THE BIOMEDICAL RESEARCH AND DEVELOPMENT PIPELINE

WHAT ARE THE BASIC PHASES OF THE RESEARCH AND DEVELOPMENT (R&D) PIPELINE?

There are five main phases in research and development (R&D): basic research, applied research, clinical trials, regulatory review, and production & distribution. Academic and independent research institutions, private companies, and the federal government play unique and complementary roles in the R&D ecosystem.

**Basic Research**
- Explore basic scientific principles.
- Understand how the frontiers of knowledge are reached and should be supported by the federal government.

**Applied Research**
- Develop applications of basic research findings.
- Private companies and academia may conduct this research.

**Clinical Trials**
- Test potential medical interventions in human subjects.
- Administered by clinical trial volunteers.

**Regulatory Review**
- Evaluate clinical trial results and evidence for product safety and effectiveness.
- Conducted by regulatory agencies.

**Production & Distribution**
- Manufacture and distribute approved medical interventions.
- Ensures availability to the public.

Even if it brings no immediate benefits, basic scientific research that advances the frontiers of knowledge is necessary and should be supported by the federal government. Agree or Disagree?

*Strongly Agree* 60%  *Somewhat Agree* 15%  *Neither Agree nor Disagree* 25%  *Somewhat Disagree* 15%  *Strongly Disagree* 20%  *Not Sure* 30%  *Dont Know* 40%

HOW DOES THE R&D PIPELINE WORK?

Health-focused R&D is not the responsibility of one sector - it is more like a relay race that plays to the strengths of the public sector, academic and independent research institutions, and the pharmaceutical and medical technology industries.

- **Grant Funding** The federal government is the largest U.S. funder of basic research. Intramural research conducted at federal agencies like the National Institutes of Health and at federal laboratories across the country contributes significantly to medical and scientific progress, but most federally-funded research is not conducted “in house.” Instead, federal agencies make use of a competitive “peer review” process to provide grant funding to universities, independent research institutes, academic health centers and small businesses across the country to conduct this research.

- **Bayh-Dole Pathway** Similarly, while federally-funded basic research is the “first leg” of the relay race, the federal government does not conduct or finance the bulk of R&D that leads to new medical advances. In fact, the private sector finances nearly 70% of U.S. biomedical R&D. Originally, the lack of a mechanism for incentivizing the entire discovery, development, delivery pipeline created a serious bottleneck, but the 1980 Bayh-Dole Act addressed this chockpoint by ensuring that intellectual property rights can be transferred from the federal government to the institutions and businesses executing each phase of the R&D pipeline.

- **Patient Contribution** Patrons and non-patient clinical trial volunteers play a critical and growing role in the research pipeline. Not only do they enable clinical research, but they inform every step of the research process to ensure progress reflects patient need.

- **Regulatory Review** The federal Food and Drug Administration assesses clinical trial results and other evidence to verify product safety and effectiveness before large-scale manufacturing and distribution occurs.

**Estimated U.S. Medical and Health R&D Expenditures in 2018 ($ in millions)**

<table>
<thead>
<tr>
<th>Category</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biopharmaceutical and medical technology sectors</td>
<td>$35,424</td>
</tr>
<tr>
<td>National Institutes of Health (NIH)</td>
<td>$21,672</td>
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<tr>
<td>Academia</td>
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<tr>
<td>Professional Societies; Associations &amp; Foundations</td>
<td>$16,036</td>
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<tr>
<td>State/Local Government</td>
<td>$15,273</td>
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<tr>
<td>Health R&amp;D Expenditures in 2018 ($ in millions)</td>
<td>$120,269</td>
</tr>
</tbody>
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How important is it for the President and Congress to assign high priority to ensuring faster medical progress?
- *Very Important* 53%  *Somewhat Important* 35%  *Neither Important nor Not Very Important* 12%  *Not Very Important* 13%  *Very Unimportant* 17%  *Not Important at All* 10%  *Not Sure* 20%  *Dont Know* 40%  *Not asked* 40%

**Federal Funding**
- Invests in basic science at research institutions across the country.

**Additional Studies**
- Conducted to translate targets into potential medical interventions.

**Potential Medical Interventions**
- Tested in diverse human populations to examine safety and effectiveness.

**Federal Review**
- Performed to evaluate if therapies are suitable for public use.