

Follow-on Drug Development: Wasteful Imitation or Productive Competition?

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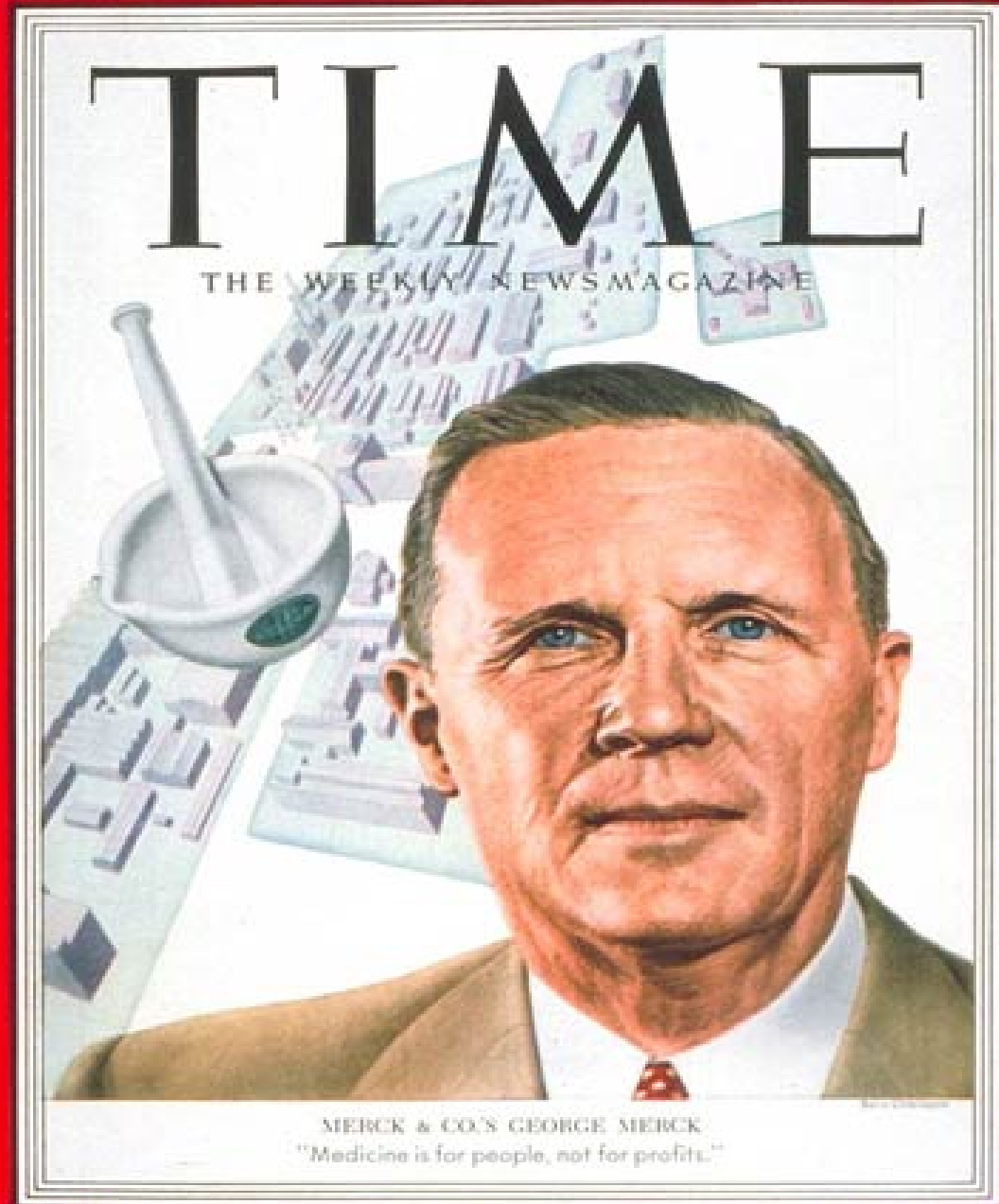
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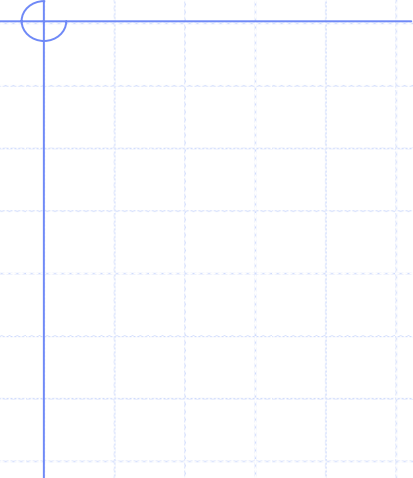
August 18, 1952

**Medicine is for
people,
not for profits.**

**George Merck,
CEO, Merck & Co.**

**Re Streptomycin,
Anti-TB agent**





**“The right context
is worth 50 IQ points.”**

- Alan Kay
Inventor of Object Oriented Programming
Visionary: Laptop Computer

Issues I:

Policy and Supply

1. The Bayh-Dole Act of 1980 (and 1984): Technology transfer between universities and industry
2. The Federal Technology Transfer Act of 1986: CRADAs between industry and government agencies
3. Prescription Drug User Fee Act [1992, 1997, 2002]:
 1. 1993-1995: 25 priority & standard NMEs/yr
 2. 1996: 53
 3. 1997-1999: 34.7/yr

