

ucts (Table 1 in the Supplementary Appendix). Particularly noteworthy was the large number of vaccines. Virtually all the important, innovative vaccines that have been introduced during the past 25 years have been created by PSRIs.

#### THERAPEUTIC CATEGORIES

The therapeutic categories into which the 153 products fall are shown in Table 1. Oncology and infectious diseases account for half the total. The order of these disease categories is very different from the priorities of the pharmaceutical industry. The disease priorities of the NIH institutes with the largest budgets<sup>25</sup> — in order, the National Cancer Institute, the National Institute of Allergy and Infectious Diseases, the National Heart, Lung, and Blood Institute, and the National Institute of Diabetes and Digestive and Kidney Diseases — broadly correlate with the top four categories of PSRI-discovered drugs (Table 2). One possible interpretation of this observation is simply that there was more funding available for research involving these disease categories, which resulted in more useful intellectual property.

#### DISCOVERING INSTITUTION AND RATE OF DISCOVERY

A total of 75 PSRIs discovered or codiscovered at least one product (Table 1 in the Supplementary Appendix). Of these institutions, the most prolific is the NIH (with 22 products), followed by the University of California system (with 11), Memorial Sloan-Kettering Cancer Center (with 8), Emory University (with 7), and Yale University (with 6). Figure 1 shows the number of new-drug and biologics license applications approved by the FDA each year.

#### CLINICAL EFFECT OF PSRI DRUGS

The FDA-approval process provides two indications of the clinical significance of a new drug. The FDA classifies new-drug applications into one of eight chemical types: type 1, a new molecular entity; type 2, a new ester, salt, or other non-covalent derivative; type 3, a new formulation; type 4, a new combination; type 5, a new manufacturer; type 6, a new indication; and type 7, a drug that is already marketed but does not have an approved new-drug application.

The FDA assigns the application one of two types of review on the basis of its therapeutic potential: priority review if the drug shows substantial improvement, as compared with currently marketed products for the treatment, diagnosis,

**Table 1. Number of Drug Products Approved by the Food and Drug Administration and Originating from Public-Sector Research, According to Therapeutic Area, 1970–2009.**

Therapeutic Area	Number
Total	153
Hematology or oncology	40
Infectious disease	36
Cardiology	12
Metabolic disease	12
Central nervous system	12
Dermatology	7
Renal disease	7
Ophthalmology	6
Immunology	6
Gastroenterology	4
Women's health	3
Allergy	2
Pulmonary disease	2
Urology	2
Anesthesiology	1
Dental disorders	1

or prevention of a disease, or standard review if the drug appears to have therapeutic qualities similar to those of one or more drugs that are already on the market. A drug that has been designated as a new molecular entity and that has received a priority review would therefore be considered by the FDA to have the highest potential therapeutic effect.

We obtained the total number of approvals of new-drug applications, according to chemical type and type of review, for the 18-year period from 1990 through 2007 from the FDA's Web site<sup>26</sup> and by a request under the Freedom of Information Act. During this period, the FDA approved 1541 new-drug applications but granted priority review to just 348 applications (22.6%) (Table 2). Of the 1541 total approvals, 143 (9.3%) resulted from PSRIs. However, of the 348 priority reviews, 66 (19.0%) resulted from PSRIs, or twice the overall rate for priority reviews. Viewed from another perspective, 46.2% of new-drug applications from PSRIs received priority reviews, as compared with 20.0% of applications that were based purely on private-sector research, an increase by a factor of 2.3.

Of the total approvals of new-drug applications, 483 (31.3%) were for new molecular entities, of which 64 (13.6%) originated at PSRIs. Of