter cited as "Antitrust Act Hearings"] [Hearings before the Subcommittee on Antitrust and Monopoly (87th Congress, 1st Session, 1961)], Part II, p. 888).

[10] Statement by Austin Smith, president of the Pharmaceutical Manufacturers Association, in *Administered Price Hearings*, Part XIX, p. 10725.

[11] Reported in *New York Times*, August 26, 1962, p. 60.

[12] *Administered Price Hearings*, Part XIX, p. 10725.