Figure 2: First in Class Approvals

1960s	= 8
1970s	= 9
1980-1984	= 5
1985-1989	= 14
1990-1994	= 15
1995-1998	= 18

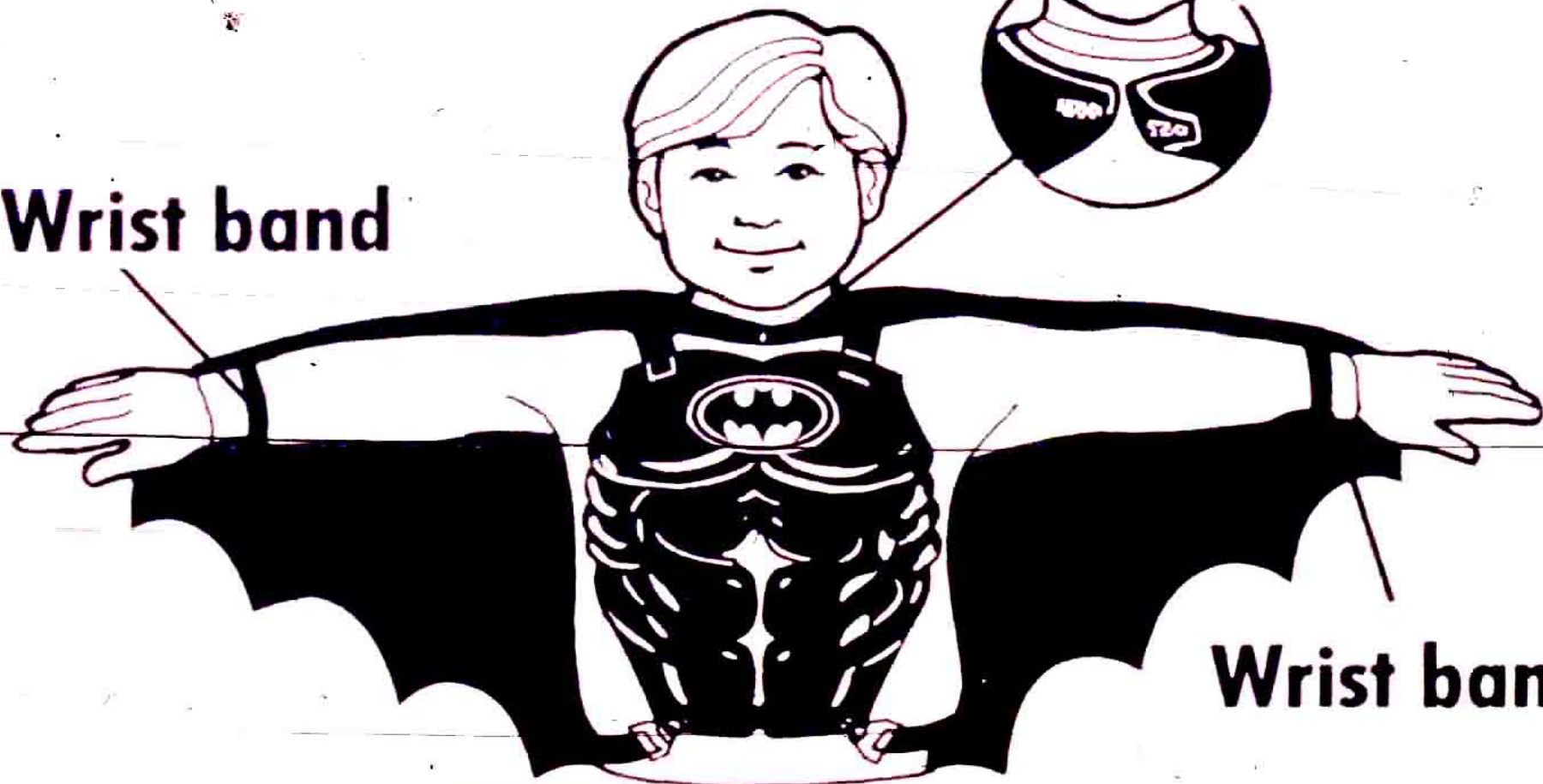
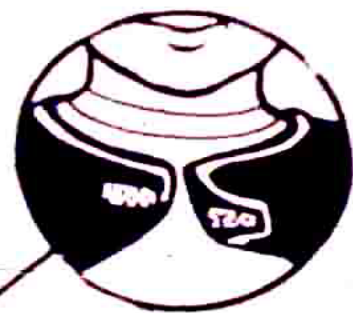
Issues II

- 1. Not all follow-on medications are alike (IMDs):**
NIHCM, May 2002: 1,035 new drug approvals during 1989-2000; 15% (153) for priority rated NMEs
- 2. Entry vs Competitive entry: Shark Fin Project (WSJ 06JUNE2002)**
- 3. Acquisition vs development:** a rising tide raises all boats, so a follow-on could be an attractive strategy
- 4. DTCA: Branding & demand pull**

2. CAPE

Fastener holds
cape around neck.

Wrist band



Wrist band

CAUTION—FOR PLAY ONLY:
Cape does not enable user to fly.