

Pharmaceutical R&D and Biotech Development



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Pharmaceutical innovation

- **Backdrop: changing factors affecting expected profitability of pharmaceutical R&D**
 - Reimbursement: differential access barriers by geographic market and by payor
 - Regulatory structure: effect of regulatory regimes on the type and pace of innovation
 - Locus of innovation: geographically and by therapy type
 - Cost structure: changes in the costs and requirements for innovation
 - Patent protection: increasing complex IP landscape

CRA study on pharmaceutical innovation

- **For the EC's Enterprise Directorate General**
 - Provided an appraisal of pharmaceutical R&D productivity
 - Worked with EMEA, the FDA, manufacturers, and investment analysts
- **Key findings**
 - No crisis in pharmaceutical innovation, but
 - Continuing decline in R&D productivity
 - Geographic shift of pharmaceutical innovation to US
 - Potential shift in the type of drugs being developed

Charles River Associates, "Innovation in the Pharmaceutical Sector" ENTR/03/28, November 8, 2004

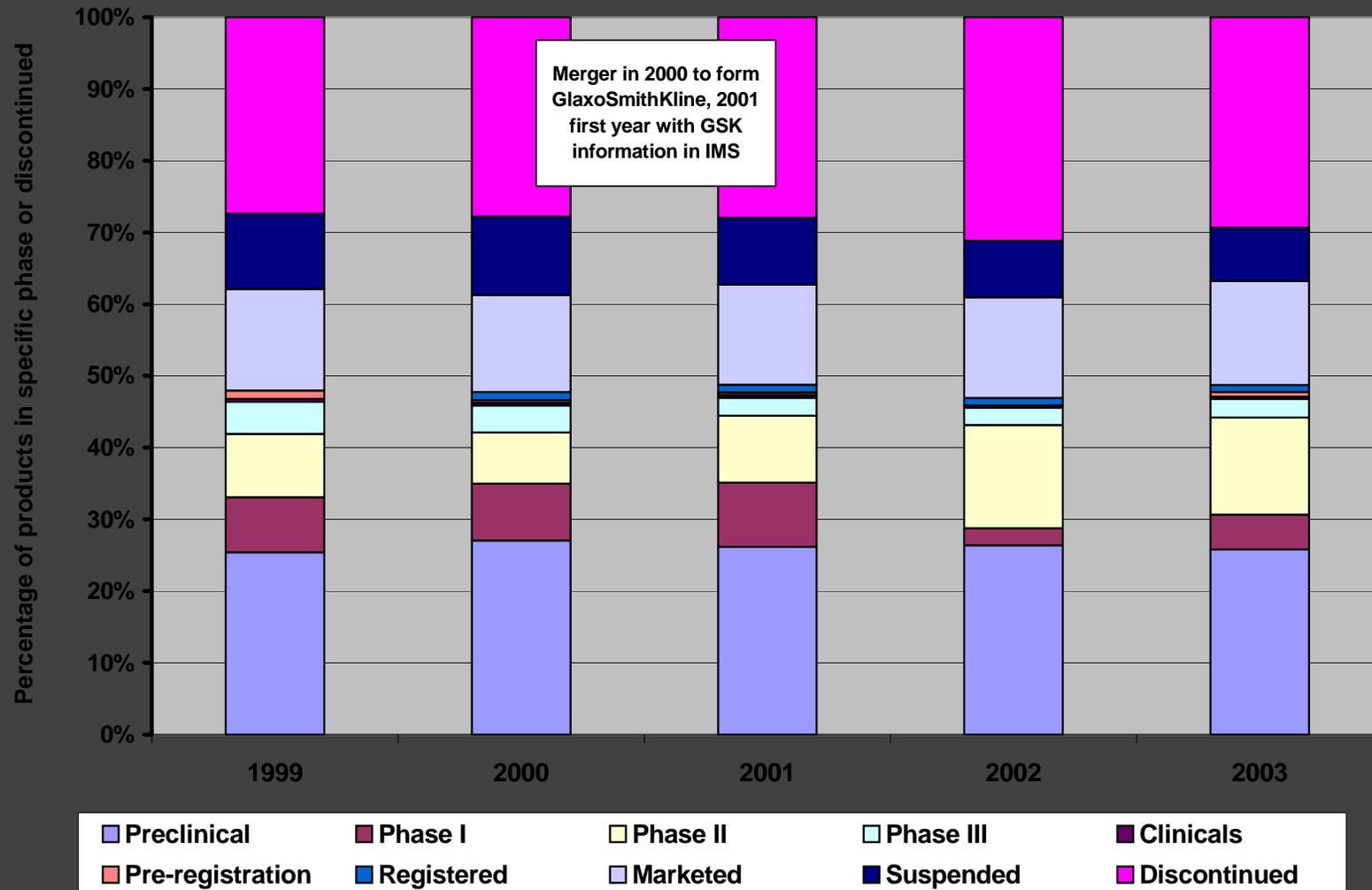
Increased breadth of patented technologies

- **Therapeutic agent**
- **Theranostics: Dx/Rx couplets that combine diagnostics and therapies**
 - Many diagnostic tests (e.g., LipoProfile, FISH) are proprietary
 - Payors might condition reimbursement on verification of genetic predisposition
 - Ownership of patent for DNA sequencing in dispute
 - Efficiencies from combined ownership
- **Devices: another level of IP issues**
 - Additional venue for disputes regarding device IP (e.g., drug eluting stents)
 - Drug delivery devices

Effect of mergers on innovation

- **Consolidation effects for innovation highly case-specific**
- **Positional expertise mergers**
 - Goal: to provide deep pipeline of therapies to build on established expertise of R&D and sales resources
 - Efficiencies often encourage greater focus in certain therapeutic categories
- **Breadth of offerings mergers**
 - Goal: to compete in wide range of therapeutic areas
 - Franchise and corporate brand efficiencies benefit from broad portfolio
 - Leverage sales and regulatory expertise
- **“Discard development”**
- **CRA study observations**
 - Mergers of select large firms did not result in noticeable R&D changes
 - Integration and related issues might detract from R&D efforts in short term

Effect of mergers on innovation: illustrative example



Source: CRA analysis of IMS Health data

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