THE WHOLE IS GREATER THAN
THE SUM OF ITS PARTS

RESEARCH, REGULATION
AND THE POLYPILL
TO BE ACCEPTABLE A FDC MUST DEMONSTRATE

Improve Benefit:Risk

• Addition or potentiation of therapeutic effect

• More efficacious than monotherapy and acceptable safety profile

• Counteracting adverse reaction of one substance by another
CLINICAL DEVELOPMENT

Depends on:

Existing knowledge about and indications of proposed active substances

Intended first, second or third line use

Intended indication (narrow, extended or broad)

• Substitution of existing treatment
• Extension of existing treatment
• Preventative treatment
I am not a number; I am a free man.

Patrick Mcgoohan